Critical appraisal tables

Research question 1. Planning in advance, including for people who experience fluctuating capacity (review 1):

- 1.1 – What interventions, tools, aids and approaches are effective and cost-effective in supporting advance planning for decision-making for people who may lack mental capacity in the future?
- 1.2 – What are the views and experiences of people who may lack mental capacity, their families and carers, practitioners and others interested in their welfare, on the acceptability of interventions, tools, aids and approaches to support planning in advance for decision-making?

Effectiveness data

1. Bravo G, Trottier L, Arcand M et al. (2016) Promoting advance care planning among community-based older adults: A randomized controlled trial. *Patient Education and Counseling* 99: 1785–1795

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To test '… whether a multimodal advance planning intervention (1) motivates community-based older adults to document their wishes regarding future healthcare and (2) guides proxies in making hypothetical health-related decisions that match those of their relatives.' (p1786). **Methodology:** Quantitative –randomised controlled trial. **Description of theoretical approach?** Yes. A multimodal advance planning intervention – using support and a guidance booklet to help older adults clarify and communicate their preferences.	**Was the exposure to the intervention and comparison as intended?** Yes. There is no indication to suggest otherwise. **Was contamination acceptably low?** Yes. Nobody outside of the intervention group received the booklet or training visits. As a community population it is unlikely families from separate conditions met to discuss their experiences. **Did either group receive additional interventions or have services provided in a different manner?** No. There is no indication that either group were treated differently. **Were outcomes relevant?** Partly. They were interested in concordance	**Does the study's research question match the review question?** Yes. Investigating approaches to improve uptake of advance care planning among people who may lack capacity in the future. **Has the study dealt appropriately with any ethical concerns?** Yes. The authors report that the '… Research Ethics Board of the University Institute of Geriatrics of Sherbrooke approved the study and all associated documents. All participants provided written consent at enrolment.' (p1786). **Were service users involved in the design of the study?** No.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
How was selection bias minimised? Randomised. **Was the allocation method concealed?** Not reported. **Were participants blinded?** Not blind. Participants knew what intervention they were receiving and were aware of the other condition. **Were providers blinded?** Blinding not possible. Providers would have known which participants were in each condition as they were provided different training. **Were investigators, outcome assessors, researchers, etc., blinded?** Not reported. **Did participants represent the target group?** Yes. **Were all participants accounted for at study conclusion?** Yes. All are accounted for in the flow diagram. Some analysis was done looking at participants that dropped out; this found that these adults were slightly older.	between people and their proxies – an important aspect of the value of an advance plan, including having it enforced later. **Were outcome measures reliable?** Yes. Vignettes were drawn from previous research, and steps were taken to prevent order effects. **Were all outcome measurements complete?** Yes. **Were all important outcomes assessed?** No. The authors did not report on important outcomes such as how much clearer or more reassured the adults felt about their decisions after the intervention. **Were there similar follow-up times in exposure and comparison groups?** Yes, participants in each group followed up immediately after session 3 and again 6 months later. **Was follow-up time meaningful?** Yes. Immediate follow-up and a reasonable time later for longer-lasting effects seems appropriate. **Were the analytical methods appropriate?** Yes. **Were exposure and comparison groups similar at baseline? If not, were these adjusted?** Yes. Both groups were equal on virtually all characteristics.	**Is there a clear focus on the guideline topic?** Yes. Interventions to promote advance care planning. **Is the study population the same as at least one of the groups covered by the guideline?** Partly. Older adults who may at some point lose capacity to make decisions. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Community settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the study outcomes relevant to the guideline?** Yes. Older adult's ability to express and record their preferences, and have their wishes understood and upheld. **Does the study have a UK perspective?** No. The study was conducted in Canada.	

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
	Was intention to treat (ITT) analysis conducted? No. It seems that the final analysis only includes those who completed each phase. **Was the study sufficiently powered to detect an intervention effect (if one exists)?** Not reported. **Were the estimates of effect size given or calculable?** Partly. Mean values, standard deviations and *p* values are given. A rough computation may be possible. The null hypothesis was accepted therefore the authors did not report effect sizes. **Was the precision of intervention effects given or calculable?** Were they meaningful? Partly. May be calculable from the means and standard deviations provided. **Do conclusions match findings?** Yes.		

2. Elbogen E, Swanson J, Appelbaum P et al. (2007) Competence to complete psychiatric advance directives: effects of facilitated decision making. Law and Human Behavior 31: 275–289

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
Study aim: The researchers aimed to examine the '… clinical and neuropsychological correlates of performance on a measure to assess competence to complete PADs and investigate the effects of a facilitated PAD intervention on decisional capacity.' (p1).	**Was the exposure to the intervention and comparison as intended?** Yes. **Was contamination acceptably low?** Not reported. Contamination not discussed in detail. It did not appear that the researchers took many	**Does the study's research question match the review question?** Yes. The study compares the effectiveness of two approaches to promote advance decision-making. **Has the study dealt appropriately with any ethical concerns?** Yes.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
Methodology: Quantitative - randomised controlled trial. **Description of theoretical approach?** Yes. **How was selection bias minimised?** Randomised. **Was the allocation method concealed?** No. As soon as participants had been randomised to a condition they themselves and the researchers delivering the intervention would have been aware regarding the support they were receiving. **Were participants blinded?** Blinding not possible. Immediately after randomisation participants would have become aware of the group to which they had been assigned. **Were providers blinded?** Blinding not possible. **Were investigators, outcome assessors, researchers, etc., blinded?** Not blind. The authors give no indication that investigators were unaware of the participant's group status when conducting follow-up assessments. **Did participants represent the target group?** Yes. Targeted individuals who experience psychotic symptoms associated with fluctuating decisional	steps to avoid it, perhaps suggesting this was meant to be a more naturalistic study. **Did either group receive additional interventions or have services provided in a different manner?** No. There is no indication that this was the case. **Were outcomes relevant?** Yes. The authors sought to investigate how best to support competence and capacity to complete a psychiatric advance directive, and the measure focused on this. **Were outcome measures reliable?** Yes. Measures are reported in detail and include citations, details on what the instrument measures and how it was developed. **Were all outcome measurements complete?** Yes. The Decisional Competence Assessment Tool for Psychiatric Advance Directives was the only outcome measure used. **Were all important outcomes assessed?** No. The researchers do not report in detail the impact of the intervention on the number of completed psychiatric advance directives, which is disappointing (although a small amount of detail on this is provided in the footnotes).	There was an informed consent process, and the study was approved by Duke University Medical Centre review board, as well as the board of local mental health care institutions. **Were service users involved in the design of the study?** No. **Is there a clear focus on the guideline topic?** Yes. The study compares the effectiveness of two approaches to promote advance decision-making. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. People who may experience loss of capacity due to psychotic episodes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Mental healthcare in the community. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Advance care planning and approaches to making it more useful. **Are the study outcomes relevant to the guideline?** Yes. The outcomes are improved competence to understand what an advance directive is and to understand why one may be useful.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
capacity – and who wanted to complete a psychiatric advance directive. A random sample was taken from the population. Only patients that were willing to be contacted were approached and then asked to give informed consent – 8% of those randomised refused; however, authors checked and found these were not significantly different to those that accepted by gender, ethnicity, or diagnosis. It is possible those who refused contact or consent were an important subgroup, but authors did all that was ethically reasonable and checked for outstanding baseline characteristics, which were found equal. Those who did not want to complete a psychiatric advance directive were also excluded as not falling under the remit of the question; however, it may have been insightful to explore this further. **Were all participants accounted for at study conclusion?** No. Reasons for attrition not reported.	**Were there similar follow-up times in exposure and comparison groups?** Yes. **Was follow-up time meaningful?** Partly. A month is a reasonably appropriate period and achieves a balance between capturing those who would want to complete a directive immediately after receiving the intervention, and those who might wish to think about it. But there may be differences between long-term effects, and the study may have benefitted from further follow-up points. The authors do not discuss the choice of follow-up points in detail. **Were the analytical methods appropriate?** Yes. Appropriate steps were taken to deal with skew in the data, and the sample sizes were large enough to make the analyses sufficiently powered. **Were exposure and comparison groups similar at baseline? If not, were these adjusted?** Not reported. There is no indication that the groups differed at baseline, but this is not reported specifically. **Was intention to treat (ITT) analysis conducted?** No. Those who were assessed at baseline but not at follow-up were not included in the final analysis.	**Does the study have a UK perspective?** No. The study was conducted in the United States.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Was the study sufficiently powered to detect an intervention effect (if one exists)? Yes. The sample sizes were large enough to detect and make meaningful findings (n > 170). **Were the estimates of effect size given or calculable?** Yes. Calculable from the change and significance. **Was the precision of intervention effects given or calculable? Were they meaningful?** Yes. **Do conclusions match findings?** Yes.		

3. Pearlman R, Starks H, Cain K et al. (2005) Improvements in advance care planning in the Veterans Affairs System: results of a multifaceted intervention. *Archives of Internal Medicine* 165: 667–674

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To evaluate the effectiveness of an advance care planning intervention utilising counselling alongside the 'Your life, your choices' workbook. **Methodology:** Quantitative – randomised controlled trial. **Description of theoretical approach?** Partly. While not going into depth, the introduction outlines the basic premise accepted in social science – that support, prompting and accessible guidance in lay language are better for encouraging advance	**Was the exposure to the intervention and comparison as intended?** Yes. **Was contamination acceptably low?** Not reported. The risk of contamination is not made clear, and the authors do not indicate whether any steps were taken to prevent it. **Did either group receive additional interventions or have services provided in a different manner?** No. **Were outcomes relevant?** Yes.	**Does the study's research question match the review question?** Yes. The study reports on an evaluation of an intervention to improve uptake of advance care plans. **Has the study dealt appropriately with any ethical concerns?** Yes. The consent process and procedures were approved by the Human Subjects Committee of the University of Washington. **Were service users involved in the design of the study?** No.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
care planning, as opposed to individual initiation and legal documents perceived to be confusing. **How was selection bias minimised?** Randomised. **Was the allocation method concealed?** Not reported. **Were participants blinded?** Blinding not possible. **Were providers blinded?** Blinding not possible. **Were investigators, outcome assessors, researchers, etc., blinded?** Not reported. There is no indication that investigators were blinded; however, this would have been possible. **Did participants represent the target group?** Partly. Half of those they sought to recruit refused to participate, suggesting they only had access to the more enthusiastic members of their target population. **Were all participants accounted for at study conclusion?** Yes.	**Were outcome measures reliable?** Partly. In some cases the use of clinical medical records is a reliable source and agreement on scores is a reasonably robust method of establishing and measuring impact; however, appropriate references, psychometric data and details on the measures used are not reported. Some of the measures (e.g. 'whether conversations have been had') may have been subject to desirability bias. **Were all outcome measurements complete?** Not reported. **Were all important outcomes assessed?** Partly. Other relevant outcomes discussed in the comments section but not measured include 'trust' in proxies and in-care providers, degree that patient is ready to commit to preferences, and cost information. **Were there similar follow-up times in exposure and comparison groups?** Yes. Four months for both. **Was follow-up time meaningful?** Partly. Follow-up was at 4 months, but no rationale for this point is provided and a longer period of follow-up may have been more appropriate. **Were the analytical methods appropriate?** Yes. Reasonable description and justification given for all methods of analysis.	**Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Partly. Participants were deemed at risk of lacking capacity to make decisions in future. However, they were all veterans, which may not be well representative of the population at large. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Community and residential care settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the study outcomes relevant to the guideline?** Yes. Patient centred outcomes relating to greater empowerment to express their wishes and better agreement between them and care staff. **Does the study have a UK perspective?** No. The study was conducted in the United States.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Were exposure and comparison groups similar at baseline? If not, were these adjusted? Yes. Very well matched, with a small variation in mental health as the only notable variation. **Was intention to treat (ITT) analysis conducted?** Not reported. It is not clear whether intention to treat analysis was conducted but this does not appear to have been the case as some numbers are omitted from results. **Was the study sufficiently powered to detect an intervention effect (if one exists)?** Yes.		

4. Seal M (2007) Patient advocacy and advance care planning in the acute hospital setting. Australian Journal of Advanced Nursing 24: 29–36

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study Aim: This study aimed to '… to explain the role of patient advocacy in the Advance Care Planning process.' (p30). **Methodology:** Mixed methods – a prospective quasi-experimental (non-randomised) controlled trial, complemented with semi-structured focus groups. **Qualitative component:** Focus groups with ward nurses. **Are the sources of qualitative data**	**Quantitative component:** Pre-post quasi-experimental survey study. **Are participants recruited in a way that minimises selection bias?** No. It's not clear why some wards were chosen to receive the intervention first. **Are measurements appropriate regarding the exposure/intervention and outcomes?** Unclear. Very little detail is provided on the measures used, how they were developed or even what they measure.	**Does the study's research question match the review question?** Yes. The study evaluates an intervention to support advance planning. **Has the study dealt appropriately with any ethical concerns?** Yes. Approval was granted by relevant research ethics committees. **Were service users involved in the study?** No. **Is there a clear focus on the guide-**	**Overall assessment of internal validity: –** **Overall assessment of external validity:** +

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
relevant to address the research question? Yes. Focus groups were conducted with nurses caring for people who may lose capacity. **Is the process for analysing qualitative data relevant to address the research question?** Partly. The researchers report that interviews were transcribed and coded into themes; however, very few details are provided and little critical consideration is given. **Is appropriate consideration given to how findings relate to the context, such as the setting, in which the data were collected?** Partly. The authors state that while they are aware that their research was only conducted within a single hospital, they believe it is typical of the workload and issues faced by other hospitals in Australia (and perhaps other similar countries) due to similar systems of ethics, policy, funding climate etc. **Is appropriate consideration given to how findings relate to researchers' influence; for example, through their interactions with participants?** No.	**In the groups being compared, are the participants comparable, or do researchers take into account (control for) the difference between these groups?** Partly. **Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?** No. The response rate for nurses working in the ward at the time was around 55%. **Is the mixed-methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed-methods question?** Yes. Given that this was a quasi-experimental study, they sought to address the design problems by supplementing the quantitative findings with further qualitative insights. **Is the integration of qualitative and quantitative data (or results) relevant to address the research question?** Partly. **Is appropriate consideration given to the limitations associated with this integration, such as the diver-**	**line topic?** Yes. Advance care planning for a range of patients. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Patients on wards in hospitals, with a risk of losing capacity to make treatment decisions. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Inpatient hospital wards. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the study outcomes relevant to the guideline?** Yes. Nurses' perception of person-centred care and ability to empower patients. Service outcomes relating to staff morale. **Are the views and experiences reported relevant to the guideline?** Yes. Views and experiences relating to patients, person-centred care, and advance care planning – before and after intervention. **Does the study have a UK perspective?** No. The study was conducted in Australia.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	gence of qualitative and quantitative data (or results)? No. The limitations associated with the study and its design are not discussed in detail.		

Views and experiences data

5. Ashton S, Roe B, Jack B et al. (2014) End of life care: The experiences of advance care planning amongst family caregivers of people with advanced dementia – a qualitative study. *Dementia* 15: 958–975

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The researchers aimed to '… explore the experiences of ACP amongst family caregivers of people with dementia.' (p961). **Methodology:** Qualitative **–** semi-structured in-depth interviews. **Is a qualitative approach appropriate?** Appropriate. **Is the study clear in what it seeks to do?** Clear. **How defensible/rigorous is the research design/methodology?** Defensible.	**How well was the data collection carried out?** Appropriately. Semi-structured, in-depth interviews. **Is the context clearly described?** Clear. **Was the sampling carried out in an appropriate way?** Appropriate. Purposeful sampling **–** family caregivers were identified by the care home manager as being the next of kin and proxy decision-makers of people with advance dementia within the specialist dementia unit. An open invitation was made and whoever responded was accepted unconditionally to participate in the research. **Were the methods reliable?** Reliable. **Are the data 'rich'?** Rich. The experience of advance care planning and the relevance of advance care planning for people with advance dementia.	**Does the study's research question match the review question?** Yes. Family carers' views and experiences about advance care planning. **Has the study dealt appropriately with any ethical concerns?** Yes. The study was approved by a national research ethics service and informed consent was sought from participants before the interview stage. Participants chose locations of interviews, and were also informed that they could withdraw at any time and were under no compulsion to take part. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. Advance care planning. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Family	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Is the analysis reliable? Reliable. Content analysis was used by 1 researcher to identify emerging categories. A sample was then analysed by another member of the research team and an agreement made on the accuracy of categories. **Are the findings convincing?** Convincing. **Are the conclusions adequate?** Adequate.	carers. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Care setting **–** specialist dementia unit within an independent nursing home. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Advance care planning. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

6. Bisson J, Hampton V, Rosser A et al. (2009) Developing a care pathway for advance decisions and powers of attorney: qualitative study. *British Journal of Psychiatry* 194: 55–61

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To '… develop a care pathway for advance decisions and powers of attorney using Huntington's disease as an exemplar.' (p55). The researchers aimed to address a number of issues specifically: '… when should advance decisions and lasting power of attorney be discussed; how should information regarding advance decisions and lasting power of attorney be delivered and by whom; how should capacity to execute an advance decision or lasting power of attorney be determined; and can a care	**How well was the data collection carried out?** Appropriately. Data collection appears to be systematic and focus groups and interviews were in-depth. The methods are well described and are appropriate for the main research objective (gathering views about advance care planning). **Is the context clearly described?** Unclear. The participants are not well described, only details regarding diagnosis or profession are provided.	**Does the study's research question match the review question?** Partly. Only the first part of the study gathers views and experiences data using qualitative methods. **Has the study dealt appropriately with any ethical concerns?** No. The authors do not report on ethical issues or how they addressed these. **Were service users involved in the study?** No.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
pathway that is acceptable to service users and clinicians be developed.' (p55). **Methodology:** Qualitative. The study uses qualitative methods to develop a care pathway for advance decision-making. Only the first part of the study is relevant to NCCSC review question 1. **Is a qualitative approach appropriate?** Appropriate. Collecting qualitative data (views of service users, carers, and professionals regarding advance care planning) in the modelling phase of the care pathway was appropriate. **Is the study clear in what it seeks to do?** Clear. The modelling section is clear in its aims. **How defensible/rigorous is the research design/methodology?** Somewhat defensible. The modelling phase aimed to gain a range of views about advance care planning and use these data to develop the care pathway. The sample ended up being very small, service users and carers were interviewed face to face and practitioners were invited to take part in focus groups. The authors provide information about the topic guides and the data recording and analysis techniques.	No details regarding gender are provided, nor is there any information regarding working environments. Bias is not discussed. **Was the sampling carried out in an appropriate way?** Appropriate. Sampling was purposeful and was intended to gather diverse views. However, the sample is small and it is difficult to tell where some interviewee's contributions are presented in the text. **Were the methods reliable?** Somewhat reliable. The methods are presented clearly, but the findings do not seem to illustrate the diversity of opinion sought by the researchers. **Are the data 'rich'?** Mixed. Some verbatim quotes are included, but the findings are not presented clearly in terms of which interviewees gave which views. We only have 1 quote from a practitioner, even though 9 were interviewed. **Is the analysis reliable?** Reliable. The interviews were recorded and transcribed, grounded theory analysis was used and themes were checked for validity using recognised techniques. **Are the findings convincing?** Somewhat convincing. The findings are not well justified or tied to the interview data. We do not learn the	**Is there a clear focus on the guideline topic?** Yes. Advance decision-making in relation to individuals with Huntington's Disease. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Those who may lack mental capacity in the future as a result of Huntington's disease. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Community healthcare settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Support for future planning. **Are the views and experiences reported relevant to the guideline?** Yes. The views of practitioners, carers and service users' views about advance care planning. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	views of each group of practitioners and there is a greater focus on the views of service users and carers. **Are the conclusions adequate?** Somewhat adequate. It is difficult to be confident as the findings are only briefly presented thematically, when the interviews appear to have been relatively lengthy, and some detail appears to have been lost, particularly that relating to practitioner views.		

7. Manthorpe J, Samsi K and Rapaport J (2014) Dementia nurses' experience of the Mental Capacity Act 2005: a follow-up study. *Dementia* 13: 131–143

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: This paper reports on the second stage of a research project in which interviews were used to follow-up with participants from the first stage. The '… overall aim of this part of the study was to explore participants' understanding, over time, their practice experience of the implementation of the MCA and their reflections of change in nursing practice. More specifically, this related to what challenges, if any, they faced in everyday practice and whether any expectations in relation to the MCA had been met.' (p133). **Methodology:** Qualitative – interviews. **Is a qualitative approach appropriate?** Appropriate.	**Is the context clearly described?** Unclear. The study does not provide a great deal of detail in relation to participants or the context in which they were working. We know that the interviews took place over the phone or in the workplace and there is some discussion of bias regarding this. **Was the sampling carried out in an appropriate way?** Not clear. The approach to sampling is not well described. It is not clear how many participants also took part in the first interviews or how interviewees were selected. **Were the methods reliable?** Somewhat reliable. Only 1 interview was conducted per person, but findings	**Does the study's research question match the review question?** Partly. The study explores the experiences of dementia nurses in relation to the Mental Capacity Act. **Has the study dealt appropriately with any ethical concerns?** No. Not reported. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. The focus is on dementia nurses' experiences of the Mental Capacity Act. These participants work with those who may lack mental capacity or lose capacity in the future. The study also describes how nurses work with carers.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Is the study clear in what it seeks to do? Clear. This study follows on from another study (Samsi, 2012) and states that it aims to gather views and perspectives from dementia nurses about their views of, and practices relating to, the *Mental Capacity Act 2005*. **How defensible/rigorous is the research design/methodology?** Defensible. The authors state that they aimed to explore participants understanding over time regarding their practice and its relationship to the Mental Capacity Act; however participants in this study were only interviewed once. Although this study may be viewed in tandem with its linked study, it appears that the 2 samples were not comprised entirely of the same participants. Despite this, the authors do provide a rationale for their overall approach and their sampling methods are well described. **How well was the data collection carried out?** Appropriately. Data collection methods are described in adequate levels of detail. The design of the semi-structured interviews is discussed as is the issue of bias. Interviewers were intentionally different from those used in the linked study. Data collection appears to have been systematic.	are discussed in relation to other studies. **Are the data 'rich'?** Mixed. The discussion is general and while some verbatim quotes are provided we do not learn in detail how many practitioners agreed on certain points. Overall the results lack detail. **Is the analysis reliable?** Reliable. Interviews were recorded and transcribed. They were analysed by two researchers and organised into themes using an iterative process. **Are the findings convincing?** Convincing. The findings appear coherent and themes are clearly presented. Some extracts from the interviews are presented. **Are the conclusions adequate?** Adequate.	**Is the study population the same as at least one of the groups covered by the guideline?** Yes. People who may lack mental capacity. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Community settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

8. Poppe M, Burleigh S, Banerjee S (2013) Qualitative evaluation of advanced care planning in early dementia (ACP-ED). PLoS ONE 8: e60412

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To explore the acceptability of discussing advance care planning with people with memory problems and mild dementia shortly after diagnosis. **Methodology:** Qualitative – interviews. **Is a qualitative approach appropriate?** Appropriate. **Is the study clear in what it seeks to do?** Clear. **How defensible/rigorous is the research design/methodology?** Defensible.	**How well was the data collection carried out?** Appropriately. A researcher with extensive experience in dementia research conducted interviews lasting about 45 minutes, using open-ended questions. **Is the context clearly described?** Clear. **Was the sampling carried out in an appropriate way?** Somewhat appropriate. Patients with mild dementia and their carers were identified by memory clinics and invited to participate. No information on how staff members were recruited is provided. **Were the methods reliable?** Reliable. Open-ended questions in interviews lasting around 45 minutes. **Are the data 'rich'?** Rich. **Is the analysis reliable?** Reliable. Interviews were audio-recorded and transcribed verbatim. Data were compared to identify similarities and differences between emerging themes. Data were collected from 3 different groups of participants to facilitate comprehensive understanding of the topic. Data were independently coded and disagreements were resolved by discussion. NVivo 8 software was used to aid the analysis of the interviews.	**Does the study's research question match the review question?** Yes. **Has the study dealt appropriately with any ethical concerns?** Yes. Approved by the South East London REC 3 Research Ethics Committee. All participants gave their informed written consent. **Were service users involved in the study?** Yes. Patients and carers were involved in the development of the Advanced Care Planning in Early Dementia tool used in this study. **Is there a clear focus on the guideline topic?** Yes. Advance care planning. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Patients (people with early dementia), carers and health staff members from clinics. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Patients' homes and care settings (memory clinic and mental health team's place of work). **Does the study relate to at least one of the activities covered by the**	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Are the findings convincing? Convincing. **Are the conclusions adequate?** Adequate.	**guideline?** Yes. Advance care planning. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

9. Robinson L, Dickinson C, Bamford C et al. (2013) A qualitative study: professionals' experiences of advance care planning in dementia and palliative care, 'a good idea in theory but ...' Palliative Medicine 25: 401–408

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors report that the '… aim of this study was to examine critically the views and experiences of a wide range of professionals, clinical and non-clinical, on ACP in 2 clinical areas, dementia and palliative care, where professionals may be more likely to introduce it due to a future loss of mental capacity and the presence of a terminal illness.' (p402). **Methodology:** Qualitative – focus groups and individual interviews. **Is a qualitative approach appropriate?** Appropriate. **Is the study clear in what it seeks to do?** Clear. Clear aims and objectives. **How defensible/rigorous is the re-**	**How well was the data collection carried out?** Appropriately. The research used focus groups and semi-structured interviews. Focus groups were facilitated and semi-structured interviews were informed by a topic guide. **Is the context clearly described?** Not clear. Participants and contexts are not that clearly described and details are only provided regarding the professionals who took part. **Was the sampling carried out in an appropriate way?** Appropriate. Study used purposive sampling and a wide range of professionals taking part. **Were the methods reliable?** Reliable. The study used 2 data collection methods and both are well described. The authors note that the interview	**Does the study's research question match the review question?** Yes. The study has good relevance to the review question given its focus on experiences of advance care planning. **Has the study dealt appropriately with any ethical concerns?** Yes. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Practitioners working with people with dementia or serious life-limiting conditions. **Is the study setting the same as at**	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
search design/methodology? Defensible. The research design is well described and sample justified.	discussion guides were influenced by findings from a systematic review. **Are the data 'rich'?** Rich. Verbatim quotes are included, several perspectives are explored and compared and detail is given to illustrate themes. **Is the analysis reliable?** Reliable. All activities were recorded and transcribed; transcripts were analysed using Nvivo (by more than 1 researcher). **Are the findings convincing?** Convincing. **Are the conclusions adequate?** Adequate. Conclusions are clearly expressed and the themes are presented in sufficient detail. The authors discuss the limitations of the study and a diversity of practitioner opinions are explored.	**least one of the settings covered by the guideline?** Yes. Professionals from a variety of health and social care backgrounds, both inpatient and community. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Planning in advance for decision-making. **Are the views and experiences reported relevant to the guideline?** Yes. Practitioner views. **Does the study have a UK perspective?** Yes.	

10. Samsi K, Manthorpe J, Rapaport P (2011) 'As people get to know it more': experiences and expectations of the Mental Capacity Act 2005 amongst local information, advice and advocacy services. Social Policy and Society 10: 41–54

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors report that they aimed to explore the views and experiences of local Age Concern staff regarding their knowledge and understanding of the *Mental Capacity Act 2005*. **Methodology:** Qualitative.	**How well was the data collection carried out?** Appropriately. The study used a convenience sample, and interviews were recorded verbatim and transcribed. Methods appear to align with the research aims. However, no information regarding the content of interview scripts is provided.	**Does the study's research question match the review question?** Yes. There is a significant enough focus on advance planning in this paper, although that is not the sole focus. **Has the study dealt appropriately with any ethical concerns?** No.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
Is a qualitative approach appropriate? Appropriate. **Is the study clear in what it seeks to do?** Clear. The aims and objectives are clearly described. **How defensible/rigorous is the research design/methodology?** Defensible. The study describes interviews with Age Concern staff which aimed to explore their experiences and understanding.	**Is the context clearly described?** Unclear. Bias is not considered and the settings are not clearly described. The only information provided relates to recruitment (Age Concern groups in London). Some information regarding participants (e.g. gender, approximate age and role) are provided. **Was the sampling carried out in an appropriate way?** Appropriate. **Were the methods reliable?** Somewhat reliable. Only 1 method was used, but the study is discussed in the context of the Mental Capacity Act and relevant literature. **Are the data 'rich'?** Rich. Points and themes are complemented with detailed verbatim quotes. **Is the analysis reliable?** Reliable. Analysis of interview transcripts used a 5-stage process of analysis. **Are the findings convincing?** Convincing. **Are the conclusions adequate?** Adequate. Themes appear plausible and verbatim quotes help to link research to findings.	**Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. Clear focus on the Mental Capacity Act from the perspective of advice and information workers. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Practitioners. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Community settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Support around advance decision-making, in this case information and advice services. **Are the views and experiences reported relevant to the guideline?** Yes. Views and experiences of Age Concern staff. **Does the study have a UK perspective?** Yes.	

11. Sinclair J, Oyebode J, Owens R (2016) Consensus views on advance care planning for dementia: a delphi study. Health and Social Care in the Community 24: 165–174

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To investigate consensus views of how advance care planning should be explained and carried out with people with dementia. **Methodology:** Survey – delphi methods using 3 rounds of questionnaire surveys. **Research design clearly specified and appropriate?** Yes. Delphi method: '… principles of multiple rounds of consultation, structured feedback and anonymity at the heart of its approach to achieving consensus (Hasson et al. 2000).' (p166). **Objectives of the study clearly stated?** Yes. To examine consensus views of how advance care planning should be explained and carried out with people with dementia.	**Clear description of context?** Unclear. Rounds of questionnaires. **Survey population and sample frame clearly described?** Yes. The authors note that there '… is no official sample size calculation for a Delphi Study: Previous studies have employed as few as 5 and up to more than 60, with little evidence that this has any effect on validity or reliability (Powell 2003).' (p166). **Describes what was measured, how it was measured and the results?** Yes, percentage of agreement levels among participants. **Measurements valid?** Yes. Five point Likert scales were used to indicate level of agreement ('strongly disagree' to 'strongly agree'). **Measurements reliable?** Yes. **Measurements reproducible?** Unclear. **Basic data adequately described?** Yes. **Results presented clearly, objectively and in enough detail for readers to make personal judgements?** Yes.	**Does the study's research question match the review question?** Yes. Advance care planning. **Has the study dealt appropriately with any ethical concerns?** Yes. Approved by a local Research Ethics Committee, and management permission was provided by the research and development departments of 1 primary care trust and 2 foundation trusts. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. To gather consensus views on advance care planning for dementia. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Policy makers, practitioners, patients with dementia and family carers. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes, advance care planning.	**Overall assessment of internal validity: +** **Overall assessment of external validity: +**

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Results internally consistent? Partly. **Clear description of data collection methods and analysis?** Yes, as per the Delphi method (3 rounds of questionnaires to gauge agreement/consensus), comments to open questions 'synthesised' by condensing similar comments into 1 comment. No interpretation was performed. Triangulation between the first and second authors was carried out on 20% of the comments. Likert scale data analysis was conducted using SPSS. **Methods appropriate for the data?** Yes, as per Delphi method. **Results can be generalised?** Unclear. **Conclusions justified?** Partly.	**Are the views and experiences reported relevant to the guideline?** Yes, to investigate consensus views from experts (representatives of healthcare professionals, policy makers, people with dementia and family carers) about advance care planning. **Does the study have a UK perspective?** Yes.	

12. Wilson E, Seymour J, Perkins P (2010) Working with the Mental Capacity Act: findings from specialist palliative and neurological care settings. Palliative Medicine 24: 396–402

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors aimed to explore '… staff perspectives on, and experiences of working with, the new MCA guidelines. The study took place in 3 palliative and 3 specialised neurological care centres run by a national charity and situated across England.' (p396).	**How well was the data collection carried out?** Appropriately. The study used face-to-face interviews; either one on one or joint, individual telephone interviews and focus groups. **Is the context clearly described?** Clear. Details regarding the job roles of participants are provided; however,	**Does the study's research question match the review question?** Yes. There is a focus on the Mental Capacity Act in practice, with a specific focus on advance care planning for people with neurological conditions or cancer. **Has the study dealt appropriately with any ethical concerns?** Yes.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Methodology: Qualitative – interviews and focus groups. **Is a qualitative approach appropriate?** Appropriate. **Is the study clear in what it seeks to do?** Clear. Clear description of aims and objectives. **How defensible/rigorous is the research design/methodology?** Defensible. The study used semi-structured interviews and focus groups with multidisciplinary teams from 6 specialised units, 3 of which were palliative care and 1 was neurological. The sample was of a moderate size (n = 26).	no details regarding their personal characteristics are reported. There is some description of working contexts. The issue of bias is raised regarding analysis, and the authors note that a different researcher coded the paper to the researcher who had conducted the interview. **Was the sampling carried out in an appropriate way?** Appropriate. The purposive sample was sought from 6 specialised units. Twenty-six practitioners from 4 of these units made up the final sample. **Were the methods reliable?** Reliable. **Are the data 'rich'?** Rich. Findings show good detail and a variety of perspectives. The views of practitioners from different units are compared. **Is the analysis reliable?** Reliable. Interviews were transcribed and anonymised. A different researcher to the one that conducted the interview coded each transcript. Framework analysis was conducted and the 5 stages approach to analysis was used. **Are the findings convincing?** Convincing. Findings are coherent and themes are clear with well-referenced material from the original transcripts included in the write-up.	**Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Practitioners working with adults who may lack mental capacity (neurological conditions or advanced cancer). **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Inpatient health settings, palliative care settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Supporting advance planning. **Are the views and experiences reported relevant to the guideline?** Yes. The views of practitioners working in neurological and palliative care settings. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
	Are the conclusions adequate? Adequate.		

Research question 1. Planning in advance, including for people who experience fluctuating capacity (review 2):

- 1.1 – What interventions, tools, aids and approaches are effective and cost-effective in supporting advance planning for decision-making for people who may lack mental capacity in the future?
- 1.2 – What are the views and experiences of people who may lack mental capacity, their families and carers, practitioners and others interested in their welfare, on the acceptability of interventions, tools, aids and approaches to support planning in advance for decision-making?

Effectiveness data

1. Borschmann R, Barrett B, Hellier JM et al. (2013) Joint crisis plans for people with borderline personality disorder: feasibility and outcomes in a randomised controlled trial. British Journal of Psychiatry 202: 357–364

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To '… examine the feasibility of recruiting and retaining adults with borderline personality disorder to a pilot RCT investigating the potential efficacy and cost-effectiveness of using a joint crisis plan.' (p357). **Methodology:** Quantitative – randomised controlled trial. **Description of theoretical approach?** Partly. Some theory is provided. The study is a randomised controlled trial, and describes its methods for recruiting participants, its criteria for selection, and how randomisation and masking were carried out (where possible, given the nature of the research). There is however, no in-depth discussion of the theories underpinning the design of the intervention. **How was selection bias minimised?** Randomised. The randomisation procedure was '…managed electronically by the Clinical Trials	**Was the exposure to the intervention and comparison as intended?** Partly. The exposure to the treatments (i.e. usual treatment and joint care plan) went as planned. However, it was not possible to ensure all members of the control group received treatment as usual that was similar to each other. They were recruited from 5 London boroughs, and treatment as usual for people with borderline personality disorder '… varies greatly between CMHTs, between clinicians and between individual service users …' (p363). The researchers acknowledge that '… participants allocated to the treatment as usual arm received considerable variation in treatment …' (p363). It is possible that some of the treatment as usual group may have had crisis contingency plans as part of that normal treatment, which may have been similar to joint crisis plans. **Was contamination acceptably low?** Not reported.	**Does the study's research question match the review question?** Yes. **Has the study dealt appropriately with any ethical concerns?** Yes. The authors report that data collection protocols were '… approved by the South London Research Ethics Committee … and the trial was registered with the International Standard Randomised Controlled Trial registry … prior to the commencement of data collection. All participants provided written informed consent prior to entering the trial, including allowing members of the research team to access their electronic records. Progress of the trial, adherence to protocol and participant safety were overseen by a trial steering committee …' (p358). **Were service users involved in the design of the study?** No.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
Unit at the King's College London Institute of Psychiatry, UK …' (p358). The groups were stratified by alcohol usage and depression, both of which have been shown to be predictive of self-harm. **Was the allocation method concealed?** Yes. **Were participants blinded?** Blinding not possible. It would not have been possible to blind participants who were receiving a joint care plan and usual care, and who were continuing to receive usual care without a joint crisis plan. **Were providers blinded?** Blinding not possible. It would not have been possible to blind providers to who was receiving a joint care plan and usual care, and who was continuing to receive usual care without a joint crisis plan. **Were investigators, outcome assessors, researchers, etc., blinded?** Blind. The authors report that all '… follow-up data were collected by a research worker who was masked to treatment allocation and all data analyses were conducted by a statistician who was also masked to treatment allocation.' (p358). **Did participants represent the target group?** Yes. All participants met the criteria for inclusion, i.e. they	**Did either group receive additional interventions or have services provided in a different manner?** No. **Were outcomes relevant?** Yes. Measuring whether people with a recent history of self-harm had self-harmed again during the follow-up period, as well as the secondary outcome measures of people's wellbeing and engagement with different services all seem to be relevant ways of assessing and comparing the potential impact of the joint crisis plans. **Were outcome measures reliable?** Partly. The researchers would have been able to measure reliably whether participants had engaged with the process. However, other measures were less reliable, particularly where it relied on self-reporting. Self-reporting on self-harm would rely on participants being open about self-harming behaviour, having a common understanding of what was being asked in the questionnaire, and having an accurate recollection after 6 months about what had happened and when. Also, only recent acts of self-harm had their severity measured medically, and questions about the intention of self-harm were not asked. **Were all outcome measurements complete?** Yes.	**Is there a clear focus on the guideline topic?** Yes. The study focused on advance plans (regarding treatment in a crisis) for people with borderline personality disorder. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. The population of the study were adults with borderline personality disorder. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. All participants were living in the community. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the study outcomes relevant to the guideline?** Yes. The study measured whether people with borderline personality disorder could be engaged in a care planning process, The primary outcome was self-harm. Secondary outcomes included depression and anxiety; working alliance between client and practitioner; satisfaction with services; engagement with services; wellbeing; social functioning; participants' experience of coercion during hospital admission; health-related quality of life and resource use. **Does the study have a UK perspective?** Yes. The study was carried out	

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
were aged 18 or older, they met the diagnostic criteria for borderline personality disorder, they had self-harmed in the previous 12 months, and they were under the care of a Community Mental Health Team. **Were all participants accounted for at study conclusion?** No. At baseline there were 46 people in the treatment group and 42 in the control group. Six-month follow-up data was obtained for 37 people (80.4%) from the treatment group and 36 (85.7%) from the control group. Eighty-three per cent of the total baseline sample was included in the follow-up.	**Were all important outcomes assessed?** Yes. Data was presented for all outcome measures, and the conclusions presented were drawn from an assessment of the results. **Were there similar follow-up times in exposure and comparison groups?** Yes. Both groups were followed-up for 6 months from baseline. **Was follow-up time meaningful?** Partly. The researchers speculated that a greater effect would have become apparent over a longer follow-up period. **Were the analytical methods appropriate?** Yes. **Were exposure and comparison groups similar at baseline? If not, were these adjusted?** Yes. Both groups met the inclusion criteria of being 18 or older, meeting diagnostic criteria for borderline personality disorder, self-harming in the last 12 months, being under the care of a community mental health team and being able to give written consent to participating in the research. In the randomisation process, both groups were stratified for alcohol use and depression. **Was intention to treat (ITT) analysis conducted?** Yes.	across south London (Lambeth, Southwark, Lewisham, Croydon and Greenwich).	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Was the study sufficiently powered to detect an intervention effect (if one exists)? Partly. The researchers report that they increased the target sample size to '… 120 in order to allow for attrition and loss of data on self-harm. This sample would also be large enough to provide 80% power to detect a constant hazard ratio between the groups of 0.29 with proportions of episodes in the 2 groups as stated above, based on the log-rank statistic assuming no accrual rate, a fixed time of follow-up and an estimated 10% rate of drop out …' (p359). However, they were only able to recruit 88 participants. **Were the estimates of effect size given or calculable?** Yes. Effect sizes are not given. However, means and standard deviations are provided, so they would be calculable. **Was the precision of intervention effects given or calculable? Were they meaningful?** Partly. The researchers only report *p* values and confidence intervals for the comparison of differences in self-harm and costs per participant. **Do conclusions match findings?** Yes. The findings and conclusions are consistent.		

2. Jones L, Harrington J, Barlow CA et al. (2011) Advance care planning in advanced cancer: can it be achieved? An exploratory randomized patient preference trial of a care planning discussion. Palliative and Supportive Care 9: 3–13

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors' aimed to determine '… the acceptability and feasibility of a patient preference randomized controlled trial of an intervention to facilitate planning for end-of-life care?' (p4) and the most appropriate outcomes to assess the effectiveness of this intervention. **Methodology:** Quantitative – randomised controlled trial. **Description of theoretical approach?** Yes. **How was selection bias minimised?** Randomised. The study had a randomised cohort and a preference cohort. **Was the allocation method concealed?** Partly. When '… a participant in the randomized cohort had given informed consent, the researcher passed their contact details to the care planning mediator who contacted the central administrator. The administrator opened the next envelope in the sequence and informed the mediator of the group allocation. The mediator contacted participants to inform them of their group allocation and arranged the first ACP discussion for those in the intervention group. The study statistician and the researchers were masked to allocation …' (p6).	**Was the exposure to the intervention and comparison as intended?** Yes. **Was contamination acceptably low?** Yes. There is no indication that contamination occurred. **Did either group receive additional interventions or have services provided in a different manner?** Not reported. **Were outcomes relevant?** Yes. **Were outcome measures reliable?** Partly. Part of the data was collected using a standardised, reliable measure of anxiety and depression (Hospital Anxiety and Depression scale). However, as the researchers were unaware of any published measures of '… pragmatic outcomes that were expected to arise from a discussion-based rather than document-based approach to advance care planning...' (p6) they developed their own visual analogue scales to reflect their outcomes of interest such as discussions about the future, satisfaction, etc. **Were all outcome measurements complete?** Yes. **Were all important outcomes assessed?** Yes.	**Does the study's research question match the review question?** Yes. The study focuses on the impact of advance care planning discussions. **Has the study dealt appropriately with any ethical concerns?** Yes. The study was approved by the Royal Free Hospital and Medical School Local Research Ethics Committee. **Were service users involved in the design of the study?** No. **Is there a clear focus on the guideline topic?** Yes. The study explores the impact of advance care planning discussions for advanced cancer patients. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Two outpatient clinics and a hospice. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the study outcomes relevant to**	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Were participants blinded? Blinding not possible. **Were providers blinded?** Blinding not possible. **Were investigators, outcome assessors, researchers, etc., blinded?** Blind. The authors report that the '… study statistician and the researchers were masked to allocation. Patients were asked not to reveal group allocation at follow-up, at which data were collected by the researcher …' (p6). **Did participants represent the target group?** Yes. All participants were patients with advanced cancer. **Were all participants accounted for at study conclusion?** No. The authors report that 9 participants '… were lost to follow up, 3 in the randomized cohort. One participant moved away from the area, 1 died, 3 became too ill, 1 was unable to be contacted; 1 stated that they found the study too 'morbid' to continue, and 2 withdrew for unknown reasons …' (p11).	**Were there similar follow-up times in exposure and comparison groups?** Yes. Eight weeks follow-up. **Was follow-up time meaningful?** Yes. Although the eight-week follow-up period was relatively short term this appears to be a realistic timescale given that the study recruited patients with advanced cancer. **Were the analytical methods appropriate?** Yes. The authors report statistical procedures in detail, noting that descriptive statistics '…of all baseline measures were generated stratified (1) by whether patients chose the trial arm or were randomized and (2) by intervention (usual care or advance care planning). We used Cronbach's alpha to estimate the internal consistency of VAS scores for each domain (discussion about the future, happiness with communication, and satisfaction with healthcare) and subdomain (professionals vs. family and friends). The scores from the scales belonging to each domain were summed and summary scores were used in the analysis. The distributions of the data were sufficiently normal for parametric tests to be used. Analysis of Covariance (ANCOVA) models of each outcome measure at follow-up (HADS depression and anxiety scores, and VAS domain and subdomain summary scores) were fitted with the baseline score and treatment group as covariates. Further adjustment for possible	**the guideline?** Yes. The study explores whether the intervention enabled participants to discuss end-of-life plans with professionals as well as family and friends; and whether their experiences of healthcare were improved. **Does the study have a UK perspective?** Yes. The study was conducted in London.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	confounding variables was investigated. Analyses were conducted separately for (1) the randomized cohort, (2) the preference cohorts, and (3) both cohorts combined. Analyses were performed on an intention-to-treat basis. As this trial was exploratory, a formal power calculation was not required' (p6–7). **Were exposure and comparison groups similar at baseline? If not, were these adjusted?** Partly. Although the study reports 'that Cronbach's alpha was .0.6 for all visual analogue domains and subdomains, indicating sufficient internal consistency for scores to be summed' (p8). There were some differences between the 4 groups being considered, perhaps inevitably given numbers in each group were quite small for data analysis purposes. One group (those who preferred usual treatment) was smaller in number at 14 than the other groups, which had 20, 21 and 22 participants. Within the randomised cohort, the mean time since diagnosis for the advance care planning group was 2 years (IQR 1 to 3.5) while for the usual treatment group it was 4 years (IQR 2 to 8.5). The group who preferred usual treatment were also likely to be older (mean 67.71, SD 7.89) compared to the other groups (mean ages of 61.95, 58.57 and 60.21). Within the preference cohort, 72.2% of those who chose advance		

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	care planning were in the high socioeconomic group, compared to 25.0 of those choosing usual treatment, while only 5.6 of those choosing advance care planning were in the low socioeconomic group, but 33.3% of those choosing usual care were in this socioeconomic group. Educationally, 57.1% of those choosing advance care planning had a postgraduate education, compared to 23.1% of those choosing usual care. **Was intention to treat (ITT) analysis conducted?** Yes. **Was the study sufficiently powered to detect an intervention effect (if one exists)?** No. The researchers report that it was not necessary to calculate whether the study was adequately powered, stating that phase II trials '… of this exploratory nature are not designed to demonstrate effectiveness, and numbers are chosen on pragmatic grounds, usually aiming for a total of 40 in each of the control and intervention arms …' (p4). **Were the estimates of effect size given or calculable?** Yes. **Was the precision of intervention effects given or calculable? Were they meaningful?** Yes. Coefficients, confidence intervals and *p* values are presented for all outcomes.		

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Do conclusions match findings? Yes.		

3. Thornicroft G, Farrelly F, Szmukler G et al. (2013) Clinical outcomes of Joint Crisis Plans to reduce compulsory treatment for people with psychosis: a randomised controlled trial. Lancet 381: 1634–1641

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The study reports on the CRIMSON (CRisis plan IMpact: Subjective and Objective coercion and eNgagement) trial, an '… individual level, randomised controlled trial that compared the effectiveness of Joint Crisis Plans with treatment as usual for people with severe mental illness. The joint crisis plan is a negotiated statement by a patient of treatment preferences for any future psychiatric emergency, when he or she might be unable to express clear views.' (p1634). **Methodology:** Mixed methods – randomised controlled trial, plus qualitative component. **Description of theoretical approach?** Partly. Although this was a mixed-methods study that included a randomised controlled trial, the paper does not report on the theoretical basis for both parts of the research and there is no discussion regarding the chosen methodology or its suitability to the research objectives. **Quantitative component:** Randomised controlled trial.	**Was the exposure to the intervention and comparison as intended?** Partly. Although fidelity to the intervention was rated as high (average across the three sites of 86%) and the joint crisis plans were rated highly, this was undermined by qualitative data indicating that many clinicians had conducted the joint crisis plan meetings in a style that was clinician rather than patient-led. Almost half (48%) of the meetings were combined with a usual care meeting, which made it hard for patients to differentiate it from their usual care planning. Clinicians taking part in the trial had not changed the clinician-patient relationship in the way the model required, e.g. there was no active discussion of treatment option or support of patient choice. Patients reported that the plans agreed in the joint crisis plan were not honoured, and few care co-ordinators (only 5/28) referred to the joint crisis plan during the study period. **Was contamination acceptably low?** Yes. There is no indication that contamination took place.	**Does the study's research question match the review question?** Yes. The researchers aimed to examine the effectiveness of an intervention designed to enable collaborative plans to be developed for future instances where the person may lack capacity. **Has the study dealt appropriately with any ethical concerns?** Yes. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. The study evaluates an intervention for people who may lack capacity in the future due to a relapse in psychosis. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. All participants in the study were living in the community at baseline, although some were admitted to psychiatric	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
How was selection bias minimised? Randomised. Participants were stratified by site and then '… randomly allocated … to intervention or control group using permuted blocks of randomly varying block size, with equal allocation to the 2 groups. The allocation sequence was generated by the independent clinical trials unit at the study coordinating centre' (p1635). **Was the allocation method concealed?** Yes. **Were participants blinded?** Blinding not possible. **Were providers blinded?** Blinding not possible. **Were investigators, outcome assessors, researchers, etc., blinded?** Part blind. The authors report that the '… research assistants (who did the follow-up), and trial statisticians were masked to allocation. Qualitative data were collected by separate researchers … who were not involved in baseline and follow-up assessments, and occurred after a participant's follow-up to ensure research assistants were not unmasked. Qualitative researchers were not masked because they specifically interviewed intervention group participants only …' (p1635).	**Did either group receive additional interventions or have services provided in a different manner?** Not reported. **Were outcomes relevant?** Yes. **Were outcome measures reliable?** Partly. **Were all outcome measurements complete?** Yes. **Were all important outcomes assessed?** Yes. **Were there similar follow-up times in exposure and comparison groups?** Yes. Both groups were followed for around 18 months. **Was follow-up time meaningful?** Yes. **Were the analytical methods appropriate?** Yes. **Were exposure and comparison groups similar at baseline? If not, were these adjusted?** Yes. **Was intention to treat (ITT) analysis conducted?** Yes. **Was the study sufficiently powered to detect an intervention effect (if one exists)?** Yes. **Were the estimates of effect size**	hospital during the follow-up period. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the study outcomes relevant to the guideline?** Yes. The primary outcome being measured was compulsory admissions to psychiatric hospital, on the hypothesis that patients who had made a joint crisis plan would require fewer compulsory admissions. Secondary outcomes measured were psychiatric admissions (voluntary or compulsory), length of stay in psychiatric units, patients' perception of coercion, patients' and clinicians' perceptions of the therapeutic relationship, and clinicians' of patients' engagement. **Does the study have a UK perspective?** Yes. Participants were recruited from 3 NHS trusts in England (Birmingham and Solihull Mental Health Foundation Trust; Lancashire Care NHS Foundation Trust and Manchester Mental Health and Social Care Trust; and South London and Maudsley NHS Foundation Trust).	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Did participants represent the target group? Yes. **Were all participants accounted for at study conclusion?** No. The researchers anticipated that 15% of the sample would be lost to follow-up. At follow-up, data '… for the primary outcome (admission to hospital under a compulsory section of the MHA) were missing (i.e. refused access) for 22 of the 569 participants (4%). Those with missing data for the primary outcome were similar to those with such data, except that the former had significantly worse self-rated therapeutic relationship (WAIC) scores (18.6 vs 15.8, *p* = 0. 043) and were more likely to be in the intervention group (n=18, 6%) than in the control group (n=4, 1%) …' (p1637). There was a higher level of missing data for the secondary outcomes and '… 20% of participants were missing perceived coercion score, 24% were missing engagement with care scores, and 22% were missing WAIC and WAIT scores at follow up. Participants missing secondary outcomes at follow-up were more likely to come from the intervention group for all outcomes: 56% perceived coercion, 60% service engagement, 64% WAIC, and 63% of those missing WAIT …' (p1637).	**given or calculable?** Yes. **Was the precision of intervention effects given or calculable? Were they meaningful?** Yes. **Do conclusions match findings?** Partly. The authors conclude that fidelity '… to the intervention was high, with an average rating of 86% across the 3 sites …' (p1637); however, the qualitative data suggest that fidelity to the model was poor. **Qualitative component:** Qualitative interviews and focus groups. These comprised 12 focus groups and 37 individual interviews. Of the focus groups, 5 were with patients only, 5 with care co-ordinators only, and 2 were mixed, with 1 psychiatrist participating in 1 of the groups. The individual interviews were conducted with 16 psychiatrists; 6 care co-ordinators and 15 patients. **Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question?** Yes. Focus groups and individual interviews were conducted with people whose views and experiences were relevant to the research objectives. **Is the process for analysing qualitative data relevant to address the research question?** Yes. The au-		

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	thors report that inductive '… thematic analysis, including constant comparison methods were used to analyse data that specifically related to explaining the trial out comes. Disconfirming evidence was sought throughout. NVIVO version 9 was used to help manage the data' (p1637). **Is appropriate consideration given to how findings relate to the context, such as the setting, in which the data were collected?** No. The authors report that '… focus groups and semi-structured interviews with intervention group participants were done at each site …' (p1636), but do not provide any details about each site, or discuss how settings may have influenced findings. **Is appropriate consideration given to how findings relate to researchers' influence; for example, through their interactions with participants?** No. The study does not consider the possibility of researcher influence on interviews. **Is the mixed-methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed-methods question?** Yes. The qualitative data adds important information to the quantitative data, and provides a different		

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
	perspective on the outcomes. **Is the integration of qualitative and quantitative data (or results) relevant to address the research question?** Yes. **Is appropriate consideration given to the limitations associated with this integration, such as the divergence of qualitative and quantitative data (or results)?** Yes. The qualitative interviews took place after the quantitative data was collected. They help to explain why the quantitative data showed no significant differences in most respects between treatment and control groups, as the advance care planning model was not being adhered to.		

Views and experiences data

4. Almack K, Cox K, Moghaddam N et al. (2012) After you: conversations between patients and healthcare professionals in planning for end of life care. BMC Palliative Care 11: 15

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The study explores with patients, carers and healthcare professionals if, when and how advance care planning conversations about patients' preferences for place of care (and death) were facilitated and documented. **Methodology:** Qualitative – exploratory case study design using retrospective audit and qualitative interviews. **Is a qualitative approach appropriate?** Appropriate. The study was exploratory and pragmatic in nature with a focus on interactions between healthcare professionals, patients and their families. **Is the study clear in what it seeks to do?** Clear. Study objectives and methodology are described. **How defensible/rigorous is the research design/methodology?** Defensible. The researchers outline their rationale for their approach to sampling and describe their data collection and data analysis methods clearly. **How well was the data collection**	**Is the context clearly described?** Not clear. Some of the characteristics of participants and settings are reported (e.g. age, gender, diagnosis and family circumstances; type and area of study sites); however, these are not exhaustive. **Was the sampling carried out in an appropriate way?** Appropriate. Professionals from each service were asked to identify individuals on their palliative care register '… using the surprise question (would I be surprised if this patient died in the next year?)' (p2). **Were the methods reliable?** Somewhat reliable. The data were collected by asking patients, relatives and healthcare professionals about their experiences of discussions between the same groups. Similar themes were explored in the follow-up interviews with an emphasis on exploring what may have changed or stayed the same and why, in terms of patient preferences. Towards the end of the study, healthcare professionals who had been involved were invited to take part in a follow-up interview to reflect and comment on the individual clinical cases they had referred. These follow-up interviews provided	**Does the study's research question match the review question?** Yes. The study explores the factors influencing if, when and how advance care planning takes place between healthcare professionals, patients and family members from the perspectives of all parties involved and how such preferences are discussed and are recorded. **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval was obtained from the local research ethics committee and approval was also sought from relevant NHS trusts. **Were service users involved in the study?** Yes. Service users were involved in the selection of participants and an advisory group were involved in the selection of services. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Patients receiving palliative care services, nominated relatives and healthcare professionals.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
carried out? Appropriately. Researchers clearly described the data collection methods.	further details regarding the process by which discussions about preferred place of care were initiated. **Are the data 'rich'?** Rich. **Is the analysis reliable?** Reliable. All interviews were digitally recorded and fully transcribed. Detailed analysis of the interview material was undertaken using a constant comparative technique. The research team initially read through a selection of interviews separately to identify emerging themes and then compared notes. This thematic analysis continued through regular research team meetings, readings and discussion of further interview transcripts. This resulted in a coding framework that was applied to a selection of transcripts. **Are the findings convincing?** Convincing. **Are the conclusions adequate?** Adequate.	**Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Palliative care services. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The study explores the perspectives of patients, relatives and health professionals in relation to advance care planning. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

5. Barnes K, Jones L, Tookman A et al. (2007) Acceptability of an advance care planning interview schedule: a focus group study. Palliative Medicine 21: 23–28

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors report that the '… aims of this phase I qualitative focus group study were (1) to explore the acceptability of an interview schedule, designed to encourage conversations regarding future care;	**Is the context clearly described?** Clear. The characteristics of the participants and settings are clearly described. In addition, to achieve a wider perspective on issues relating	**Does the study's research question match the review question?** Yes.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
and (2) to explore the suitability of such discussions and inquire about their possible timing, nature and impact.' (p23). **Methodology:** Qualitative – focus groups. **Is a qualitative approach appropriate?** Appropriate. Focus groups provide an environment where the sensitive issue of end of life care can be discussed and shared in a wider forum, therefore allowing any individual study participant not to have to consider the topic in the context of their own experiences alone. Eight focus groups were held, each lasting for approximately 1 hour. **Is the study clear in what it seeks to do?** Clear. The study aimed to address the gap in research regarding patients' views of advance care planning; to help health professionals work with patients to plan end of life care in advance of the introduction of the *Mental Capacity Act 2005*. **How defensible/rigorous is the research design/methodology?** Defensible. The authors explain why a focus group format is best suited to this topic. In particular, it allows for study participants to reflect and express their views on a sensitive topic at a general level and without the spotlight being on their own particular circumstances.	to advance care planning, the researchers explored the views of patients at different stages of disease and also included the views of their families or other persons close to them. **Was the sampling carried out in an appropriate way?** Appropriate. Purposive sampling was used to achieve a sample of 22 palliative care and oncology patients, relatives and user group members. The sample consisted mostly of oncology patients in remission with patients at various stages of disease. The authors note that the sample was not ethnically diverse (all participants were white). **Were the methods reliable?** Reliable. **Are the data 'rich'?** Rich. Detailed contextualised narratives are provided. **Is the analysis reliable?** Reliable. Audio recordings were transcribed verbatim, and supplemented with field notes that recorded non-verbal behaviours providing further detail. Transcripts were analysed using thematic content analysis. A researcher studied the transcripts in detail drawing out the key points and categorising these under headings or emerging themes. Another researcher reviewed a 20% sample of the tran-	**Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval for this study was granted from the Royal Free Hospital Local Research Ethics Committee. **Were service users involved in the study?** No. Only as research participants. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Palliative care and oncology patients, relatives and service user group members. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Study conducted in an outpatient clinic. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. Views reported are those of palliative care and oncology patients, relatives and service user group members.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
How well was the data collection carried out? Appropriately. Clinicians introduced the study to oncology patients at an outpatient clinic. Nursing team members introduced the study to patients and relatives at a local hospice, and the chairperson of oncology user groups introduced the study to user group members. Following this, the researcher provided information, while seeking informed consent from interested patients. After reflecting on the advance care planning interview schedule for a week, participants attended a focus group, which was audio-recorded. There were up to 4 participants per group to facilitate in-depth and frank discussion of sensitive topics. The groups were facilitated by a research physician in palliative care and followed a topic guide. A research nurse captured the discussions in written format.	scripts. Discrepancies in interpretation were resolved and the key points made by each participant were collated in 1 document, categorised under emerging headings and themes, and then summarised. During the process of analysis, both researchers read and reread the transcripts to ensure that emerging themes could be linked back to the original data. New themes were identified through this process, and some points re-categorised as necessary. **Are the findings convincing?** Convincing. Clear and coherent reporting of findings. **Are the conclusions adequate?** Adequate. The study concludes that some patients with cancer welcome discussions about advance care planning. However, as the study was based on a small sample, findings cannot be generalised broadly. The authors note that some of the issues highlighted, such as the process and timing of advance care planning, should be explored further in a larger study. They also suggest further study into the cultural and ethnic differences that could have an impact on attitudes towards end of life care.	**Does the study have a UK perspective?** Yes.	

6. Barnes KA, Barlow CA, Harrington J et al. (2011) Advance care planning discussions in advanced cancer: analysis of dialogues between patients and care planning mediators. Palliative and Supportive Care 9: 73–79

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To explore the views of people with recurrent progressive cancer about advance care planning as an aid to consider, discuss and plan their future care with health professionals. **Methodology:** Qualitative – discussion sessions with mediators. **Is a qualitative approach appropriate?** Appropriate. **Is the study clear in what it seeks to do?** Clear. Advance care planning discussions. **How defensible/rigorous is the research design/methodology?** Defensible. **How well was the data collection carried out?** Appropriately. Advance care planning discussions with professionally trained mediators.	**Is the context clearly described?** Clear. Participants were seen alone for the first discussion but were invited to bring persons close to them to subsequent meetings if they wished. **Was the sampling carried out in an appropriate way?** Somewhat appropriate. Participants were randomly selected to advance care planning discussion intervention in the context of an exploratory patient preference randomised controlled trial. **Were the methods reliable?** Somewhat reliable. **Are the data 'rich'?** Rich. **Is the analysis reliable?** Reliable. Transcripts were analysed using thematic content analysis to explore the content and context of discussions. All sessions were audio-recorded and transcribed verbatim. **Are the findings convincing?** Convincing. **Are the conclusions adequate?** Adequate.	**Does the study's research question match the review question?** Yes. To explore views of people with recurrent progressive cancer about advance care planning as an aid to consider, discuss and plan their future care with health professionals. **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval granted by Royal Free Hospital and Medical School Research Ethics Committee, with informed consent from participants. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. Advance care planning discussions. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Advance care planning discussions. **Are the views and experiences reported relevant to the guideline?**	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
		Yes. **Does the study have a UK perspective?** Yes. The study was conducted in London.	

7. Bond CJ and Lowton K (2011) Geriatricians' views of advance decisions and their use in clinical care in England: qualitative study. Age and Ageing 40: 450–456

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors aimed to '... to elicit geriatricians' views on advance decisions and their use in decision-making in England.' (p450). **Methodology:** Qualitative – semi-structured interviews. **Is a qualitative approach appropriate?** Appropriate. The study's purpose was to explore the views of geriatricians' – a qualitative approach is appropriate for this. **Is the study clear in what it seeks to do?** Clear. Aims and objectives clearly stated. **How defensible/rigorous is the research design/methodology?** Somewhat defensible. The sample was very small and it should be noted that the study used hypothetical scenarios to prompt responses about responding to Advance Decisions to Refuse Treatment. **How well was the data collection**	**Is the context clearly described?** Clear. The characteristics of the participants are well described; information on their job roles, length of time in post, age and gender are provided. The authors do not provide details about the contexts they work in, but all participants have experience of using advance care planning documents. **Was the sampling carried out in an appropriate way?** Appropriate. Sample was purposive, which is appropriate for this type of study. **Were the methods reliable?** Somewhat reliable. The sample was very small, and interviews were only conducted once; it is unclear if more than 1 researcher conducted the analysis, and the issue of bias is not discussed. **Are the data 'rich'?** Mixed. The study presents some rich data and verbatim quotes. These fit well with the themes and strengthen findings.	**Does the study's research question match the review question?** Partly. **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval granted by University College London Hospital Ethics Committee. All participants gave written informed consent. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. The study focuses on advance planning and clinical decision-making. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Geriatricians. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Various clini-	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
carried out? Appropriately. Interviews typically lasted 40 minutes and were audio-recorded and transcribed verbatim.	**Is the analysis reliable?** Somewhat reliable. The analysis is described relatively clearly (grounded theory approach). Interviews were transcribed and recorded and analysed using grounded theory. However, it is not clear if more than 1 researcher analysed transcripts or if bias was an issue. **Are the findings convincing?** Convincing. The themes are supported by detailed quotes and the findings are discussed in depth. **Are the conclusions adequate?** Adequate. The study describes findings in relation to the interview material and study characteristics well. Themes appear appropriate.	cal settings. Not clear whether inpatient or community. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Advance planning. **Are the views and experiences reported relevant to the guideline?** Yes. Practitioner views – geriatricians. **Does the study have a UK perspective?** Yes. The study sample was comprised of geriatricians working in the London area.	

8. Boot M and Wilson C (2014) Clinical nurse specialists' perspectives on advance care planning conversations: a qualitative study. International Journal of Palliative Nursing 20: 9–14

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The aim of the study was to identify the challenges experienced by clinical nurse specialists when facilitating advance care planning conversations with terminally ill patients. This paper focuses on the factors that influence clinical nurse specialists when they are deciding whether to open an advance care planning discussion. **Methodology:** Qualitative – semi-	**Is the context clearly described?** Unclear. The characteristics of the participants and settings are not clearly defined. **Was the sampling carried out in an appropriate way?** Somewhat appropriate. Geographically separate teams were selected so that cultural influences regarding advance care planning might emerge from the findings.	**Does the study's research question match the review question?** Yes. The aim of the study was to identify the challenges experienced by clinical nurse specialists when facilitating advance care planning conversations with terminally ill patients, and the review is about advance care planning. **Has the study dealt appropriately with any ethical concerns?** Yes.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
structured interviews. **Is a qualitative approach appropriate?** Somewhat appropriate. The study could have been strengthened by the use of a mixed-method design. **Is the study clear in what it seeks to do?** Clear. **How defensible/rigorous is the research design/methodology?** Somewhat defensible. Qualitative methods were used to explore and understand nurses' experiences and perspectives. **How well was the data collection carried out?** Appropriately. The data was gathered from individual semi-structured interviews. These were audio-recorded and transcribed verbatim.	**Were the methods reliable?** Reliable. **Are the data 'rich'?** Mixed. Data includes verbatim quotes from participants. **Is the analysis reliable?** Reliable. The coded transcripts were discussed with a second experienced researcher for verification. **Are the findings convincing?** Convincing. **Are the conclusions adequate?** Adequate.	Ethical approval was granted by the Hertfordshire Integrated Research Application System Ethics Committee, the North Central London Research Consortium, and the University of Bedfordshire. **Were service users involved in the study?** Yes. All of the participants were offered the opportunity to review the transcripts of their interview. **Is there a clear focus on the guideline topic?** Yes. The aim of the study was to identify the challenges experienced by clinical nurse specialists when facilitating advance care planning conversations with terminally ill patients. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Clinical nurse specialists involved in advance care planning. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Palliative care community settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The aim of the study was to identify the challenges experienced by clinical nurse specialists when facilitating advance care planning conversations with terminally ill patients.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
		Are the views and experiences reported relevant to the guideline? Yes. **Does the study have a UK perspective?** Yes.	

9. Brazil K, Carter G, Galway K et al. (2015) General practitioners perceptions on advance care planning for patients living with dementia. BMC Palliative Care 14: 14

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To describe the attitudes and practice preferences of general practitioners working within the National Health System regarding communication and decision-making for patients with dementia and their families. **Methodology:** Survey – cross sectional survey using a purposive cluster sample. **Research design clearly specified and appropriate?** Yes. The design, sampling and survey instruments are clearly described and appropriate to the research question. **Objectives of the study clearly stated?** Partly. There is no specific section on study objectives. The authors simply state that the '… purpose of this study was to describe the attitudes and practice preferences of GPs working within the UK's National	**Describes what was measured, how it was measured and the results?** Yes. **Measurements valid?** Partly. Validity is neither tested nor reported (except to the extent that the construction of the sampling frame and response rates reflect the generalisability) Content validity appears to be good judging by the research question compared with the items in the survey instrument. **Measurements reliable?** Partly. The researchers did not formally calculate the reliability of the instrument. However the instrument was based on recommendations made by the European Association for Palliative Care regarding the palliative care of people with dementia. **Measurements reproducible?** Yes. The instrument is available in an additional file with the published paper.	**Does the study's research question match the review question?** Partly. The question covers communication as well as decision-making and is not therefore entirely aligned with the review question. **Has the study dealt appropriately with any ethical concerns?** Yes. The study was approved by the research ethics committee at the School of Nursing and Midwifery, Queen's University Belfast. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. People with care and support needs and who may lack capacity in the future.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Health System (NHS) regarding communication and decision-making for patients with dementia and their families.' (p2). **Clear description of context?** Yes. The context is clearly described, including that the Mental Capacity Act does not apply in Northern Ireland, although a regulatory framework does exist there with the aim of protecting '… the interests of those who do not have decisional capacity to manage their affairs and personal care …' (p2). The study is conducted within the context of the National Health Service. **References made to original work if existing tool used?** Partly. The instrument was designed by the researchers specifically for use in this study. However, it was based on recommendations made by the European Association for Palliative Care on palliative care for people with dementia. The instrument was then tested on a sample of palliative care physicians and general practitioners. **Reliability and validity of new tool reported?** No. The instrument was tested before the main survey but there is no discussion about its reliability or validity. **Survey population and sample frame clearly described?** Yes. Described in sufficient detail.	**Basic data adequately described?** Yes. Including demographic characteristics with means and standard deviation as well as frequencies for the question responses. **Results presented clearly, objectively and in enough detail for readers to make personal judgements?** Partly. Clearly presented in tabular form, with the exception of responses regarding barriers to the provision of palliative care, which are not easily discernible. **Results internally consistent?** Partly. Judging by the number of responses for the individual questions – and for the participants' characteristics – it appears that not all parts of the questionnaire were completed by all respondents. **Data suitable for analysis?** Yes. **Clear description of data collection methods and analysis?** Yes. Data collection methods clearly described. Data were inputted and managed using SPSS. **Methods appropriate for the data?** Yes. **Statistics correctly performed and interpreted?** Yes. Analysis was basic but correctly performed.	**Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Advance care planning. **Does the study have a UK perspective?** Yes. The study was conducted in Northern Ireland.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Representativeness of sample is described? Yes. The purposive sampling is clearly described. **Subject of study represents full spectrum of population of interest?** Partly. Represents practitioners supporting people in advance care planning, but not people with palliative care needs themselves and not families/carers. **Study large enough to achieve its objectives, sample size estimates performed?** No. Sample size estimates were not performed. **All subjects accounted for?** Yes. A total of 138 responses were received, of these 133 provided completed surveys, of the remaining 5 responses, 4 respondents indicated that they were too busy to complete the survey and 1 respondent submitted their completed survey after data analysis, giving a response rate of 40.6% (138/340), representing 60.9% (106/174) of the surveyed practices. **Measures for contacting non-responders?** No. **Response rate:** Separate response rate before and after contact is not reported. Response rate = 40.6% (138/340) of surveyed general practitioners and 60.9% (106/174) of the surveyed practices.	**Response rate calculation provided?** Yes. **Methods for handling missing data described?** No. None are described, for instance, there's no comparison between respondents and non-respondents (either overall or for individual items). Also no methods using statistical software are reported. **Difference between non-respondents and respondents described?** No. **Results discussed in relation to existing knowledge on subject and study objectives?** Partly. To the extent that the authors highlight that this is a unique study – they state that there has been no other such a survey undertaken on this topic within the United Kingdom. The discussion does also refer to existing evidence about the effectiveness of educational materials to support families and carers. **Limitations of the study stated?** Partly. They are stated, particularly in terms of the generalisability of findings – limited to Northern Ireland and a sampling frame, which only included general practitioners with familiarity with people living with dementia. However, the authors do not refer to testing of the survey. **Results can be generalised?** Partly.		

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Within Northern Ireland and among general practitioners who have familiarity of working with people with a dementia diagnosis and their families. The authors caution against generalising to the rest of the United Kingdom. **Appropriate attempts made to establish 'reliability' and 'validity' of analysis?** Partly. **Conclusions justified?** Partly. Justified but the discussion of findings lacks depth.		

10. Farrelly S, Lester H, Rose D et al. (2014) What service users with psychotic disorders want in a mental health crisis or relapse: thematic analysis of joint crisis plans. Social Psychiatry and Psychiatric Epidemiology 49: 1609–1617

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To '… examine mental health service users' preferences and priorities in the event of a future mental health crisis or relapse.' (p1608). **Methodology:** Qualitative - the authors report that the '… paper describes a sub-study of the CRIMSON trial. The CRIMSON trial was a multi-site randomised controlled trial of JCPs compared with treatment as usual for individuals with psychotic disorders. This sub-study analyses the content of JCPs to explore what types of requests service users make for crisis care.' (p1610).	**Is the context clearly described?** Clear. Characteristics of the participants and settings clearly defined. **Was the sampling carried out in an appropriate way?** Appropriate. The sample was comprised of 221 service users randomised to the intervention group who had completed a joint crisis plan. The authors report that to ensure '... the representativeness of the sub-sample, comparisons were made (Chi-square/Wilcoxon-rank-sum tests) between those who did and those who did not complete a joint crisis plan on sex, age, marital status, ethnic group, diagnosis and	**Does the study's research question match the review question?** Yes. **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical issues are dealt with in the main CRIMSON trial, of which this paper is a sub-study. The trial received ethical approval by the King's College Hospital Research Ethics Committee. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Is a qualitative approach appropriate? Appropriate. A qualitative approach is best suited to understanding service user preferences related to the use of joint crisis plans. **Is the study clear in what it seeks to do?** Clear. **How defensible/rigorous is the research design/methodology?** Defensible. This study was a thematic analysis of 221 joint crisis plans which were developed by service users and various members of their clinical team as part of the CRIMSON randomised controlled trial. **How well was the data collection carried out?** Appropriately. Data collection was carried out by exploring service user preferences for care in the event of a future relapse/crisis through 2 meetings.	number of admissions prior to baseline … There were no differences between those who completed a joint crisis plan and those who did not in terms of these categories, except that those who did not complete a joint crisis plan had a slightly higher number of admissions in the 2 years prior to baseline (Wilcoxon-rank-sum test, $z = 2.05$, $p = 0.04$).' (p1611). **Were the methods reliable?** Reliable. Data collected by joint crisis plan facilitator at the joint crisis plan meetings. **Are the data 'rich'?** Rich. The authors note that the '… strengths to this study include: a large number of crisis plans from 4 geographical locations in England would suggest that these findings are likely to be generalisable; and the analysis provides clinically relevant service user preferences for approaches to crisis care and highlights the richness of information generated by this approach, compared to routine practice.' (p1615). **Is the analysis reliable?** Reliable. The authors' report that they used inductive thematic analysis and provide a clear and detailed description of this. **Are the findings convincing?** Somewhat convincing. The authors themselves note that the data has	**Is the study population the same as at least one of the groups covered by the guideline?** Yes. Service users with psychotic disorders. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Community Mental Health Teams. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	limitations, suggesting that while the '… presence of the Facilitator and clinicians is the strength of the JCP approach, it is possible that their involvement may have limited free expression of service users' treatment preferences. The comparatively low proportion of refusals (i.e. 43%) may underestimate the number of service users who might refuse treatment/make unfeasible requests. Similarly, while the Facilitator was present to empower service users, it is difficult to definitively alter existing communication patterns with 1 meeting. In this context, these data may overestimate the extent to which service users request interventions currently being delivered. Finally, considering the higher proportion of admissions in those who did not make a JCP, this sample may underrepresent individuals with more severe, relapsing conditions.' (p1615). **Are the conclusions adequate?** Adequate.		

11. Farrelly S, Lester H, Rose D et al. (2016) Barriers to shared decision making in mental health care: qualitative study of the Joint Crisis Plan for psychosis. Health Expectations 19: 448–458

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To explore clinicians' and service users' views of a joint crisis plan delivered as part of an earlier pilot study. Although a pilot study had found the intervention to be effective	**Is the context clearly described?** Unclear. The characteristics of the participants, such as ethnicity and severity of mental health condition are not explicitly reported and there are no details provided regarding the 4	**Does the study's research question match the review question?** Yes. The study focuses on advance planning for people with fluctuating capacity.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
in reducing the use of compulsory admissions made under the *Mental Health Act 2005*, the 'definitive' trial (CRIMSON) conducted across 4 English mental health trusts, contradicted these results. The authors therefore focused specifically in this study on the barriers to shared decision-making. **Methodology:** Qualitative – focus groups and semi-structured interviews. **Is a qualitative approach appropriate?** Appropriate. A qualitative approach best suits this research question, where focus groups and interviews were used to explore experiences to shared decision-making through the use of a joint crisis plan. **Is the study clear in what it seeks to do?** Clear. The study is clear in that it explains how the expertise of both clinicians and service users in shared decision-making helps achieve better outcomes. A pilot study conducted in London concluded that the joint crisis plan was effective in reducing compulsory treatment under the Mental Health Act. However, the findings of the CRIMSON trial conducted in 4 mental health trusts in England contradicted this. The study, therefore, intended to understand the reasons behind this, including gaining an understanding of	mental health trusts and any similarities or differences between them. It is therefore difficult to extrapolate from these findings. **Was the sampling carried out in an appropriate way?** Appropriate. Caseloads were screened and eligible service user participants approached. If they agreed to take part their named clinician was asked to complete necessary questionnaires, and if allocated to the intervention group, then take part in the joint crisis plan meetings. The authors note that sampling '… was initially designed to recruit a diverse range of service users and clinicians, and was refined using the principles of theoretical sampling. Clinicians from different professional groups (e.g. psychiatrists, nurses, social workers) were purposively approached if they had participated in at least 1 JCP meeting. Willing participants provided written and informed consent. Further details of the sample have been reported elsewhere.' (p451). **Were the methods reliable?** Reliable. Focus group and interview data was analysed using grounded theory to understand stakeholders' views about the joint crisis plan and the barriers to shared decision-making. **Are the data 'rich'?** Rich. Stakeholder views described in the narra-	**Has the study dealt appropriately with any ethical concerns?** Yes. The authors note that the '… the trial, including the qualitative aspects, received ethical approval by the King's College Hospital Research Ethics Committee (07_H0808_174). In addition, local approvals were received from the mental health trusts, clinical directors and clinical teams.' (p450). **Were service users involved in the study?** Yes. Though service users were not involved in the conception and design of the study, they were involved in a discrete focus group (with clinicians) to verify the emerging themes from the analysis of the focus groups and interviews. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Adult service users with psychotic disorders. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Mental health settings within 4 trusts in England. **Does the study relate to at least one of the activities covered by the guideline?** Yes.	

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
the barriers to shared decision-making. **How defensible/rigorous is the research design/methodology?** Defensible. Focus groups and interviews with clinicians and service users provide appropriate context to the research objectives. **How well was the data collection carried out?** Appropriately. Data collection methods involved focus groups and semi-structured interviews. Each interview or focus group was audio-recorded, transcribed and checked for accuracy. Data was collected until data saturation was reached.	tive are detailed and rich, with reference to specific examples reflecting the barriers to shared decision-making from the point of view of both service users and clinicians. **Is the analysis reliable?** Reliable. The data was coded using constructivist grounded theory methods and then analysed and coded line-by-line. **Are the findings convincing?** Convincing. Findings are clearly presented and address the stated research question. **Are the conclusions adequate?** Adequate.	**Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

12. Henderson C, Flood C, Leese M et al. (2009) Views of service users and providers on joint crisis plans. Social Psychiatry and Psychiatric Epidemiology 44: 369–376

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
Study aim: To report participants' and case managers' use of joint crisis plans and their views regarding the plans. **Methodology:** Survey – questionnaires (postal and interview). **Research design clearly specified and appropriate?** Yes. Survey of views of participants in an intervention group who had created a joint crisis plan (and their case managers).	**Describes what was measured, how it was measured and the results?** Yes. Views data presented quantitatively. **Measurements valid?** Yes. **Measurements reliable?** Yes. **Measurements reproducible?** Unclear. **Basic data adequately described?** No.	**Does the study's research question match the review question?** Yes. To report participants' and case managers' use of and views on the value of joint crisis plans on whether they reduce compulsory hospitalisation and violence. **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical committees for all the NHS trusts involved approved the study and written informed consent was given by all participants.	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Objectives of the study clearly stated? Yes. To report participants' and case managers' use of and views on the value of joint crisis plans and whether they help to reduce compulsory hospitalisation or levels of violence. **Clear description of context?** Yes. Participants were patients with mental illness who were randomly selected into the intervention group in the context of the larger randomised controlled trial evaluating the effectiveness of joint crisis plans. **References made to original work if existing tool used?** Partly. **Reliability and validity of new tool reported?** Yes. Likert scales used. **Survey population and sample frame clearly described?** Yes. Service users who had contact with their Community Mental Health Team, and had been admitted to a psychiatric inpatient service at least once in the previous 2 years. **Representativeness of sample is described?** Yes. Participants were patients with mental illness who were randomly selected into the intervention group in the context of a randomised controlled trial. **Subject of study represents full**	**Results presented clearly, objectively and in enough detail for readers to make personal judgements?** Partly. **Results internally consistent?** Partly. **Data suitable for analysis?** Yes. **Clear description of data collection methods and analysis?** Yes. Data collected using postal and interview questionnaires. **Methods appropriate for the data?** Yes. **Statistics correctly performed and interpreted?** Yes. Quantitative analysis of views (in Likert scales) using McNemar test to examine the relationship between the responses of the participants (joint crisis plan holders) and the case managers. **Response rate calculation provided?** Unclear. **Methods for handling missing data described?** Unclear. **Difference between non-respondents and respondents described?** No. **Results discussed in relation to existing knowledge on subject and**	**Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. Views of people with mental illness and their case managers on advance planning for decision-making. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Community Mental Health Teams. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
spectrum of population of interest? Yes. Participants were patients with mental illness who were randomly selected into the intervention group in the context of a randomised controlled trial. **Study large enough to achieve its objectives, sample size estimates performed?** Unclear. Small sample size. **All subjects accounted for?** Partly. Sixty-five out of 80 participants randomised did receive a joint crisis plan, 69% (45/65) completed initial follow-up questionnaires. At 15-month follow-up, 80% (52) were interviewed. Ninety-five per cent (62/65) people who received a joint crisis plan were interviewed at least once. **Response rate:** Sixty-nine per cent of participants (45/65) completed initial follow-up questionnaires. At 15-month follow-up, 80% (52) were interviewed. Ninety-five per cent (62/65) people who received a joint crisis plan were interviewed at least once. A disproportionate number of participants rated at baseline by case managers as less adherent to treatment did not receive a 15-month follow-up interview. Case manager questionnaires were partially or fully completed regarding 60% (39/65) of joint crisis plans holders.	**study objectives?** Yes. **Limitations of the study stated?** No. **Results can be generalised?** Partly. A small sample size and low completion rate makes this difficult. **Appropriate attempts made to establish 'reliability' and 'validity' of analysis?** Partly. **Conclusions justified?** Partly. The low response rate is not taken into consideration.		

13. Horn R (2014) ‘I don’t need my patients’ opinion to withdraw treatment’: patient preferences at the end-of-life and physician attitudes towards advance directives in England and France. Medicine, Health Care, and Philosophy 17: 425–435

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The author presents ‘… the results of a qualitative interview study exploring English and French physicians’ moral perspectives and attitudes towards end-of-life decisions when patients lack capacity to make decisions for themselves. The paper aims to examine the importance physicians from different contexts accord to patient preferences and to explore the (potential) role of advance directives (ADs) in each context [...] Identifying cultural differences that complicate efforts to develop the practical implementation of ADs can help to inform national policies governing ADs and to better adapt them to practice ...’ (p425–26). **Methodology: Qualitative** - semi-structured face to face interviews. **Is a qualitative approach appropriate?** Appropriate. Since the study aimed to ‘… examine the importance physicians from different contexts accord to patient preferences and to explore the (potential) role of advance directives …’ (p425), qualitative interviews is an appropriate way of ascertaining the physicians’ views on these matters. **Is the study clear in what it seeks to do?** Mixed. The study concerns doctors’ ‘… moral perspectives and attitudes towards end-of-life decisions	**Is the context clearly described?** Clear. The context of the interviews was quiet rooms in hospitals. The participants are described in terms of their gender, place of work (urban university hospitals), and medical specialism. **Was the sampling carried out in an appropriate way?** Somewhat appropriate. The recruitment process for the study was not random. The participating doctors were recruited from 2 English and 3 French university hospitals in 2 different cities in each country. There are no clues about geographical location, or how these cities and hospitals came to be selected. It is stated that in France access to the doctors was negotiated through the head of hospital services, but no information is provided about how individual doctors were recruited. In England the doctors were approached after the hospital’s medical director made the initial contact with them, inviting them to get in touch with the researcher if they were interested in participating. Again, there is no description of the criteria for selecting individual participants recruited to the study. **Were the methods reliable?** Somewhat reliable. The study aims to explore differences between two countries, but actually draws interviewees	**Does the study’s research question match the review question?** Yes. The study concerns the attitudes of doctors in two countries towards advance directives, setting their views in the legal, cultural and philosophical-historical context of each country. **Has the study dealt appropriately with any ethical concerns?** Yes. ‘Ethical approval for the study was sought in England from an NHS Research Ethics Committee; in France, the Commission Nationale de l’Informatique et des Liberte´s confirmed that no specific approval procedure was needed for this study. However, access was negotiated with the head of the hospital services and appropriate standards for interviews set out, including guarantees of the anonymity of participants. In England, according to the requirements of the local research ethics committee, physicians were approached after initial contact by the medical director of each hospital, who invited them to contact the researcher if they wished to participate in the study. Each participant received an information sheet about the study and written consent was taken prior to the interviews.’ (p427). **Were service users involved in the study?** No.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
when patients lack capacity to make decisions for themselves …' (p425). The study does attempt to place the doctors' moral perspectives and attitudes in their philosophical-historical context, citing Locke and Mill as influencing the ethical and legal context for the English doctors, and ultimately their own ethical positions, and Rousseau as doing the same for the French context. However, while these may be accurate citations, there is little specific explanation of what their views are and how they came to be so influential. There are, however, some brief explanation of the legislation covering advance directives in both countries, and the different levels of obligation to comply with these expressed wishes in the 2 countries. Arguably though these are legal and not moral matters which are presented for contextualisation. **How defensible/rigorous is the research design/methodology?** Defensible. The study aims to examine how doctors in 2 countries perceive the exercise of patient autonomy through advance directives about end-of-life treatment and care, in the context of the law and culture of these 2 countries. Qualitative methods are an appropriate way of gaining data about the views and experiences of doctors on these matters. **How well was the data collection carried out?** Appropriately. Data	from quite a narrow pool within each country, from a total of 5 hospitals in 4 cities across the 2 countries. While the study does make clear that it makes no claim to the findings being generalisable to all French or English doctors, it makes little sense to explore national differences without seeing the interviewees as being in some sense representative, but there is no way to know how representative these interviewees are. **Are the data 'rich'?** Rich. The study does provide a range of views in the groups of participants, allowing for exploration of the complex issues. **Is the analysis reliable?** Somewhat reliable. This study is the work of 1 researcher. The data from the interviews was categorised into 4 pre-defined themes, i.e. global themes were identified in advance. Sub-categories emerged from the data, and this was '… followed by identifying and refining comparable recurrent themes and patterns that came out during the interviews and that describe English and French physicians' attitudes and experiences …' (p427). **Are the findings convincing?** Convincing. The findings are clearly presented and thematically categorised. Data is presented (and referenced) to support the analysis. The data address the research question.	**Is there a clear focus on the guideline topic?** Partly. The study documents the views of doctors about specific best interests decisions when people lack capacity, and people's involvement in those decisions through advance directives. However, the relevance to the research question is limited, as the study is mainly concerned with attitudes and cultural context rather than views about effectiveness. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. The study presents the views and experiences of doctors about what happens when specific best interest decisions are being made on people's behalf if they are assessed as lacking capacity. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. The doctors interviewed are all hospital doctors, so their data all concerns people who are hospital inpatients. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The study concerns the responses of doctors to people planning in advance for decision-making, especially if they have a condition likely to cause changes in mental capacity.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
were collected through face-to-face interviews which '... were conducted by an experienced sociologist in a quiet room in hospitals. Each interview lasted approximately 45 min, was audio-recorded and transcribed.' (p427).	**Are the conclusions adequate?** Somewhat adequate. However, a study that was founded on the premise that there are significant cultural and attitudinal differences between 2 countries found that there are significant cultural and attitudinal differences. I would be interested to know to what extent this premise was challenged in the interviews, or whether there is an element of confirmation bias in the findings. However, setting this aside, the conclusions are clearly drawn from the data and findings presented in the report.	**Are the views and experiences reported relevant to the guideline?** Partly. The views and experiences reported in the study are those of doctors who deal with hospital inpatients, and deal with their views and experiences of advance directives. However, the study deals more with general attitudes rather than practical experiences. **Does the study have a UK perspective?** Yes. The study has a UK and French perspective.	

14. Kazmierski M and King N (2015) Role of the community matron in advance care planning and 'do not attempt CPR' decision-making: a qualitative study. British Journal of Community Nursing 20: 19–24

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The overall aim of the study was to explore community matrons' experience of end-of-life decision-making for individuals with a life-limiting long-term condition, focusing in particular on advance care planning and Do Not Attempt Cardio Pulmonary Resuscitation decision-making. **Methodology:** Qualitative – broad interpretive phenomenological perspective. **Is a qualitative approach appropriate?** Appropriate. **Is the study clear in what it seeks**	**Is the context clearly described?** Unclear. The authors only provide details regarding participants' work experience, and no other characteristics are reported although a small amount of detail regarding setting is included. The research was conducted within the NHS Yorkshire and the Humber region. The authors note that in 2010 NHS Yorkshire and the Humber developed and implemented a single, patient-held Do Not Attempt Cardio Pulmonary Resuscitation forms across all care providers and the ambulance service. **Was the sampling carried out in an**	**Does the study's research question match the review question?** Yes. The study focuses on community matrons' experience of end-of-life decision-making for individuals with a life-limiting long-term condition, particularly in relation to advance care planning and Do Not Attempt Cardio Pulmonary Resuscitation decision-making. **Has the study dealt appropriately with any ethical concerns?** Yes. Local NHS Research and Development Governance approval was obtained. Ethical approval was provided by the Research Ethics Panel at the	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
to do? Clear. The study had 3 specific objectives, which are clearly stated. **How defensible/rigorous is the research design/methodology?** Defensible. Study used purposive sampling which is justified for phenomenological research. In keeping with a semi-structured approach, the topic guide was used flexibly, allowing participants the opportunity to expand on issues of relevance to them. To obtain rich data that were focused on personal lived experience, participants were encouraged to think of particular patients and to 'walk' the researcher through their stories in relation to advance care planning and Do Not Attempt Cardio Pulmonary Resuscitation. Data were analysed using the template analysis. **How well was the data collection carried out?** Appropriately. Semi-structured interviews with participants were carried out, using a topic guide which was used flexibly, allowing participants the opportunity to expand on issues of relevance to them. To obtain rich data that were focused on personal lived experience, participants were encouraged to think of particular patients and to 'walk' the researcher through their stories in relation to advance care planning and Do Not Attempt Cardio Pulmonary Resuscitation. Interviews were audio-recorded with participant consent,	**appropriate way?** Somewhat appropriate. Purposive sampling was used with a brief overview of the research aims given at the community matrons' monthly team meeting. Interested community matrons were then invited to take part. A total of 6 community matrons were sampled – 3 from each of 2 adjacent NHS trusts. **Were the methods reliable?** Somewhat reliable. Semi-structured interviews with participants were carried out, using a topic guide. To obtain rich data that were focused on personal lived experience, participants were encouraged to think of particular patients and to 'walk' the researcher through their stories in relation to advance care planning and Do Not Attempt Cardio Pulmonary Resuscitation decisions. Interviews were audio-recorded with participant consent, and transcribed verbatim in full. **Are the data 'rich'?** Rich. **Is the analysis reliable?** Reliable. Data were analysed using template thematic analysis. In this study the first-named author developed the initial template on the basis of 3 of the transcripts. The second-named author carried out a blind coding of a sample of the data to facilitate critical reflection on the emerging thematic structure. The full data set was then coded with several iterations of the	School of Human and Health Sciences, University of Huddersfield. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Participants are community matrons with experiences relating to advance care planning and Do Not Attempt Cardio Pulmonary Resuscitation. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes. Northern England.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
and transcribed verbatim.	template until a final version was defined. **Are the findings convincing?** Convincing. **Are the conclusions adequate?** Adequate.		

15. MacPherson A, Walshe C, O'Donnell V et al. (2013) The views of patients with severe chronic obstructive pulmonary disease on advance care planning: a qualitative study. Palliative Medicine 27: 265–272

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The study was designed to '… explore the views of people with severe COPD about advance care planning.' (p265). **Methodology:** Qualitative – semi-structured interviews. **Is a qualitative approach appropriate?** Appropriate. The study sought to elicit the views of people about end-of-life treatment and care, so a qualitative approach was appropriate. **Is the study clear in what it seeks to do?** Clear. The study's research questions are clear and were designed to '… answer whether people with COPD think that advance care planning could be a useful part of their care, and to explore their reasoning behind this view. This included discussion of their knowledge of their diagnosis, as well as their thoughts about their future and any	**Is the context clearly described?** Clear. Inclusion criteria were clearly specified. The study considers the participants' attitudes towards 2 settings where they could be cared for, home and hospital, although it should be noted that none of the participants discussed hospice care. The interviews took place in participants' own homes and the study is contextualised through reference to existing research on the subject. **Was the sampling carried out in an appropriate way?** Appropriate. The study was clear about who its participants were. They were all required to have severe chronic obstructive pulmonary disease, which was defined according to Standard Framework Criteria for Severe chronic obstructive pulmonary disease. The authors note that the '… participant was excluded if the principal researcher knew them in a clinical capacity …' (p266). The	**Does the study's research question match the review question?** Yes. The study explores the views of people who have chronic obstructive pulmonary disease about future decision-making regarding medical treatment. **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval was provided by relevant research committees and consent was sought from participants. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. The study focuses on people's views and feelings about making specific health and social care decisions about end-of-life treatment, in circumstances where they may lack the capacity to make their views known due to their illness	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
discussions about their future that had taken place. Their opinion on the advance care planning process was explored, including their feelings about the discussions.' (p266). **How defensible/rigorous is the research design/methodology?** Defensible. The researchers describe their aims, which make qualitative methods the most appropriate choice for data collection. They describe how interested patients were recruited, and the criteria used to select participants – those who were too unwell or unable to give consent were not included. A British Lung Foundation support group for people with conditions, was consulted regarding the creation of the interview topic guides (the authors note that this 'evolved' as the study progressed). The interviews were semi-structured, which is appropriate in a study in which the authors do not seek to limit the areas discussed by respondents, within the scope of the research question. **How well was the data collection carried out?** Appropriately. Interviews were digitally audio-recorded and field notes added immediately afterwards.	study also discusses the influence of researchers' backgrounds and attitudes on data collection and analysis, noting the principal researcher's experience as palliative care clinician. They aimed to counteract any biases arising from this through regular feedback on data collection and emerging analysis by the whole team. The authors also acknowledge the risk of bias arising as a result of a self-selected sample. **Were the methods reliable?** Somewhat reliable. Only 1 method of data collection was used, semi-structured qualitative interviews, which were recorded and transcribed with field notes added immediately after the interviews. The authors state that there has not previously been research into what people with chronic obstructive pulmonary disease think about advance care planning, but do link their findings to other research into patients with other chronic diseases in their discussion about the findings. **Are the data 'rich'?** Rich. The study identifies a number of key themes, and presents various views on these themes. **Is the analysis reliable?** Reliable. The analysis was based on verbatim transcriptions of the interviews and field notes. A preliminary coding framework was designed using grounded theory analysis techniques,	(chronic obstructive pulmonary disease). **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Participants were interviewed in their own homes, and data were collected on their views about both community settings (home) and hospital inpatient settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The study collected data on participants' views about the circumstances in which they would want to make advance care plans, involving family members in this, and decisions about treatment options at times when this is urgent and people may lack the physical or mental capacity to make their wishes known. **Are the views and experiences reported relevant to the guideline?** Yes. The study is relevant as it considers the views of people who have a condition which is progressive but which also fluctuates in its impact. It highlighted their concerns about making binding statements about their wishes with regard to future end-of-life treatment.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	which was adjusted on the basis of data relating to participants' opinions, experiences and emotion. A separate author coded 2 of manuscripts. The results of the analysis were sent out to participants who were still well enough; however, it should be noted that nearly half of participants were too ill to provide feedback. **Are the findings convincing?** Convincing. There is a clear structure to the presentation of the data, and different perspectives on the same issues are reported. All data presented are relevant to the study question, and extracts from the original data are included. **Are the conclusions adequate?** Adequate. The authors make clear the links between their findings and the conclusions they draw. The study provides information that is relevant to practitioners providing care and treatment and helping people with chronic obstructive pulmonary disease to plan in advance, when fluctuating capacity may be an issue. The authors discuss the limitations of the study such as a very small sample size, lack of ethnic diversity, and self-selected nature of the sample (likely to be comfortable discussing a potentially distressing subject), which they suggest is not too problematic given the 'reasonable' response from those who had been approached by investi-	**Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	gators. They also note that the presence of a spouse (where requested by the participant may '… have affected how the participant responded; the researcher was aware of this and specifically tried to ensure the individual opinions were included.' (p271).		

16. Musa I, Seymour J, Narayanasamy MJ et al. (2015) A survey of older peoples' attitudes towards advance care planning. Age and Ageing 44: 371–376

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The aim of the study was '… to assess the attitudes of older people in East Midlands [towards advance care planning] through the development and administration of a survey.' (p371). **Methodology:** Survey – postal survey. **Research design clearly specified and appropriate?** Yes. Having decided to explore attitudes through carrying out a survey, the authors describe the steps they took in drawing up the questions for the survey questionnaire. They report that '… literature reviews informed focus group areas for discussion … Themes from exploratory focus group informed the survey and in addition relevant items from previous surveys were reused to aid comparison with other studies … A further workshop was held involving an expert advisory team about the	**Describes what was measured, how it was measured and the results?** Yes. The study presents data from responses to the questionnaire about attitudes towards advance care planning. **Measurements valid?** Yes. **Measurements reliable?** Yes. Most of the data presented is a simple count of responses to survey questions, with percentages. There is some correlation of responses with demographic data. **Measurements reproducible?** Yes. It would entirely feasible to repeat this in another area. **Basic data adequately described?** Yes. **Results presented clearly, objectively and in enough detail for**	**Does the study's research question match the review question?** Yes. The study considers the attitudes of older people towards advance decision-making about health treatment options/choices. **Has the study dealt appropriately with any ethical concerns?** Yes. 'Ethical approval was obtained from the University of Leicester Ethics Committee for the focus group work. For the survey, ethical approval was obtained from the National Research Ethics Committee.' (p373). **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. The study explores attitudes about making advance care plans, including advance decisions to end treatment.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
design of the survey questionnaire based on the outcomes of the focus group work … The final questions for each item were tested with the lay volunteers and a local patient and public involvement forum.' (p372). **Objectives of the study clearly stated?** Yes. **Clear description of context?** Yes. The authors provide a description of the research context in which the decision to undertake the survey was made, i.e. that there was no study assessing the attitudes of people in the community towards advance care planning. The survey was sent via post to people living in the community. **References made to original work if existing tool used?** N/A. There does not appear to have been any use of an existing tool. The authors describe using a process of consultation, focus groups and trialling to design their own original questionnaire for the survey. **Reliability and validity of new tool reported?** Partly. Testing of reliability is reported, but it does not demonstrate reliability – '… test–retest reliability was ascertained on a sample of 15 people, 2 weeks apart. The overall reliability was moderate (κ = 0.53); 5 questions had a κ < 0.4. In 4 of the questions the disagreement could be	**readers to make personal judgements?** Yes. **Results internally consistent?** Yes. **Data suitable for analysis?** Partly. Large-scale questionnaire with apparently only a small number of questions, so not a huge amount of analysis possible. **Clear description of data collection methods and analysis?** Yes. **Methods appropriate for the data?** Yes. **Statistics correctly performed and interpreted?** Partly. Not all correlations presented, presumably only those considered by authors to be of interest – there are no tables where readers can make their own judgement. **Response rate calculation provided?** Yes. Data is presented on what the estimated 65+ population is for the whole area (270,000), the numbers who are sent a survey questionnaire, and then the number of responses received. **Methods for handling missing data described?** No.	**Is the study population the same as at least one of the groups covered by the guideline?** Yes. The study explores the attitudes of older adults about specific best interest decisions being made on their behalf if they are assessed as lacking capacity in the future. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Participants were living in the community. **Does the study relate to at least one of the activities covered by the guideline?** Partly. The study concerned people's attitudes towards planning in advance for decision-making, if they should have a condition likely to cause changes in mental capacity. There was no requirement for participants to have such a condition, just to consider what their attitude would be. They were all aged 65 or over. **Does the study have a UK perspective?** Yes. Participants were from 13 general practices located in urban and rural areas in Leicestershire and Nottinghamshire.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
accounted for by changes in responses from ‘agree’ to ‘strongly agree’—rather than substantial changes from agree to disagree. The remaining question with a κ score of < 0.4 reflected concerns that making an advance care plan would lead to doctors stopping treatment too soon. This may reflect the fact that questions were being misinterpreted on different occasions as there was some variability within individual responses.’ (p373). **Survey population and sample frame clearly described?** Yes. Thirteen general practices agreed to participate – 8 from inner city Leicester, 2 from Leicestershire, 1 from Nottingham city and 2 from Nottinghamshire county. Five thousand, three hundred and seventy-five potential participants were sent a questionnaire. One thousand, eight hundred and thirty-two (34%) were returned, of which 9 were blank, leaving 1,823 participants in the survey. **Representativeness of sample is described?** No. Data regarding this issue are presented in an appendix that was inaccessible to the review team. The main body of the report does not describe how representative the sample is of the general population in terms of urban/rural dwellers or ethnicity. Women were 59% of the sample. While it is common knowledge that women have a	**Difference between non-respondents and respondents described?** No. **Results discussed in relation to existing knowledge on subject and study objectives?** Yes. The authors noted that they detected a higher response rate for having an advance care planning document (17%) in this survey than had been found in other surveys (8%). **Limitations of the study stated?** Partly. The report acknowledges people from ethnic minorities may have been under-represented – as they were only 5% of participants this seems very likely. The authors also note that a ‘… very brief and broad explanation was given of advance care planning at the beginning of the survey and depending on how this may have been interpreted may have affected the responses which may also be a weakness of the study. Finally, we are only able to report upon those participants that engaged in the study; it is possible that two-thirds of people who did not respond to the survey may be less engaged / interested in ACP.’ (p375). The study states that its inclusion of a range of settings (urban/rural, various levels of deprivation) are a strength, but does not state how representative the populations are proportionately. The issue of test-retest reliability which		

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
greater life expectancy than men, the report does not state whether there is a gender bias in the sample. **Subject of study represents full spectrum of population of interest?** Unclear. **Study large enough to achieve its objectives, sample size estimates performed?** Partly. No sample size estimates are provided, but the sample size of 1,823 is large enough to achieve its objectives. **All subjects accounted for?** Partly. 5,375 questionnaires sent out, 1,832 returned, 9 of these were blank, calculations were made using the remaining 1,823. **All appropriate outcomes considered?** Unclear. **Response rate:** 34% of responses sent out were returned.	arose during the design period is not dealt with. Nor is the male/female balance of 59% / 41% discussed. **Results can be generalised?** Partly. This is a large sample size, but there is not enough data to say how representative it is. **Appropriate attempts made to establish 'reliability' and 'validity' of analysis?** No. **Conclusions justified?** Yes. The conclusion states a '… third of respondents would be keen to explore advance care planning with their GP, but only a relative minority (17%) had actively engaged; those who had been active had predominantly been so through non-professional routes. It is not clear from this study if older people would like more engagement from professionals or not. Further work is needed to explore what people understand by ACP, views from different ethnic groups, the role of professionals in ACP and how we can improve ACP in patients who already lack capacity such as in dementia …' (p375).		

17. Preston H, Cohen Fineberg I, Callagher P et al. (2011) The Preferred Priorities for Care document in Motor Neurone Disease: Views of bereaved relatives and carers. Palliative Medicine 26: 132–138

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors aimed to explore the experiences of bereaved	**Is the context clearly described?** Not clear. Only minimal details are	**Does the study's research question match the review question?**	**Overall assessment of internal validity: +**

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
relatives of people with a motor neurone disease regarding their views on Preferred Priorities for Care documents and the impact of these on end-of-life care. **Methodology:** Qualitative – semi-structured face-to-face interviews. **Is a qualitative approach appropriate?** Appropriate. The researchers aimed to explore the experiences of the bereaved relatives of people with a motor neurone disease regarding their views on Preferred Priorities for Care documents and a qualitative approach is an appropriate means of doing so. **Is the study clear in what it seeks to do?** Clear. The authors provide a clear description of their goals and make appropriate references to the existing evidence base. **How defensible/rigorous is the research design/methodology?** Somewhat defensible. The study design is appropriate to the research question although no rationale for the chosen methodology is provided. Relatively clear accounts of the sampling, data collection and data analysis techniques are also provided. **How well was the data collection carried out?** Appropriately. A relatively clear description of the data collection methods is provided and	provided in relation to the characteristics of participants and the settings in which data were collected and the authors do not discuss the issue of context bias. **Was the sampling carried out in an appropriate way?** Appropriate. **Were the methods reliable?** Somewhat reliable. Data appear to have been collected via 1 method only. **Are the data 'rich'?** Mixed. Although a reasonable number of verbatim quotes are provided, the lack of details regarding context limit the findings somewhat; however, the authors illustrate the detail and depth of their data relatively well. **Is the analysis reliable?** Not clear/not reported. It is not clear whether more than 1 researcher analysed and coded the raw data and there is no indication that participants were invited to feedback on transcripts/data. **Are the findings convincing?** Convincing. The findings are clearly presented and are internally coherent with a reasonable number of verbatim quotes provided. **Are the conclusions adequate?** Adequate. There are clear links between the raw data, the authors' interpretation of these and their conclusions	Yes. The authors aimed to explore the experiences of the bereaved relatives of people with a motor neurone disease regarding their views on Preferred Priorities for Care documents and the impact of these on end-of-life care. **Has the study dealt appropriately with any ethical concerns?** No. The authors do not report on consent processes or provide any details regarding ethical approval. **Were service users involved in the study?** No. Service users were not involved in the design of the study. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes. The study was conducted	**Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
these were appropriate to the research objectives.	which are themselves plausible and coherent. There is also discussion of the limitations of the study.	in England.	

18. Seamark D, Blake S, Seamark C et al. (2012) Is hospitalisation for COPD an opportunity for advance care planning? A qualitative study. Primary Care Respiratory Journal 21: 261–266

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The aim of this study was '… to examine whether an admission to hospital for an exacerbation of COPD is an opportunity for ACP and to understand, from the patient perspective, the optimum circumstances for ACP.' (p261). **Methodology:** Qualitative – interviews. **Is a qualitative approach appropriate?** Appropriate. A qualitative approach best suits this research question, where interviews were an appropriate method to explore the views of patients and their carers about advance care planning in a hospital context. **Is the study clear in what it seeks to do?** Clear. The End of Life Care Strategy for England advocates that all patients with advanced, progressive, incurable illness should be given the chance to take part in advance care planning, while the Department of Health Strategy Document for chronic obstructive pulmonary disease promotes end-of-life care and	**Is the context clearly described?** Clear. In all, 38 patients were invited by letter and 18 agreed to participate in the study. Sixteen patients aged 58–90 years were interviewed with a range of mild, moderate to severe disease. Two men with severe disease who had agreed to take part died before their interview could take place. Of the 16 who did take part, one participant was a non-smoker, one was a current smoker, and 14 were ex-smokers. Four of the participants were interviewed with their spouse and full-time carer present and one with their daughter who was their part-time carer. For eight participants it was their first hospital admission with an exacerbation of chronic obstructive pulmonary disease and the other eight had had at least one previous admission. **Was the sampling carried out in an appropriate way?** Appropriate. The authors report that cases '… were drawn from two general practices in Devon (a semi-rural practice of 16,500 and a city-based practice of	**Does the study's research question match the review question?** Yes. **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval was obtained from the Exeter Research Ethics Committee. **Were service users involved in the study?** No. Only as research participants. **Is there a clear focus on the guideline topic?** Yes. This study relates to the overall topic of the guideline which is about decision-making and mental capacity for people using health and social services aged 16 and over. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. People with chronic obstructive pulmonary disease and their carers. However, note that there is no evidence of carer views within the narrative.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
structured hospital admission and specialist intervention. But in practice not many patients take part in advance care planning for reasons including a wish to avoid facing discussions about life and death, patients being too old or too young, too well or too ill and a lack of clarity about whose role it is. One potential solution to promoting discussions about advance care planning has been the identification of key transitions in end-of-life care and for individuals with chronic obstructive pulmonary disease, a key transition point may be admission to hospital for an exacerbation of chronic obstructive pulmonary disease. It was within this context that the researchers wished to examine whether or not an admission actually provided scope to discuss issues concerning resuscitation, ventilation, and advance care planning. **How defensible/rigorous is the research design/methodology?** Defensible. The research design is appropriate to the research question. An interview schedule was developed after a review of the research, practice, and policy literature and after talking with key informants including a respiratory physician, a patient with severe chronic obstructive pulmonary disease and his wife and a professor of palliative care with a specific interest in chronic obstructive pulmonary disease. The schedule was designed to	30,700 patients). Admissions were either identified from discharge data or from cases referred direct to the research team by their general practitioner. The doctor reviewed each potential case with exclusion criteria including severe cognitive impairment, non-English speaking, and terminal illness from any cause at the general practitioner's discretion. Patients were invited via a letter signed by their own doctor with the offer of an interview to be conducted face-to-face or over the telephone. Patients were free to have a family member or friend participate in the interview.' (p262). The number of participants and response rate was adequate for a qualitative study of this type and saturation of data was achieved. **Were the methods reliable?** Reliable. The authors report that the '… group considered triangulation by review of the hospital notes, but personal experience (DH) indicated that many of the discussions about ceilings of treatment and decisions regarding acute resuscitation are made soon after admission and hence, although it is likely that a resuscitation status would be documented, it would not be a reliable source of knowing what had been discussed.' (p265). **Are the data 'rich'?** Rich. Rich contextualised patient views provided. **Is the analysis reliable?** Reliable.	**Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Inpatient hospital settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Study relates to more than 1 category in the scope activities section. **Are the views and experiences reported relevant to the guideline?** Yes. The views of people with chronic obstructive pulmonary disease are reported. Though the study also makes reference to carers, there is no evidence of carers' views in the narrative. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
explore events before, during, and after an admission. The study population was made up of patients with a hospital admission for an exacerbation of chronic obstructive pulmonary disease in the previous year to the local District General Hospital during 2009. Cases were selected from 2 general practices in Devon. Admissions were either identified from discharge data or from cases referred direct to the research team by their general practitioner. **How well was the data collection carried out?** Appropriately. The schedule was designed to include questions about events before, during, and after an admission. The audio recordings from each interview were transcribed verbatim and field notes regarding participant interactions were added where relevant. The authors describe the process by which the researchers identified and analysed core themes from the transcripts. Data saturation was achieved when analysis of new transcripts did not produce any new themes or categories and the content overlapped with the findings from earlier transcripts.	Each transcript was read by 2 of the authors and key themes were identified. These themes were further analysed by 1 of the 2 authors using a simple qualitative content analysis and constant comparison methods. This process allowed the data to be organised into a set of concepts and higher-level themes and categories, which were then refined further by the research group. **Are the findings convincing?** Convincing. Clear and coherent reporting of data. **Are the conclusions adequate?** Adequate. The authors note that the '… study was based on admissions to a single average-sized teaching hospital with well-organised respiratory medicine services and outpatient care. It is likely that these findings would be reflected in other hospitals in the UK. None of the participants was from an ethnic minority, although the cohort did represent a varied demographic group.' (p264). The study concludes that the duration of hospitalisation may not be the best time to start advance care planning but may be a milestone that can lead to discussions. General practitioners should be alert to that opportunity after discharge from hospital.		

19. Stewart F, Goddard C, Schiff R et al. (2011) Advanced care planning in homes for older people. Age and Ageing 40: 330–335

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The purpose of the study, was to explore the views of care home staff and the families of older residents on advance care planning. **Methodology:** Qualitative – individual semi-structured interviews. **Is a qualitative approach appropriate?** Appropriate. Individual semi-structured interviews are appropriate for the qualitative exploration of the views of care home staff and the family of older people residing in care homes. **Is the study clear in what it seeks to do?** Clear. **How defensible/rigorous is the research design/methodology?** Defensible. Adequate justification is given for sampling, data collection and data analysis. **How well was the data collection carried out?** Appropriately. The interviews were guided by a topic guide designed to be flexible to the participant's ability and willingness to answer the questions. The topic guide was piloted on a participant from each group and was simplified and shortened as appropriate.	**Is the context clearly described?** Unclear. No details are provided regarding participant characteristics or settings. **Was the sampling carried out in an appropriate way?** Appropriate. Care homes for older people in 2 London boroughs were identified through the Commission for Social Care website and the local Care Home Support Team. Participating homes were grouped into 4 mutually exclusive subsets; a care home was randomly selected from each subset in order to achieve a purposeful sample In each home, the manager and a randomly selected nurse and care assistant were invited to participate. In care homes providing personal care only and that did not employ nurses, a community nurse who visited the home was invited to participate. If a nurse or care assistant declined to participate, another participant was randomly selected from staff lists. **Were the methods reliable?** Somewhat reliable. Data was collected mainly by interviews but authors discussed their findings alongside other studies. **Are the data 'rich'?** Mixed. Data includes quotes to illustrate themes. **Is the analysis reliable?** Reliable. The interviews were analysed using	**Does the study's research question match the review question?** Yes. The purpose of the study was to explore the views of care home staff and the families of older residents on advance care planning. **Has the study dealt appropriately with any ethical concerns?** Yes. The study was approved by King's College Research Ethics Committee. Written informed consent was obtained from all participants. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Care home staff and the family of residents in care homes for older people. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Care homes for the elderly in 2 London boroughs. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. Views of care home staff and	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
	the framework analysis approach, which allowed the exploration of new themes while content coding categorical questions and allowing comparison of themes between participants. **Are the findings convincing?** Convincing. **Are the conclusions adequate?** Adequate.	families regarding advance care planning in homes providing nursing care or personal care only. **Does the study have a UK perspective?** Yes.	

20. Stone L, Kinley J, Hockley J (2013) Advance care planning in care homes: the experience of staff, residents, and family members. International Journal of Palliative Nursing 19: 550–557

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
Study aim: This study aimed to explore the experience of staff, residents, and families having advance care planning discussions within the context of care homes with nursing. **Methodology:** Qualitative – semi-structured interviews. **Is a qualitative approach appropriate?** Appropriate. A qualitative approach is appropriate for this study which is focused on the experiences of staff, residents and family members. **Is the study clear in what it seeks to do?** Clear. **How defensible/rigorous is the research design/methodology?** Somewhat defensible. The care	**Is the context clearly described?** Not clear. Care home study sites had 54–58 beds and were located in 1 Primary Care Trust in south-east England. One was privately owned, 1 charity-run, and the other part of a cooperative. All used the Gold Standards Framework in Care Homes Looking Ahead document (National Gold Standards Framework Centre, 2011). Characteristics of study residents described only in terms of medical conditions – no details on age, gender, ethnicity, etc. are provided and the characteristics of family members are not reported. The only details provided in relation to staff are their roles. **Was the sampling carried out in an appropriate way?** Appropriate. Three care homes undertaking phase	**Does the study's research question match the review question?** Yes. **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval was granted by a local research ethics. Confidentiality and anonymity were maintained during the study. **Were service users involved in the study?** No. Service users involved as research participants only. **Is there a clear focus on the guideline topic?** Yes. The study is about the experience of staff, residents, and families having advance care planning discussions within the environment of nursing care homes.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
home staff acted as gatekeepers in that it was they who initially told residents about the study, but it was possible that they could have missed eligible residents. Staff had little experience of advance care planning and this may have had an impact on the findings. Lastly, the study did not explore issues relating to residents with limited capacity. **How well was the data collection carried out?** Appropriately. Access to each study site was arranged by the local facilitator for the Gold Standards Framework in Care Homes. Subsequently, a teaching session on advance care planning by an experienced clinical nurse specialist in palliative care was delivered to the nursing care home staff. After further advance care planning conversations, the staff member undertaking the discussion invited the resident and family members (if present) to take part in the study and contacted a member from the research team who then approached (residents and family), explained the study and arranged an interview if they consented. The interview schedule was reviewed by members of the Care Home Project Team at St Christopher's Hospice with experience of having advance care planning discussions in a care home setting. It was not piloted. Residents were given the option to be interviewed alone. Interviews were held with staff. All interviews were digitally	5 of the Gold Standards Framework in Care Homes programme across 1 Primary Care Trust in south-east England were invited to take part. Care homes that only provided care for residents with dementia or learning disability were excluded, as well as residents with a diagnosis of dementia. The potential study participants included all residents and family members as well as the care home staff who had led their discussion. It was intended that up to 15 resident–family–staff triads would be recruited. **Were the methods reliable?** Somewhat reliable. Data was collected using an interview schedule, which was reviewed by an expert team; however, it was not piloted. The authors do, however, discuss their findings alongside other studies. **Are the data 'rich'?** Rich. Data is detailed and the context within which data is situated is clearly described. Views represent a diversity of stakeholders, i.e. service user, family member and staff. **Is the analysis reliable?** Reliable. The authors provide a clear description of their analysis, stating that '… transcriptions were stored using NVivo 8 software. Content analysis was initially undertaken with each group of transcripts (the collective staff transcripts, resident transcripts, and family member transcripts).	**Is the study population the same as at least one of the groups covered by the guideline?** Yes. Study participants consisted of residents, family members and care home staff. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Three care homes across one primary care trust in South-East England. **Does the study relate to at least one of the activities covered by the guideline?** Yes. This study relates to several of the activities covered by the guideline. **Are the views and experiences reported relevant to the guideline?** Yes. Views and experiences explored were those of service users, family members and staff. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
recorded and transcribed verbatim.	Three members of the research team independently coded and compared the first 2 transcripts in each of the 3 groups and then discussed and agreed emerging themes and categories. One researcher then carried out the remaining analysis. After all sets of transcripts had been analysed, similar main categories had emerged and therefore the resident, family, and staff groups were merged to form “a more coherent whole.” (p552). **Are the findings convincing?** Convincing. **Are the conclusions adequate?** Adequate. Implications of the research are clearly defined and there is adequate discussion of limitations.		

21. Whitehead B, O’Brien MR, Jack BA (2011) Experiences of dying, death and bereavement in motor neurone disease: A qualitative study. Palliative Medicine 26: 368–378

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To ‘… explore the experiences of people with Motor Neurone Disease (MND), current and bereaved carers in the final stages of the disease and bereavement period.’ (p369). This included discussion of advance care planning. **Methodology:** Qualitative – narrative interviews (face to face and email). **Is a qualitative approach appropriate?** Appropriate. The authors aimed	**Is the context clearly described?** Not clear. While some information regarding the characteristics of participants is provided, little information regarding the context in which interviews took place is provided and the authors do not specifically discuss the potential for context bias. **Was the sampling carried out in an appropriate way?** Appropriate.	**Does the study’s research question match the review question?** Partly. The authors aimed to ‘…explore the experiences of people with Motor Neurone Disease (MND), current and bereaved carers in the final stages of the disease and bereavement period.’ (p369). This included discussion of advance care planning. **Has the study dealt appropriately with any ethical concerns?** Yes. The study received National Health	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
to understand the experiences of people with motor neurone disease and their carers and a qualitative approach is the most appropriate means of doing so. **Is the study clear in what it seeks to do?** Clear. A clear description of the research objectives are provided and adequate reference to the literature is made. **How defensible/rigorous is the research design/methodology?** Defensible. The design is appropriate to the research question, with clear accounts of the rationale for the choice of certain techniques provided. **How well was the data collection carried out?** Appropriately. The data collection methods are clearly described, and appropriate data were collected to address the research question.	**Were the methods reliable?** Somewhat reliable. Although the researchers conducted interviews by email in order to enable the involvement of people with severe communication difficulties, and participants were offered the option to complete a personal diary for a period of 1 year in order to record how their experiences may have changed over time, data were only collected via 1 method (narrative interviews). **Are the data 'rich'?** Mixed. The contexts of the data are not described in great detail and there is no attempt to compare and contrast responses; however, the authors provide a good level of understanding of the detail and depth. **Is the analysis reliable?** Somewhat reliable. More than 1 researcher coded a small number of transcripts; however, no details are reported on how differences were resolved. There is no indication that participants were invited to feedback on transcripts /data. **Are the findings convincing?** Convincing. Findings are clearly presented and are internally coherent with an adequate number of extracts from the original data included. **Are the conclusions adequate?** Somewhat adequate. The conclusions are plausible and coherent;	Service ethical approval and process consent was obtained from participants. **Were service users involved in the study?** No. Service users were not involved in the design of the study. **Is there a clear focus on the guideline topic?** Partly. The study focuses on the experiences of people with a motor neurone disease and their carers at the end-of-life stage. This included discussion of advance care planning. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes. The study was conducted in England.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	however, links between the data, the authors' interpretation of these and the conclusions that are drawn are not always clear.		

Research question 2. Supporting decision-making on the presumption of mental capacity:

- 2.1 – What interventions, tools, aids and approaches are effective and cost-effective in supporting people, on the presumption of capacity, to make decisions?
- 2.2 – What are the views and experiences of people who may lack capacity, their families and carers, practitioners and others interested in their welfare on the acceptability of interventions, tools, aids and approaches to support people, on the presumption of capacity, to make decisions?

Effectiveness data

1. Dukes E and McGuire BE (2009) Enhancing capacity to make sexuality-related decisions in people with an intellectual disability. Journal of Intellectual Disability Research 53: 727–734

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To apply an intervention to the area of sexual knowledge in order to determine if capacity to make sexuality-related decisions could be improved. **Methodology:** Quantitative – before and after study. **Description of theoretical approach?** Studies have shown that people with learning disabilities have a relatively low level of knowledge about sexuality, which may put them at certain disadvantages, for example in negotiating safe sex. At the same time data are beginning to emerge about the benefits of sexuality education programmes for people with learning disabilities. The complexities in this area centre on capacity to make informed choices – the ability to do so in relation to sexual contact relies on knowledge and understanding. The study hypothesis was that increasing knowledge and understanding about sexuality among adults with learning disabilities would improve	**Was the exposure to the intervention and comparison as intended?** Not reported/relevant – no comparison group. **Was contamination acceptably low?** Not reported/relevant – no comparison group. **Did either group receive additional interventions or have services provided in a different manner?** Not reported/relevant – no comparison group. **Were outcomes relevant?** Yes. The outcomes measured change in knowledge in 4 areas related to sex and sexuality and capacity to make sexuality-related decisions. **Were outcome measures reliable?** Yes. The Sexual Consent and Education Assessment has high internal stability and inter-rater reliability and satisfactory test, re-test reliability. (Kennedy, 1999) p729.	**Does the study's research question match the review question?** Partly. The study is focused on people's capacity to make sexuality related decisions. The reviewers felt that on balance, sexuality-related decisions for people with learning disabilities, living in community group homes, impact on general wellbeing. In the context of the Care Act, care and support services should promote and improve wellbeing and this includes physical, emotional and mental wellbeing and protection from abuse. On this basis, the reviewers decided that the study made a useful contribution to addressing the review question. **Has the study dealt appropriately with any ethical concerns?** Partly. Ethical consent was obtained from the service provider rather than any independent body such as a university research ethics committee or a central government research ethics committee.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** −

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
their capacity to make decisions in this area. **How was selection bias minimised?** No comparison group. However, the study was included for review because of the paucity within scope quantitative studies and the relevance of this area of study to the review question. **Was the allocation method concealed?** Not relevant – no group allocation. **Were participants blinded?** Not relevant – no group allocation. **Were providers blinded?** Not relevant – no group allocation. **Were investigators, outcome assessors, researchers, etc., blinded?** Not relevant – no group allocation. **Did participants represent the target group?** No. There is no information which indicates whether participants represent the target group and no information about the basis on which the participants were recruited. **Were all participants accounted for at study conclusion?** No. Follow-up results are not reported for 1 participant – although the authors make no reference to this.	**Were all outcome measurements complete?** Partly. All except follow-up for 1 participant. **Were all important outcomes assessed?** Partly. The study did not assess the participants' satisfaction with the sex education programme or try to understand from their perspective whether they felt they were in a better position to make sexuality-related decisions. **Were there similar follow-up times in exposure and comparison groups?** Not relevant – no comparison group. **Was follow-up time meaningful?** Partly. Six months seems to be an appropriate follow-up time although as 1 person was lost to follow-up, it may have been too long. **Were the analytical methods appropriate?** Not applicable. This question is about how the researchers analysed their data and whether they factored in differences between the groups which might mean that the results also differed between the groups. Because there was no comparison group included in this study design, the question is therefore not applicable. **Were exposure and comparison groups similar at baseline? If not, were these adjusted?** Not reported.	Informed consent was obtained from participants with ‘every effort made’ to adhere to the criteria for doing this – although details are not provided. Each participant was also offered the opportunity to take part in the study. **Were service users involved in the design of the study?** No. **Is there a clear focus on the guideline topic?** Yes. Support for decision-making. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Adults with a learning disability. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the study outcomes relevant to the guideline?** Yes. Increasing knowledge to enable people to make decisions. **Does the study have a UK perspective?** No. The study was conducted in the Republic of Ireland.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	There was no comparison group included in this study design so the question is not applicable. **Was intention to treat (ITT) analysis conducted?** Not reported. Analysis as such was not conducted -—results were simply presented in graphical form. The missing result at follow-up from 1 participant was evident but not discussed. **Was the study sufficiently powered to detect an intervention effect (if one exists)?** Not reported. **Were the estimates of effect size given or calculable?** Not reported. **Was the precision of intervention effects given or calculable? Were they meaningful?** Not reported. **Do conclusions match findings?** Partly. There is an overall good match between the results and the conclusion; that a sexual education programme seems to improve the ability of people with learning disabilities to make informed decisions. However, the authors do rather overstate the causal effect" '… clearly demonstrates a relationship between the intervention and the increased knowledge' (p733) – given the lack of a control group in the study design.		

2. Ferguson L and Murphy GH (2013) The effects of training on the ability of adults with an intellectual disability to give informed consent to medication. Journal of Intellectual Disability Research 58: 864–873

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To '… investigate the capacity of individuals with intellectual disabilities (ID) to make decisions about their medications, and to evaluate whether the provision of training (information) sessions on medications would increase their capacity.' (p864). **Methodology:** Quantitative – before and after study. **Description of theoretical approach?** No. The authors do not provide a logic model or explain the theoretical underpinnings of the intervention. **How was selection bias minimised?** No comparison group. Despite this methodological weakness, the study has been included for review due to the absence of studies with a higher quality design relevant to review question 2. **Was the allocation method concealed?** Not reported – not relevant as there was no comparison group. **Were participants blinded?** Not reported – not relevant as there was no comparison group. **Were providers blinded?** Not reported – not relevant as there was no comparison group.	**Was the exposure to the intervention and comparison as intended?** Not reported. Not relevant due to absence of concurrent control group. **Was contamination acceptably low?** Not reported. Not relevant due to absence of concurrent control group. **Did either group receive additional interventions or have services provided in a different manner?** Not reported. Not relevant due to absence of concurrent control group. **Were outcomes relevant?** Partly. Knowledge of medications and capacity to consent to medications were both measured using the Adapted – Assessment of Capacity Questionnaire. The authors judged a participant to have capacity to consent to their medication if they scored at least 1 point on each of the questions on the Adapted – Assessment of Capacity Questionnaire relevant to the medication they were taking, but no rationale for this is provided and it is not clear whether this is appropriate. **Were outcome measures reliable?** Unclear. Knowledge of medications and capacity to consent to medications were both measured using the Adapted – Assessment of Capacity	**Does the study's research question match the review question?** Yes. The study aimed '… to investigate the capacity of individuals with intellectual disabilities (ID) to make decisions about their medications, and to evaluate whether the provision of training (information) sessions on medications would increase their capacity.' (p864). **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval given by relevant national ethical body, and written consent was sought from participants by following a consent process adapted to reflect the needs of participants with intellectual disabilities. **Were service users involved in the study?** No. Service users involved as participants only. There is no indication that service users were involved in the design of the study or the interpretation of findings. **Is there a clear focus on the guideline topic?** Yes. The study evaluates the impact of training on capacity to give informed consent for treatment in people with intellectual disabilities. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Participants were adults over the age of 18	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
Were investigators, outcome assessors, researchers, etc., blinded? Not blind. Outcomes assessors not blinded although this would have been possible. **Did participants reflect target group?** Partly. It is unclear how many individuals were selected and whether the sample is representative of people with a learning disability who take Metformin, Epilim, or Haloperidol. The guideline committee should also note that only those individuals who could consent to their participation in the study were included, and that people who were not taking medication, or were taking multiple medications were excluded. Similarly, it is not clear how the researchers determined the 'level' of an individual's disability and how this impacted on selection procedure; although it is reported that after the initial identification of potential participants by practitioners, a number of individuals were excluded due to the severity of their intellectual disability or communication difficulties. **Were all participants accounted for at study conclusion?** Yes. No participants were lost to follow-up.	Questionnaire. Although the researchers discuss and provide data relating to reliability and validity of original measure, they do not provide data regarding the adapted tool. NB. The authors judged a participant to have capacity to consent to their medication if they scored at least 1 point on each of the questions on the Adapted – Assessment of Capacity Questionnaire relevant to the medication they were taking. **Were all outcome measurements complete?** Yes. Although it is disappointing that treatment compliance/treatment related outcomes were not measured, given the focus on medication. **Were all important outcomes assessed?** Partly. The study did not include safety related outcomes such as treatment compliance. **Were there similar follow-up times in exposure and comparison groups?** Not reported. Not relevant due to absence of concurrent control group. **Was follow-up time meaningful?** Partly. Outcomes were only measured in the short term and it is not possible to determine whether reported improvements were maintained.	with a mild to moderate learning disability. The guideline committee may wish to note that a number of individuals were excluded due to the severity of their learning disability or communication difficulties. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the study outcomes relevant to the guideline?** Yes. The study evaluated the impact of the intervention on capacity to consent to treatment. **Does the study have a UK perspective?** Yes. England. No further details reported.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Were exposure and comparison groups similar at baseline? If not, were these adjusted? Not reported. Not relevant due to absence of concurrent control group. **Was intention to treat (ITT) analysis conducted?** Not reported. Not relevant due to absence of concurrent control group. **Was the study sufficiently powered to detect an intervention effect (if one exists)?** Not reported. Power calculation not presented and no information presented regarding optimal sample size. **Were the estimates of effect size given or calculable?** Partly. **Were the analytical methods appropriate?** Yes. **Was the precision of intervention effects given or calculable?** Partly. **Do conclusions match findings?** Partly. The authors are relatively cautious in their conclusion, reporting that the '… provision of information that is formatted in a way that individuals with ID can understand may be a useful way to increase knowledge on medications …' (p864). And while the inherent limitations caused by an absence of a 'formal' control group is noted in the discussion section, the suggestion that the 2-week 'control		

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	period' between baseline and 'first re-assessment' is sufficient mitigation for this is a flawed argument.		

3. Murphy J and Oliver T (2013) The use of Talking Mats to support people with dementia and their carers to make decisions together. Health and Social Care in the Community 21: 171–180

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To '… explore whether Talking Mats could help people with dementia and family carers feel more involved in decisions about managing their daily living than using their usual communication methods …' (p173). **Methodology:** Mixed methods – before and after outcome evaluation and observational interviews. **Qualitative component:** Observational interviews conducted as part of sessions using Talking Mats. **Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question?** Partly. No details are provided on sampling strategies (e.g. how the agencies involved were selected); however, people with dementia were eligible if they had a diagnosis of dementia and had a friend or relative who had knowledge of their daily life. The authors report the reasons why some of those participants who originally agreed to take part could no longer do so (death, ill health and inability to	**Quantitative component:** Before and after outcome evaluation. **Are participants (organisations) recruited in a way that minimises selection bias?** Unclear. Only very limited details are provided regarding sampling and recruitment strategies. Although the authors do report inclusion and exclusion criteria and the reasons why a number of individuals who originally agreed to take part, details provided regarding participants is minimal (e.g. socioeconomic background, ethnicity, specific diagnoses, etc.) and it is therefore difficult to understand whether the sample was representative. **Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups when appropriate) regarding the exposure/intervention and outcomes?** No. Perceptions of involvement and satisfaction in discussions were measured using the Involvement Measure, which uses questions adapted from the Freedom of Choice	**Does the study's research question match the review question?** Yes. The researchers aimed to '… explore whether Talking Mats could help people with dementia and family carers feel more involved in decisions about managing their daily living than using their usual communication methods …' (p173). **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval granted by an ethics committee and informed consent sought from participants (following a comprehensive consent procedure outlined in a prior study by the first author). **Were service users involved in the design of the study?** No. Service users involved as participants only. There is no indication that service users were involved in the design of the study or the interpretation of findings. **Is there a clear focus on the guideline topic?** Yes. The study reports on an intervention designed to aid people with dementia and their carers to	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
use the Talking Mats – no further details are provided regarding this). The guideline committee may wish to note that people with dementia and poor vision were excluded from the study as the tool is primarily a visual one. **Is the process for analysing qualitative data relevant to address the research question?** Partly**.** The authors report that qualitative data were analysed using 'cognitive mapping' (Jones 1985). No details are provided regarding this process and only limited details are provided regarding collection and management of qualitative data in general. **Is appropriate consideration given to how findings relate to the context, such as the setting, in which the data were collected?** Partly. The authors do not discuss in detail how their findings relate to the context in which data were generated. **Is appropriate consideration given to how findings relate to researchers' influence; for example, through their interactions with participants?** Partly. The researchers do not discuss in detail how their findings relate to their perspectives, and their role and interactions with participants.	Interview Schedule (Frossard et al. 2001). It is unclear why this adaptation was developed and there is no consideration of reliability and validity issues. **In the groups being compared (exposed versus non-exposed; with intervention versus without; cases versus controls), are the participants comparable or do researchers take into account (control for) the difference between these groups?** N/A. No concurrent control group. **Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?** Yes. All outcome data collected as planned.	make and communicate decisions with/to each other. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. People with dementia (and their family carers). Although the guideline committee may wish to note that people with dementia and poor vision were excluded from the study (the tool under evaluation is a visual aid). **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. The study was conducted in participant's homes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The study reports on the use of Talking Mats by people with dementia and their carers to discuss and communicate decisions regarding daily activities. **Are the study outcomes relevant to the guideline?** Yes. The study reports on perceptions of involvement in discussions and overall satisfaction (for both the person with dementia and their carer). **Are the views and experiences reported relevant to the guideline?** Yes. The study reports the views of participants regarding the use of	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
		Talking Mats as a means of supporting people with dementia and their carers to make and communicate decisions with/to each other. **Does the study have a UK perspective?** Yes. The study was conducted in Scotland and the North of England.	

4. Naughton M, Nulty A, Abidin Z et al. (2012) Effects of group metacognitive training (MCT) on mental capacity and functioning in patients with psychosis in a secure forensic psychiatric hospital: a prospective-cohort waiting list controlled study. BMC Research Notes 5: 302

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To evaluate the effects of group metacognitive training on capacity to consent to treatment, fitness to plead, global functioning, and symptoms of schizophrenia in patients in a secure forensic hospital. **Methodology:** Quantitative – prospective waitlist controlled study. **Description of theoretical approach?** Partly. The authors do not provide a logic model but there is some discussion of the theoretical principles underlying the intervention. **How was selection bias minimised?** Unmatched groups. Participants were allocated to the intervention on a chronological basis ('first come first served', p4). **Was the allocation method concealed?** No.	**Was the exposure to the intervention and comparison as intended?** Yes. **Was contamination acceptably low?** Yes. Although the authors do not report on contamination specifically, there is no indication that this was an issue. **Did either group receive additional interventions or have services provided in a different manner?** No. There is no indication that participants in either group received additional support or were treated differently. **Were outcomes relevant?** Yes. **Were outcome measures reliable?** Yes. All outcome measures appear to have established reliability and validity; however, no data are presented to demonstrate this.	**Does the study's research question match the review question?** Yes. The study aimed to evaluate the effects of group metacognitive training on capacity to consent to treatment, fitness to plead, global functioning, and symptoms of schizophrenia in patients in a secure forensic hospital. **Has the study dealt appropriately with any ethical concerns?** Yes. The study was approved by relevant ethics committees and informed consent was sought from participants. **Were service users involved in the design of the study?** No. Service users involved as participants only. There is no indication that service users were involved in the design of the study or the interpretation of findings. **Is there a clear focus on the guideline topic?** Yes. The study evaluates	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Were participants blinded? Not blinded. Due to the nature of the intervention participants could not be blinded to group assignment. **Were providers blinded?** Not blinded. Due to the nature of the intervention providers could not be blinded to group assignment. **Were investigators, outcome assessors, researchers, etc., blinded?** Not blinded. Outcomes assessors were not blinded to treatment status; however, this would have been possible. **Did participants reflect target group?** Partly. There is a lack of clarity regarding participant selection and inclusion/exclusion criteria for the study are not clearly reported; however, the authors note that participants had been referred to the study because of incomplete responses to anti-psychotic medication. They go on to state that 2 participants originally referred '… were not deemed suitable; one for security issues and the second as the patient was deemed to be highly functioning with good insight.' (p4). Four of those originally referred refused to participate. **Were all participants accounted for at study conclusion?** Yes. There was no loss to follow-up.	**Were all outcome measurements complete?** Yes. All data appear to have been collected and reported as planned. **Were all important outcomes assessed?** Yes. **Were there similar follow-up times in exposure and comparison groups?** Yes. Both groups were followed-up for the same length of time. **Was follow-up time meaningful?** No. Follow-up took place at the end of the treatment/waitlist control period and the impact of the intervention could therefore not be determined in the medium to long term. **Were the analytical methods appropriate?** Yes. **Were exposure and comparison groups similar at baseline? If not, were these adjusted?** No. There were significant differences between the 2 groups at baseline with regards to substance misuse problems and exposure to destabilisers and stress. It is not clear whether these were adjusted for analyses. **Was intention to treat (ITT) analysis conducted?** Yes. **Was the study sufficiently powered to detect an intervention effect (if**	the impact of group metacognitive training on capacity to consent to treatment. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. All participants met DSM-IV-TR criteria for a psychotic disorder. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. The study was conducted in a secure forensic psychiatric hospital. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The study evaluates the impact of group metacognitive training on capacity to consent to treatment. **Are the study outcomes relevant to the guideline?** Yes. The study evaluates the impact of group metacognitive training on capacity to consent to treatment. **Does the study have a UK perspective?** No. The study was conducted in Dublin, Ireland.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	one exists)? Not reported. The authors do not report results of power calculations. **Were the estimates of effect size given or calculable?** Yes. **Was the precision of intervention effects given or calculable?** Yes. **Do conclusions match findings?** Yes.		

5. Turner D, MacBeth A, Larkin A et al. (2017) The relationship between the 'jumping to conclusions' bias and treatment decision-making capacity in psychosis: A participant-blind randomised controlled experiment (unpublished)

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To test the hypothesis that meta-cognitive therapy would improve treatment related capacity and that this would be mediated by changes in the 'jumping to conclusions' bias in patients with psychosis. **Methodology:** Quantitative – randomised controlled trial. **Description of theoretical approach?** Yes. The authors describe their theoretical approach and the rationale for evaluating the intervention. **How was selection bias minimised?** Randomised. Performed at second assessment (in an attempt to minimise attrition bias) session using online randomisation.	**Was the exposure to the intervention and comparison as intended?** Yes. There is no indication that the interventions did not go as planned, or that any changes were made during the course of the study. **Was contamination acceptably low?** Yes. There is no indication that contamination took place and the design of the trial meant that there was little risk of this. **Did either group receive additional interventions or have services provided in a different manner?** No. There is no indication that the groups were treated differently other than the provision of the intervention.	**Does the study's research question match the review question?** Yes. The authors aimed to test the hypothesis that meta-cognitive therapy would improve treatment related capacity and that outcome would be mediated by changes in the 'jumping to conclusions' bias in patients with psychosis. **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval granted by relevant committees and informed consent was sought from participants (individuals unable to consent to the research were excluded). **Were service users involved in the design of the study?** No. There is no indication that service users were	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Was the allocation method concealed? Yes. The authors report that allocation was concealed from clinical practitioners, investigators, and patients. **Were participants blinded?** Blind. The authors report that participants were blind to study hypothesis and group allocation. **Were providers blinded?** Part blind. Clinical staff were blind to group allocation but not study hypothesis. **Were investigators, outcome assessors, researchers, etc., blinded?** Not blind. Assessments and interventions were conducted by the same researcher. **Did participants represent the target group?** Partly. It is unclear how many eligible patients were recruited. The guideline committee should also note that all participants identified themselves as being of white ethnicity, and that the majority of participants were male and had been ill for a period of more than 10 years. **Were all participants accounted for at study conclusion?** Yes. The number of participants lost to follow-up was acceptable.	**Were outcomes relevant?** Yes. The outcome measures used clearly relate to the outcomes which the researchers expected to impact upon. **Were outcome measures reliable?** Partly. All outcome measures appear to have established reliability and validity, although data on this are not always presented. The guideline committee should also note that the MacArthur Competency Assessment Tool for Treatment does not offer a total score or cut-off, although the researchers did calculate this. **Were all outcome measurements complete?** Yes. All data was collected as planned; however, there were some missing data that the researchers dealt with by using multiple imputations. **Were all important outcomes assessed?** Partly. It is unclear why symptoms of psychosis were not also measured at post-treatment. **Were there similar follow-up times in exposure and comparison groups?** Yes. Both groups were followed-up for an equal length of time. **Was follow-up time meaningful?** Partly. Follow-up took place immediately after delivery of the intervention	involved in the design of the study or the interpretation of findings. **Is there a clear focus on the guideline topic?** Yes. The study evaluates the impact of metacognitive training session designed to reduce the 'jumping to conclusions' bias on capacity to make treatment decisions. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. People with a diagnosed psychotic illness. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Support for decision-making. **Are the study outcomes relevant to the guideline?** Yes. The primary outcome was capacity to make treatment decisions. **Does the study have a UK perspective?** Yes. The research was conducted in Scotland.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	and while this is defensible, it is disappointing that no further follow-up took place. **Were the analytical methods appropriate?** Appropriate. **Were exposure and comparison groups similar at baseline? If not, were these adjusted?** Yes. The authors report that there were no significant differences between groups at baseline regarding demographic characteristics. Participants in the intervention group did have significantly higher depression scores at baseline (as measured by the depression subscale of the Hospital Anxiety and Depression Scale); however, the authors report that this was accounted for by performing an analysis of mean change. **Was intention to treat (ITT) analysis conducted?** Yes. **Was the study sufficiently powered to detect an intervention effect (if one exists)?** No. Power calculations estimated that 26 participants in each group was required to detect an effect on the primary outcome for the 0.05 alpha level at 80% power. **Were the estimates of effect size given or calculable?** Yes. Effect sizes are presented as appropriate.		

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Was the precision of intervention effects given or calculable? Were they meaningful? Yes. Confidence intervals and *p* values are presented as appropriate. **Do conclusions match findings?** Yes.		

6. Woltmann EM, Wilkniss SM, Teachout A et al. (2011) Trial of an electronic decision support system to facilitate shared decision making in community mental health. Psychiatric Services 62: 54–60

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To examine the feasibility of using an electronic decision support system to improve communication between service users and practitioners in mental health decisions making and to determine the impact of the system on outcomes. **Methodology:** Quantitative – cluster randomised controlled trial. **Description of theoretical approach?** No. The authors do not provide a logic model or discuss the theoretical principles underlying the intervention. **How was selection bias minimised?** Randomised. Cluster randomised – case managers based at 1 of 3 clinics were randomly assigned to the intervention group or comparison group (treatment as usual). Service users were assigned to the	**Was the exposure to the intervention and comparison as intended?** Yes. **Was contamination acceptably low?** Not reported. The authors do not report on contamination specifically. Although the intervention is a discrete technological tool, clustering resulted in case managers delivering the intervention on multiple occasions and this may have had had an impact on results. **Did either group receive additional interventions or have services provided in a different manner?** No. There is no indication that participants in either group received additional support or were treated differently. **Were outcomes relevant?** Yes. **Were outcome measures reliable?**	**Does the study's research question match the review question?** Yes. The researchers aimed to examine the feasibility of using an electronic decision support system to improve communication between service users and practitioners in mental health decisions making and to determine the impact of the system on service user and practitioner satisfaction with care planning processes as well as service user recall of care plans. **Has the study dealt appropriately with any ethical concerns?** Yes. The study received approval from relevant ethics committees and full informed consent was sought from participants. **Were service users involved in the design of the study?** No. Service users involved as participants only. There is no indication that service users were involved in the design of the	**Overall assessment of internal validity: +** **Overall assessment of external validity: ++**

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
groups according to the assignment of their case manager. Cluster randomisation meant that case managers participated in delivery of the intervention multiple times. Because there was a difference in the size of the clinics, over half of the participants were recruited by the largest clinic. **Was the allocation method concealed?** Not reported. No details provided regarding clustering methods. **Were participants blinded?** Not blinded. Due to the nature of the intervention participants could not be blinded to group assignment. **Were providers blinded?** Not blinded. Due to the nature of the intervention providers could not be blinded to group assignment. **Were investigators, outcome assessors, researchers, etc., blinded?** Not reported. The authors do not report whether investigators were blinded to group assignment; however, this should have been possible. **Did participants represent the target group?** No. Only limited details are provided regarding the clinics and it is not clear what criteria were used	Partly. It is unclear why the researchers chose to develop bespoke questionnaires to assess practitioner and service user satisfaction with care planning sessions. While they report reliability data for both case manager and service user questionnaires, they do not discuss the validity of the tools at all. **Were all outcome measurements complete?** Yes. All data appear to have been collected and reported as planned. **Were all important outcomes assessed?** Partly. Although the study focuses on satisfaction and the very short-term recall of service users regarding recall of care plan, it is disappointing that outcomes such as longer-term adherence to care plans, treatment compliance or mental health-related outcomes were not measured at all. **Were there similar follow-up times in exposure and comparison groups?** Yes. Service users and case managers completed questionnaires 'immediately' after participation in the study. Service users were also contacted around two to four days later to assess their recall of care plans. **Was follow-up time meaningful?** Partly. Recall of care plans were only measured in the short term.	study or the interpretation of findings. **Is there a clear focus on the guideline topic?** Yes. The study reports on the feasibility of an electronic decision support system and its impact on service user and practitioner satisfaction with care planning processes as well as service user recall of care plans. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. The	

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
to select these or whether any inclusion/exclusion criteria were used to select service users. Participants had a primary diagnosis of – schizophrenia or schizoaffective disorder, bipolar disorder, major depressive disorder, or posttraumatic stress disorder. **Were all participants accounted for at study conclusion?** No. There were 2 control group sessions for which case managers failed to complete satisfaction questionnaires (no explanation provided) and the researchers were only able to contact 86% of service user participants in order to assess their recall of care plans.	**Were the analytical methods appropriate?** Yes. **Were exposure and comparison groups similar at baseline? If not, were these adjusted?** Partly. There was a significant difference between groups regarding the length of time that service users had been working with their case manager as a result of randomisation failure. This was controlled for in the analyses. **Was intention to treat (ITT) analysis conducted?** Partly. Participants were analysed in the groups to which they were originally allocated; however, the authors do not report any procedures for dealing with missing data. **Was the study sufficiently powered to detect an intervention effect (if one exists)?** Not reported. The authors do not report results of power calculations. **Were the estimates of effect size given or calculable?** Yes. **Was the precision of intervention effects given or calculable? Were they meaningful?** Yes. *p* values reported. **Do conclusions match findings?** Yes.	sample is comprised of ‘mental health consumers’ (participants had a primary diagnosis of schizophrenia or schizoaffective disorder, bipolar disorder, major depressive disorder, or post-traumatic stress disorder). **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The study reports on the feasibility of an electronic decision support system for shared decision-making and is therefore relevant to the NCCSC review question focusing on support for decision-making. **Are the study outcomes relevant to the guideline?** Yes. The study reports on satisfaction with the care planning process including perceptions of involvement in decision-making. **Does the study have a UK perspective?** No. The study was conducted in the United States.	

7. Boyle G (2013) Facilitating decision-making by people with dementia: is spousal support gendered? Journal of Social Welfare and Family Law 35: 227–243

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
Study aim: To explore the social process of every day decision-making by couples living with dementia. In particular, to identify the different strategies used by spouses to support decision-making by their partners with dementia. **Methodology:** Qualitative – observation and interviews. **Is a qualitative approach appropriate?** Appropriate. The study aimed to examine the social processes of decision-making between couples living with dementia. **Is the study clear in what it seeks to do?** Mixed. The study appears to be about decisional autonomy but actually also explored executional autonomy – the extent to which spouse carers support their partners with dementia to carry out activities of daily living. **How defensible/rigorous is the research design/methodology**? Defensible. Use of individual interviews is justified, as are the observations and home visits – designed to build up familiarity and develop trust between researcher and participants.	**Is the context clearly described?** Unclear. The only details provided in relation to participants relate to gender and ethnicity. The age range (40 to 80 years) is provided rather than individual ages and there is no detailed description of the progress/ severity of the dementia diagnoses, nor the time since diagnosis. **Was the sampling carried out in an appropriate way?** Appropriate. The sample was recruited in a way which was not likely to affect what the respondents told the researchers. Methods ensured that people known and not known to services were recruited. **Were the methods reliable?** Reliable. Data were collected via observations and interviews and the interviews were adapted to the cognitive needs/abilities of the adults living with dementia. Other studies were discussed alongside the findings of the study. **Are the data 'rich'?** Rich. The contexts of the data are described and the diversity of perspectives and contents are explored. Detailed findings	**Does the study's research question match the review question?** Partly. The research question aims to determine whether spousal decision-making (when one person has dementia) is gendered. This does not match the NCCSC review question, but the design of the study is such that it provides insight into how people living with dementia are supported (or not) to make decisions. **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval obtained from the Social Care Research Ethics Committee, England. Both partners were asked to complete written consent forms (where feasible). Where the people with dementia did not have capacity to consent, then according to the *Mental Capacity Act 2005*, their spouses were consulted as to whether they were happy for them to take part. **Were service users involved in the study?** No. Only as participants, not as advisors or co researchers. **Is there a clear focus on the guideline topic?** Yes. Supporting people to make decisions – people with a dementia diagnosis.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
How well was the data collection carried out? Somewhat appropriately. The data collection methods are not very clearly described but they are appropriate to address the research question. Data collection and record-keeping were systematic - interviews were digitally recorded and transcribed verbatim, and fieldwork notes were also recorded.	are provided and discussed with differences and common themes highlighted. **Is the analysis reliable?** Somewhat reliable. Thematic analysis was undertaken manually and in 2 stages. For the first level, key themes were identified in order to explore the couple's perspective and to enable the views/experiences of respective partners to be discerned. There is no indication that this first stage of analysis involved more than 1 researcher, for example through discussion about key themes. For the second level of analysis, data from all couples were analysed to investigate whether the decision-making provided by carer spouses varied depending on social factors (e.g. gender). These analyses were conducted by 2 researchers and discussed among the whole research team. In addition, respondents fed back on the themes that had been identified from their data and given the opportunity to, say, verify the accuracy of interpretations. **Are the findings convincing?** Convincing. The findings are clearly presented. It is especially helpful to have findings organised according to the different strategies used by carers' spouses to support their partners with dementia in making decisions. The findings are internally coherent in that	**Is the study population the same as at least one of the least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Partly. Views and experiences relate to 2 main areas; providing support to make decisions (in scope) and providing support to conduct every day activities (not in scope). Only the data about decision-making is therefore extracted and presented to the guideline committee. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
	they address the study question, although those relating to decisional autonomy and those relating to executional autonomy are a little confused, making interpretation more challenging. Extracts from the original data are, however, included and supported by appropriately referenced quotes. **Are the conclusions adequate?** Somewhat adequate. There are clear links between data, interpretation and conclusions; and the conclusions seem plausible and coherent. The study does enhance understanding about supporting decision-making for people living with dementia and the extent to which gender influences the nature of this support. The implications of the research are clearly defined, especially in terms of the implementation of the Mental Capacity Act. The only drawback is the researchers do not appear to explore different explanations – other than gender and gender relations – for the differences in support provided for making decisions.		

8. Goldsmith L, Woodward V, Jackson L et al. (2013) Informed consent for blood tests in people with a learning disability. Journal of Advanced Nursing 69: 1966–1976

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
Study aim: The aim of the study was to examine the ways in which informed consent for routine blood tests was obtained from people with a learning disability.	**Is the context clearly described?** Clear. Some details relating to the characteristics of participants, such as age, type of living, marital status,	**Does the study's research question match the review question?** Yes. The study explored the information needs of people with learning disabilities with respect to consent for	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Methodology: Qualitative – focused ethnography. **Is a qualitative approach appropriate?** Appropriate. To explore the information needs of people with learning disabilities with respect to consent for blood test, a qualitative approach is appropriate. **Is the study clear in what it seeks to do?** Clear. The aims of the study were to explore the information needs of people with mild to moderate learning disabilities with respect to consent for blood tests and to identify ways of facilitating informed consent, and the findings also reported the information requirement and ways to facilitate the consent process. **How defensible/rigorous is the research design/methodology?** Defensible. Design adopted is focused ethnography and done in a rigorous manner. One researcher transcribed data. Two experienced researchers carried out Independent coding of several transcripts to maximise trustworthiness. Reflexive notes were made, as a key element in ethnographic research is a certain level of self-awareness by the researcher. **How well was the data collection carried out?** Appropriately. Data were collected using observation and	are provided. Clear description of settings were included. Data collected using observation, interview, video-recording, note-taking etc. **Was the sampling carried out in an appropriate way?** Somewhat appropriate. Participants were recruited through gate-keepers and their judgement may have influenced the selection. Authors felt that to achieve a maximum variation sample, it would have been useful to recruit more young participants and those living at home with family as well as participants declining a blood test. **Were the methods reliable?** Reliable. Data were collected using observation and semi-structured interview. Observations of consultations were video-recorded and supplemented by note-taking. **Are the data 'rich'?** Rich. Yes, different approaches to data collection were used including observation, interviews, video-recording and note-taking. One researcher transcribed data. Two experienced researchers carried out Independent coding of several transcripts to maximise reliability. **Is the analysis reliable?** Reliable. Yes, based on the original transcript, codes were identified, grouped into categories and themes and analysed	blood tests and identified ways of facilitating informed consent. The NCCSC review question focuses on support for decision-making processes in people with limited mental capacity. **Has the study dealt appropriately with any ethical concerns?** Yes. Study approved by an NHS research ethics committee; and consent was obtained from participants. Study materials were provided in an accessible format. **Were service users involved in the study?** Yes. Participants were recruited via gate-keepers who nominated participants. Study materials for people with learning disabilities were provided in an accessible format. Participants were actively involved in providing data through interviews. **Is there a clear focus on the guideline topic?** Yes. The guideline focuses on support for decision-making and the study explores the issue of providing consent for a blood test and how to facilitate that process of decision-making. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. The study focuses on people with a learning disability.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
semi-structured interview. For the observation data, the researcher was an observer during participants' attendance for a routine blood test at a general practitioner surgery. Each participant was observed having 1 blood test, the observation period ranged from 3 to 6 minutes. Consultations and interviews were video and audio-recorded to ensure accurate transcription and enable observation of non-verbal behaviour.	thematically. Data analysis was approached in an inductive way, considered appropriate for an exploratory, descriptive study. Observations of consultations were video-recorded and supplemented by note-taking. NVivo 8 (QSR International 2008) specialist software was used to record and store data for coding. The visual data were used to identify behavioural cues and check any incongruence between speech and expression. **Are the findings convincing?** Convincing. Yes, Findings are clearly presented and address the research question. The data collection, analysis and reporting is coherent. **Are the conclusions adequate?** Adequate. The conclusions summarise the study's findings relatively well and provide explanations regarding the inconsistent application of the Mental Capacity Act by health professionals.	**Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Study took place in health settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Study explored the views and experience of people with learning disabilities with respect to consent processes for blood test. **Are the views and experiences reported relevant to the guideline?** Yes. The guideline focuses on supporting the decision-making processes of people with limited mental capacity and the study explored the means by which informed consent for blood tests for people with a learning disability could be facilitated. **Does the study have a UK perspective?** Yes.	

9. Stovell D, Wearden A, Morrison AP et al. (2016) Service users' experiences of the treatment decision-making process in psychosis: a phenomenological analysis. Psychosis 8: 311–323

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To explore the treatment decision-making experiences of individuals with psychosis, and their implications for increasing service users' autonomy through clinical practice and research.	**Is the context clearly described?** Clear. Participant characteristics such as age, gender, ethnic background, marital and employment status, current level of care, duration of psychosis and experience of mental health system were included.	**Does the study's research question match the review question?** Yes. The study aimed to explore the treatment decision-making experiences of individuals with psychosis and the review question focuses on the views and experiences of people	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Methodology: Qualitative – interpretative phenomenological analysis. **Is a qualitative approach appropriate?** Appropriate. Interpretative Phenomenological Analysis, a qualitative method that uses in-depth, semi-structured interviews, was used to explore service users' experience of decision-making around treatment for psychosis. **Is the study clear in what it seeks to do?** Clear. Yes, study question, methodology and findings align well and are clear. **How defensible/rigorous is the research design/methodology?** Defensible. The use of Interpretative Phenomenological Analysis is defensible as it uses in-depth, semi-structured interviews to explore service users' experience of decision-making around treatment for psychosis and recognises the contribution of cognition, affect and social context to an individuals' perspective. The researcher's interpretative perspective is acknowledged here, influenced by critical social psychology, clinical psychology and work in recovery-oriented clinical services. **How well was the data collection carried out?** Appropriately. Interviews took place at home or on NHS premises, and lasted 1 to 2 hours. The interview schedule was used	**Was the sampling carried out in an appropriate way?** Somewhat appropriate. Interpretative Phenomenological Analysis assumes human capacities to share reflections on experiences of personal significance, but this was not possible for some participants, resulting in impoverished data that precluded meaningful analysis. This represented a weakness in recruitment procedures; reliance on care coordinators judgements about who met inclusion criteria proved not wholly reliable. **Were the methods reliable?** Somewhat reliable. It may also highlight a limitation to the Interpretative Phenomenological Analysis methodology, wherein the perspectives of already-disempowered individuals may be rendered invisible. Although homogeneity of sampling is recommended in Interpretative Phenomenological Analysis practice, the study's cultural specificity should also be acknowledged. **Are the data 'rich'?** Rich. **Is the analysis reliable?** Reliable. The analysis process began with researchers listening to each interview and reading the transcript a number of times, noting features that appeared significant. Emergent themes were then iteratively grouped and regrouped, and ultimately organised in	who may lack mental capacity in decision-making. **Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval was obtained from the UK National Research and Ethics Service (13/NW/0244). **Were service users involved in the study?** Yes. Prior to data collection, service users were involved in recruiting the participants. Participants were recruited through care coordinator referrals from Community Mental Health Teams and Early Intervention in Psychosis Teams and self-referrals from voluntary mental health organisations. The interview schedule was developed in consultation with experienced researchers and a service-user focus group. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
flexibly so as to honour participants' particular experiences. Interviews were recorded and transcribed verbatim. The first author kept a reflective diary throughout the research process.	a table under theme and subtheme headings, alongside illustrative files of transcript excerpts. The second researcher periodically provided feedback on the emerging analysis and, later in process, the theme structure was discussed at 2 meetings of the research team, with consensus being reached through discussion. Decision-making and analytic procedures were recorded throughout. **Are the findings convincing?** Convincing. The themes and sub-themes are clearly generated from participants' views and the process is illustrated in the article. **Are the conclusions adequate?** Adequate. Conclusions appropriately summarise the findings and provide implications for clinical practice and research. The conclusions are also discussed in the context of other studies on the subject.	**Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes. The study was conducted in the United Kingdom.	

Research question 3. Assessment of mental capacity:

- 3.1 – What interventions, tools and approaches are effective and cost-effective in supporting the assessment of mental capacity?
- 3.2 – What are the views and experiences of people who may lack mental capacity, their families and carers and others interested in their welfare on the acceptability of interventions, tools and approaches to support the assessment of mental capacity?

Effectiveness data

1. Aydin Er R and Sehiralti M (2014) Comparing assessments of the decision-making competencies of psychiatric inpatients as provided by physicians, nurses, relatives and an assessment tool. Journal of Medical Ethics 40: 453–457

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To compare the evaluations provided by physicians, nurses and family members with the results of the MacArthur Competence Assessment Tool-Treatment with respect to their agreement regarding the decision-making competence of psychiatric inpatients. **Methodology:** Cross-sectional – descriptive comparative study of assessments in decision-making. The study has been critically appraised using a checklist for diagnostic accuracy studies (a modified version of the QUADAS-2 tool, as recommended in the NICE methods manual). **Was a consecutive or random sample of patients enrolled?** No. Eighty-three patients were selected from 129 patients admitted to the psychiatric clinic during the study period (June 2007 to February 2008), using inclusion criteria.	**Is the reference standard likely to correctly classify the target condition?** Partly. The MacArthur Competence Assessment Tool-Treatment test which is considered as the reference standard in the study does not yield a limit score or a total score on understanding, appreciation, reasoning and the expression of choice. However, in a limited number of studies, cut-off scores for understanding, appreciation and reasoning were determined. Patients with a low score in 1 of these dimensions were considered as incompetent in decision-making. **Were the reference standard results interpreted without knowledge of the results of the index test?** No. The main purpose of the study was to compare evaluations made by physician, nurse, patient's relatives (index test) and the MacArthur Competence Assessment Tool-Treatment (reference test). The re-	**Does the study's research question match the review question?** Yes. The guideline question focuses on assessment of mental capacity and the study assesses the decision-making competencies of psychiatric inpatients. **Has the study dealt appropriately with any ethical concerns?** Yes. The study was approved by the Kocaeli University Human Research Ethics Committee (KUHREC Date: 19 June 2007, Project number: 57). Informed consent was obtained from all patients, physicians and nurses, and those relatives who agreed to participate. **Were service users involved in the study?** Not reported. There is no information about service user involvement in the design of the study. **Is there a clear focus on the guideline topic?** Yes.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Were the index test results interpreted without knowledge of the results of the reference standard? No. In this study index test was the question asked to the physicians and nurses responsible for each patient and to the patient's relatives – “how do you evaluate your patient's competence to make treatment decisions?” Physicians, nurses and relatives were asked to judge the patient as competent, partially competent, or incompetent. The authors have taken the cut-off scores for MacArthur Competence Assessment Tool-Treatment which could be considered as reference standard according to a published study of the original authors of the tool. **If a threshold was used, was it pre-specified?** Not applicable. The index test was a question which was asked to the physicians and nurses responsible for each patient's care and to the patient's relatives. **Were the methods for performing the test described in sufficient detail?** Yes. The researchers in the study report the question, which was asked to those physicians and nurses responsible for each patient's care and to the patient's relatives to judge the patient’s competency in decision-making. Relatives were given an explanation about decision-making competency. The data collection procedure is reported in the study.	searchers were aware of the evaluations of both index and reference tests and comparisons were made and reported. **Was the interval between index test and reference standard appropriate?** Yes. In this study the index test and reference standard were carried out simultaneously, as there was no need to include an interval between the tests. **Did all patients receive the same reference standard? Did all patients get the diagnostic test *and* the reference standard?** Yes. The decision-making competence of each patient was assessed with the MacArthur Competence Assessment Tool-Treatment which is the reference standard. **Were all patients included in the analysis?** Yes. The study recruited 83 patients and all were included in the analysis. **Are the sensitivity and specificity and/or likelihood ratios presented or are the results presented in such a way that we can work them out?** No. The study used Cohen κ test to explore the relationship between the competency evaluations of the physicians, nurses and relatives. The relationships between these 3 competence assessments and the demographic and clinical features of	**Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The study focuses on assessment of the decision-making competence of psychiatric inpatients, which is one of the activities covered by the guideline under research question 3 – assessment of mental capacity. **Does the index test, its conduct, or interpretation differ from the review question?** No. The index test is MacArthur Competence Assessment Tool-Treatment which assesses the decision-making competence. The guideline does not specify any particular test but includes mental capacity assessment forms.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	the patients (along with their decision-making competence) were evaluated using Pearson's χ^2 test. **How sure are we about the results, consequences and cost of alternatives performed?** Yes. The results are presented in a convincing manner and data are reported in tables and text. The authors intended to compare the assessments and appropriate statistical analyses were used. There was no cost analysis or alternative reported. The authors propose objective evaluations with appropriate tools must be carried out for those patients whose decision-making competence is questionable. **Is the disease status of the tested population clearly described? (spectrum bias)** Yes. All the participants were psychiatric inpatients. Based on the diagnostic criteria, 39.8% of the patients had a mood disorder, 27.7% had a psychotic disorder, 18.1% had an anxiety disorder, and 14.5% had alcohol/substance dependence.	**Does the target condition as defined by the reference standard match the question?** Yes. The reference test is MacArthur Competence Assessment Tool-Treatment, which assesses decision-making competence which is in line with research question 3 – assessment of mental capacity, methods and tools for conducting and recording assessments. **Can the test be applied to your patient or population of interest?** Yes. The authors report that the MacArthur Competence Assessment Tools (Treatment and Research) are the most commonly recommended tools in assessments of competence, as their validity and reliability have been tested in a large number of patients and a wide range of diseases. In this study the tool is administered to psychiatric inpatients. However, the tool assesses decision-making competence and it can be applied to the population covered by the guideline. **Does the study have a UK perspective?** No. The study was conducted in Turkey.	

2. Carling-Rowland A, Black S, McDonald L et al. (2014) Increasing access to fair capacity evaluation for discharge decision-making for people with aphasia: a randomised controlled trial. Aphasiology 28: 750–765

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To develop and test the effectiveness of a communicatively	**Was the exposure to the intervention and comparison as intended?**	**Does the study's research question match the review question?**	**Overall assessment of internal validity: +**

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
accessible capacity evaluation tool with communication training supports; thus, allowing healthcare professionals to evaluate more equitably the capacity of people living with aphasia to consent to be admitted to long- term care. **Methodology:** Randomised controlled trial with repeated measures. **Description of theoretical approach?** No. Not reported. **How was selection bias minimised?** Randomised. Through randomisation software, the participant pairs were divided into 2 groups, experimental and control. **Was the allocation method concealed?** Not reported. **Were participants blinded?** Part blind. The participants were unaware of their group membership until after the first capacity evaluation. Social workers were blinded partially to the fact that the people with aphasia had been judged to have capacity. They were provided with all information except the language comprehension abilities. **Were providers blinded?** Not reported. **Were investigators, outcome assessors, researchers, etc.,**	Yes. The researchers do not report any changes made to the intervention. **Was contamination acceptably low?** Not reported. **Did either group receive additional interventions or have services provided in a different manner?** Not reported. **Were outcomes relevant?** Yes. The following outcomes were measured – capacity determination of people with aphasia; social worker evaluators' communication skills; social worker evaluators' confidence in capacity determination; perspectives of people with aphasia. **Were outcome measures reliable?** Partly. The study used the Capacity to Make Admissions Decisions tool to determine the baseline measurement of capacity, which has not been subjected to psychometric testing. This questionnaire was developed by the Ontario Ministry of Health and Long-Term Care (1997). The Communication Aid to Capacity Evaluation was administered to the experimental group. The Communication Aid to Capacity Evaluation is a communicatively accessible version of the Capacity to Make Admissions Decisions which was developed for the study – its psychometric properties were not tested. Other tools used included the	Yes. The review question focuses on assessments of mental capacity and the research evaluates a communication tool to assess the capacity of people living with aphasia to consent to admission to long-term care. **Has the study dealt appropriately with any ethical concerns?** Yes. The authors confirm that the study received ethical approval and that consent was sought from participants. **Were service users involved in the design of the study?** Yes. The intervention (Communication Aid to Capacity Evaluation) was developed with the assistance of three working groups – 5 speech and language pathologists providing services to people with aphasia across the continuum of healthcare; 4 social workers who work with individuals with stroke and aphasia and who evaluate capacity on a regular basis; and 5 people with aphasia attending a community aphasia centre (not part of the study). An individual with Broca's aphasia and a speech and language pathologist trained in Supported Conversation for Adults with Aphasia contributed to the training DVD. **Is there a clear focus on the guideline topic?** Yes. The study evaluates a communication tool to assess the capacity of people living with aphasia to consent to be admitted to long-term care.	**Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
blinded? Part blind. Social workers who participated in the study also took on the role of outcome assessors. Social workers were blinded partially to the fact that the people with aphasia had been judged to have capacity. They were provided with all information except the language comprehension abilities. **Did participants represent the target group?** Yes. The participants with aphasia were recruited from 4 aphasia centres and 1 hospital outpatient clinic in Ontario. The social worker evaluators were recruited from 4 teaching hospitals and 1 subacute hospital in Ontario. **Were all participants accounted for at study conclusion?** Not reported.	Measure of Participation in Conversation and the Measure of Skill in Supported Conversation (which have undergone some psychometric evaluation). **Were all outcome measurements complete?** Yes. The study reported the results of all outcome measures as planned. **Were all important outcomes assessed?** Yes. The study assessed all important outcomes. **Were there similar follow-up times in exposure and comparison groups?** Yes. Both experimental and control groups were assessed and followed-up at similar times. **Was follow-up time meaningful?** Partly. Repeat capacity evaluation took place a minimum of 2 weeks after the intervention, which seems relatively short term. The researchers conducted post evaluation surveys which was not on the main outcome. An aphasia-friendly survey was administered to participants with aphasia, and social worker evaluators were assessed on their perceived confidence in their decisions regarding capacity (or lack of it). **Were the analytical methods appropriate?** Yes. The experimental and control group social worker eval-	**Is the study population the same as at least one of the groups covered by the guideline?** Yes. All study participants had a diagnosis of stroke (apart from one with a subdural haematoma) and had aphasia. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. The study took place at aphasia centres and an outpatient clinic. **Does the study relate to at least one of the activities covered by the guideline?** Yes. One of the activities covered by the Guideline is the assessment of mental capacity. This research evaluates a communication tool to assess the capacity of people living with aphasia to consent to be admitted to long-term care. **Are the study outcomes relevant to the guideline?** Yes. The following study outcomes are relevant to the Guideline – capacity determination of people with aphasia; social worker evaluators' communication skills; social worker evaluators' confidence in capacity determination; perspectives of people with aphasia. **Does the study have a UK perspective?** No. The study was conducted in Canada.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	uators were compared with a) capacity evaluation using frequency and percentages b) communication skills using analysis of covariance to measure inter-group comparisons c) confidence in capacity determination by repeated measures analysis of variance to determine if statistically significant change occurred. The potential difference in the participants with aphasia perspectives in experimental group means between pre-test and post-test survey results was measured by a paired samples t-test. Further, a logistical regression analysis was used to analyse the data as the dependent variable was dichotomous (able or unable to determine capacity). **Were exposure and comparison groups similar at baseline? If not, were these adjusted?** Not reported. The social worker evaluators from both groups administered the Capacity to Make Admissions Decisions questionnaire with their paired participants with aphasia to determine a baseline measurement of capacity, but it is not reported if the groups were comparable at baseline. Similarly, differences between groups on other outcome measures are not reported at baseline. **Was intention to treat (ITT) analysis conducted?** Not reported. **Was the study sufficiently powered**		

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	to detect an intervention effect (if one exists)? Yes. The sample size for this study was calculated at 36; 18 participant pairs (one aphasia participant and 1 social worker) for each group, experimental and control (Cohen's *d* = 1.35). Following participant withdrawal, 32 participant pairs completed the study protocol, 17 participant pairs in the experimental group and 15 in the control group. **Were the estimates of effect size given or calculable?** Partly. Effect size was available for social worker evaluators' communication skills. **Was the precision of intervention effects given or calculable? Were they meaningful?** Partly. Effect size was available for social worker evaluators' communication skill and confidence intervals were calculated. Neither effect size nor confidence interval could be calculated for other outcome measures. **Do conclusions match findings?** Yes.		

3. Feng BS, Person C, Phillips-Sabolet J et al. (2014) Comparison between a standardized questionnaire and expert clinicians for capacity assessment in stroke clinical trials. Stroke 45: e229–e232

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The study aims to compare a standardised questionnaire (modified, stroke-specific, version of the Aid to Capacity Evaluation) and	**Is the reference standard likely to correctly classify the target condition?** Yes. Psychiatrist and neuropsychologist assessments are used	**Does the study's research question match the review question?** Yes. The review question focuses on assessment of mental capacity and	**Overall assessment of internal validity:** +

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
expert clinicians' capacity assessments. **Methodology:** Prospective pilot study comparing 3 different capacity evaluations performed in a single group of stroke patients. The study has been critically appraised using a checklist for diagnostic accuracy studies (a modified version of the QUADAS-2 tool), as recommended in the NICE methods manual. **Was a consecutive or random sample of patients enrolled?** No. Patients were selected using purposive or non-random sampling. **Was a case-control design avoided?** Yes. The study did not use a case-control design, all study participants had disease, i.e. stroke. **Did the study avoid inappropriate exclusions?** Partly. Patients were excluded who were unable to hear despite assisted devices, declared legally incompetent, encephalopathic, severely lethargic or obtunded, diagnosed with dementia or severe cognitive decline, or had a current psychiatric diagnosis (schizophrenia, major depression) that would interfere with study assessment. **Were the index test results interpreted without knowledge of the results of the reference standard?**	as reference standards and are considered to be the clinical gold standards. **Were the reference standard results interpreted without knowledge of the results of the index test?** Yes. There were 3 types of assessment performed in the study. The reference tests were the assessments conducted by psychiatrists and neuropsychologists and the index test which is the modified stroke version of Aid to Capacity Evaluation was performed by a trained rater. All 3 tests were conducted by different individuals who were blinded to the results of the each other's assessments as well as methods used. **Was the interval between index test and reference standard appropriate?** Yes. All assessments (index test and reference standards) were performed independently within the same day or within ±24 hours. **Did all patients receive the same reference standard? Did all patients get the diagnostic test *and* the reference standard?** Yes. All 30 patients completed the Aid to Capacity Evaluation which is the index test, 29 patients each completed reference standard which is the assessment by psychiatrist and neuropsychologists. **Were all patients included in the**	the study focuses on capacity assessment of stroke patients by comparing results from a standardised questionnaire to expert clinician assessments. **Has the study dealt appropriately with any ethical concerns?** Yes. The authors report that the study was approved by the Institutional Committee for Protection of Human Subjects. **Were service users involved in the study?** Not reported. **Is there a clear focus on the guideline topic?** Yes. The guideline focuses on decision-making and mental capacity and includes a question on assessment of mental capacity. The study focuses on capacity assessment of stroke patients by comparing results from a standardised questionnaire to expert clinician assessments. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. The study sample is comprised of stroke patients and lack of decision-making capacity is very common in this group. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Study was conducted in the stroke, rehabilitation, and neurological intensive care	**Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
Yes. There were 3 types of assessment performed in the study. The index test, which is the modified stroke version of Aid to Capacity Evaluation, was performed by a trained rater, the other 2 assessments were done by psychiatrist and neuropsychologists. All 3 tests were done by different individuals and were blinded to the results of the other's assessments as well as methods used. **If a threshold was used, was it pre-specified?** Yes. The details of the index test, the stroke specific version of Aid to Capacity Evaluation and the standardised version of the Aid to Capacity Evaluation are reported by the authors in a supplement. The scoring system and the algorithm to generate decisions are also provided. **Were the methods for performing the test described in sufficient detail?** Yes. The supplemental papers provided by the study authors describe in detail the administration of the test.	**analysis?** Yes. All 30 patients completed the Aid to Capacity Evaluation which is the index test, 29 patients each completed reference standard which is the assessment by psychiatrist and neuropsychologists. All of them were included in the analysis. **Are the sensitivity and specificity and/or likelihood ratios presented or are the results presented in such a way that we can work them out?** Yes. **How sure are we about the results, consequences and cost of alternatives performed?** Yes. Confidence limits of sensitivity, specificity, positive predictive value, negative predictive value are given. **Is the disease status of the tested population clearly described? (spectrum bias)** Yes. All patients were hospitalised patients in stroke, rehabilitation, or neurological intensive care units of a single tertiary-care university medical centre. Patients were diagnosed with either an ischemic or haemorrhagic stroke (National Institutes of Health Stroke Scale [NIHSS] score ≥1) within 10 days of symptom onset. Sixty per cent of patients were men with mild to moderate ischemic stroke. Thirty-seven per cent exhibited aphasia and neglect, whereas the remaining participants lacked these deficits.	units of a single tertiary care university medical centre. The guideline covers inpatient healthcare settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The guideline focuses on decision-making and mental capacity (including assessment of capacity) and the study focuses on the assessment of capacity in stroke patients by comparing results from a standardised questionnaire to assessments made by expert clinicians. **Does the index test, its conduct, or interpretation differ from the review question?** No. The review question in this context does not specify any particular type of test, it includes all type of assessment tools that assess mental capacity and decision-making. In this study the index test is a standardised questionnaire (modified, stroke-specific, version of the Aid to Capacity Evaluation) to assess the capacity of stroke patients in decision-making. **Does the target condition as defined by the reference standard match the question?** Yes. The target condition in the study is stroke and it matches the review question. **Can the test be applied to your patient or population of interest?** Partly. The test in the study is specifically modified for stroke patients and	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
		it can be applied to stroke patients to accurately identify those who can participate in stroke trials. It cannot be generally applied to all populations who may lack decision-making capacity. **Does the study have a UK perspective?** No. The study was conducted in the United States.	

4. Gregory R, Roked F, Jones L et al. (2007) Is the degree of cognitive impairment in patients with Alzheimer's disease related to their capacity to appoint an enduring power of attorney? Age and Ageing 36: 527–531

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To investigate the capacity to create an Enduring Power of Attorney as determined by a clinical assessment, is significantly related to a degree of cognitive impairment, and whether Mini Mental State Examination (Folstein et al. 1975) score is a good predictor of a patient's capacity. To examine whether any socio-demographic factors (age, gender, education, and qualifications), are related to a patient's capacity to create an Enduring Power of Attorney. **Methodology:** Cross-sectional – quantitative descriptive cross-sectional study. The study has been critically appraised using a checklist for diagnostic accuracy studies (a modified version of the QUADAS-2 tool), as recommended in the NICE methods manual.	**Is the reference standard likely to correctly classify the target condition?** Partly. Though Mini Mental State Examination is used widely to assess the degree of capacity, it does not allow for a comprehensive cognitive assessment. Therefore the results would not be generalisable to patients with other forms of dementia, such as frontotemporal or Lewy body dementias, where loss of specific areas of cognitive function, such as executive function, are not reflected by the Mini Mental State Examination score. **Were the reference standard results interpreted without knowledge of the results of the index test?** Yes. All 3 assessors of capacity (index test) were blinded to the participants' Mini Mental State Examination score (reference standard).	**Does the study's research question match the review question?** Yes. The review question is about assessment of mental capacity and the study is about assessing patients with Alzheimer's disease capacity to create an Enduring Power of Attorney. **Has the study dealt appropriately with any ethical concerns?** Yes. Informed consent was obtained from those willing to participate, and carers gave their assent. The study received local research ethics committee approval and NHS Research and Development approval. **Were service users involved in the study?** Not reported. **Is there a clear focus on the guideline topic?** Yes. The guideline is about decision-making and mental	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Was a consecutive or random sample of patients enrolled? No. Participants were recruited from 2 old age psychiatry consultant teams based at the Queen Elizabeth Psychiatric Hospital, Birmingham, UK. All patients referred to these 2 teams between January 2005 and January 2006 with a DSM-IV diagnosis of Alzheimer's disease were included. **Did the study avoid inappropriate exclusions?** Yes. Patients were excluded who did not have a reasonable standard of spoken English, or suffered from severe expressive/receptive dysphasia. **Were the index test results interpreted without knowledge of the results of the reference standard?** Yes. Index tests (semi-structured interview) and reference standard (Mini Mental State Examination) were administered by different assessors. It was reported that the assessors of capacity were blinded to the participants' Mini Mental State Examination score. **If a threshold was used, was it pre-specified?** No. Not pre-specified, only mentioned the following in the analysis. ROC analysis showed that optimal sensitivity and specificity were obtained using a cut-off Mini Mental State Examination score of 18.	Both index test and reference standard were done by separate individuals and different timings. **Was the interval between index test and reference standard appropriate?** Yes. All participants were first assessed using the Mini Mental State Examination, carried out by a consultant psychiatrist. This was followed on the same morning by a semi-structured interview designed to assess capacity to create an Enduring Power of Attorney. **Did all patients receive the same reference standard? Did all patients get the diagnostic test *and* the reference standard?** Yes. **Were all patients included in the analysis?** Yes. **Are the sensitivity and specificity and/or likelihood ratios presented or are the results presented in such a way that we can work them out?** Yes. Optimal sensitivity and specificity were obtained using a cut-off Mini Mental State Examination score of 18: sensitivity 86.2% (95% CI 67.4 - 95.5), specificity 82.2% (95% CI 67.4 - 91.5). Positive predictive value 75.8% (95% CI 57 - 88%), Negative predictive value 90.2% (95% CI 76 - 97%). Likelihood ratio for a positive result (LR+ve) = 4.84 (95% CI 2.54 - 9.24) likelihood ratio for a negative result (LR−ve) =0.16	capacity and assessment of mental capacity is 1 of the guideline question. This study is about assessing patients with Alzheimer's disease capacity to create an Enduring Power of Attorney as well as the predictors and factors of patient's capacity. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Study population were people with Alzheimer's disease. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Participants were recruited from 2 old age psychiatry consultant teams based at the Queen Elizabeth Psychiatric Hospital, Birmingham, UK. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The study focuses on the assessment of patients with Alzheimer's disease capacity to create an Enduring Power of Attorney as well as the predictors and factors of patient's capacity. **Does the index test, its conduct, or interpretation differ from the review question?** No. Review question does not specify any particular tool; however, all tools/ tests that assess the ability of adults who lack mental capacity to make decisions could be included. The index test is a	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Were the methods for performing the test described in sufficient detail? Yes. The study reports the timing of the test, assessor, method of data collection, and resolving disagreements and the items of the tool.	(95% CI 0.06 - 0.42). **How sure are we about the results, consequences and cost of alternatives performed?** Yes. The study reported confidence intervals. **Is the disease status of the tested population clearly described? (spectrum bias)** Yes. All participants with a DSM-IV diagnosis of Alzheimer's disease. Twenty patients (27%) were classed as suffering from severe cognitive impairment, 27 (36.5%) were moderate and 27 (36.5%) mildly cognitively impaired.	semi-structured interview designed to assess the capacity to create an Enduring Power of Attorney. **Does the target condition as defined by the reference standard match the question?** Yes. The target condition in the study is patients with Alzheimer's disease which matches the review question. **Can the test be applied to your patient or population of interest?** Yes. Although the interview used to assess capacity (index test) had not been validated, there was a high level of agreement between raters, and the use of the semi-structured interview made the capacity assessment as close as possible to the methods used in clinical practice. The Mini Mental State Examination (reference standard in the study) could be used as a screening tool to help inform a clinical capacity assessment in patients with Alzheimer's disease. However, given the complex nature of capacity, Mini Mental State Examination score should not be used in isolation, and individual assessment of the patient should always be undertaken where possible. **Does the study have a UK perspective?** Yes. The study was conducted in the United Kingdom.	

5. Lai JM, Gill TM, Cooney LM et al. (2008) Everyday decision-making ability in older persons with cognitive impairment. American Journal of Geriatric Psychiatry 16: 693–696

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To demonstrate the reliability and validity of the Assessment of Capacity for Everyday Decision-Making, an instrument to evaluate everyday decision-making. **Methodology:** Cross-sectional – this is a cross-sectional study to assess the reliability and validity of an instrument. The study has been critically appraised using a checklist for diagnostic accuracy studies (a modified version of the QUADAS-2 tool), as recommended in the NICE methods manual. **Was a consecutive or random sample of patients enrolled?** No. Sampling techniques are not reported specifically but from the description provided it can be assumed that purposive sampling was used. **Did the study avoid inappropriate exclusions?** No. Persons with untreated depression, active psychosis, or delirium were excluded. **Were the index test results interpreted without knowledge of the results of the reference standard?** Yes. The index test interviewer was blinded to the participants' cognitive testing and MacArthur Competence Assessment Tool-Treatment interview, which is the reference standard.	**Is the reference standard likely to correctly classify the target condition?** Yes. The reference standard used in the study is a modified version of the MacArthur Competency Assessment Tool for Treatment MacArthur Competence Assessment Tool-Treatment to assess the capacity of participants to make a decision about taking a medicine that could slow the progression of memory loss. This has been validated in persons with very mild to moderate severity Alzheimer disease. **Were the reference standard results interpreted without knowledge of the results of the index test?** Partly. A research assistant administered the MacArthur Competence Assessment Tool-Treatment (reference standard) and was blinded to the initial Assessment of Capacity for Everyday Decision-Making interviews (index test). However, they performed an additional Assessment of Capacity for Everyday Decision-Making interview in a patient subset. **Was the interval between index test and reference standard appropriate?** No. Not reported. **Did all patients receive the same reference standard? Did all patients get the diagnostic test *and***	**Does the study's research question match the review question?** Yes. The review question focuses on assessment of mental capacity and the study explores the everyday decision-making ability of older persons with cognitive impairment. **Has the study dealt appropriately with any ethical concerns?** Yes. All participants provided informed consent (or a proxy provided assent when required). The Yale University Human Investigation Committee approved the study. **Were service users involved in the study?** Not reported. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Data collection of the study occurred in clinics or the participant's home. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The review question focuses on assessment of mental capacity and the study explores the	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
If a threshold was used, was it pre-specified? Not applicable. It is not reported whether a threshold was used. **Were the methods for performing the test described in sufficient detail?** Partly. The detailed administration of the test is not described in the article; however, the authors note that copies of the test are available upon request.	**the reference standard?** Yes. All 39 patients received the same reference standard (modified version of the MacArthur Competency Assessment Tool for Treatment). **Were all patients included in the analysis?** Yes. All 39 patients included in the analysis. **Are the sensitivity and specificity and/or likelihood ratios presented or are the results presented in such a way that we can work them out?** Not applicable (non-binary data). For reliability – intraclass correlation coefficient and internal consistency reliability with a Cronbach alpha. For validity – Spearman's rank correlation coefficient was used in the study. **How sure are we about the results, consequences and cost of alternatives performed?** Partly. Authors reported inter-scorer reliability by intraclass correlation coefficient and internal consistency by Cronbach alpha which provides a reasonable insight into reliability. To examine validity, the authors used the Spearman's rank correlation coefficient to evaluate associations between index tests (Assessment of Capacity for Everyday Decision-Making ability scores) and demographic characteristics, cognition, and the MacArthur Competence Assessment Tool-Treatment ability measures.	everyday decision-making ability of older persons with cognitive impairment. **Does the index test, its conduct, or interpretation differ from the review question?** No. The review question is about general assessment of mental capacity which includes assessment forms, protocols, tests etc. The index test in the study is a tool called The Assessment of Capacity for Everyday Decision-making instrument and uses a semi-structured interview format to assess 4 decision-making abilities: understanding, appreciation, reasoning, and expressing a choice. **Does the target condition as defined by the reference standard match the question?** Yes. The target condition in the study is the decision-making capacity and to measure everyday decision-making capacity of older persons with cognitive impairment which matches the review question. **Can the test be applied to your patient or population of interest?** Yes. The guideline includes people above 16 years with diverse conditions whose capacity to make specific decisions about care needs to be assessed. The study which is about measurement of decision-making capacity of older people with cognitive impairment could be applied.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Is the disease status of the tested population clearly described? (spectrum bias) Yes. Participants were divided into 3 Mini Mental State Examination (Folstein et al. 1975) defined categories: very mild (25 to 30), mild (20 to 24), and moderate (12 to 19) impairment. Thirty-six of the 39 (92%) participants had a diagnosis (50% Alzheimer's disease, 3% vascular dementia, and 47% unspecified type), and 3 had mild cognitive impairment.	**Does the study have a UK perspective?** No. The study was conducted in the United States.	

6. Mills W, Regev T, Kunik M et al. (2014) Making and Executing Decisions for Safe and Independent Living (MED-SAIL): development and validation of a brief screening tool. American Journal of Geriatric Psychiatry 22: 285–293

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The purpose of the study was to describe the development and preliminary validation of the Making and Executing Decisions for Safe and Independent Living (MED-SAIL), a brief screening tool for capacity to live safely and independently in the community. **Methodology:** Prospective preliminary validation study. The study has been critically appraised using a checklist for diagnostic accuracy studies (a modified version of the QUADAS-2 tool), as recommended in the NICE methods manual. **Was a consecutive or random sample of patients enrolled?** No.	**Is the reference standard likely to correctly classify the target condition?** Yes. The study used 5 standardised measures, which are included in the criterion standard capacity assessment, and could be considered as reference standard. Each test had a different focus as described below 1.The St. Louis University Mental Status Examination – to identify a diagnosis of mild neurocognitive disorder 2. The Patient Health Questionnaire – based on the DSM-IV diagnostic criteria for major depressive disorder. 3. Independent Living Scales to determine the respondent's knowledge of information, ability to perform self-care tasks, and care for property; 4 and 5 – Activities of	**Does the study's research question match the review question?** Yes. The review question focuses on assessment of mental capacity and the study is details the development and validation of a brief screening tool (MED -SAIL) for capacity to live safely and independently in the community for older adults. **Has the study dealt appropriately with any ethical concerns?** Yes. This study was approved by institutional review boards at Baylor College of Medicine, Harris County Hospital District, and the Michael E. DeBakey Veterans Affairs Medical Center.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Over a 2-year period, MED-SAIL was administered to 49 participants as part of routine care for patients referred to the clinic's existing comprehensive capacity evaluation program. **Did the study avoid inappropriate exclusions?** Yes. **Were the index test results interpreted without knowledge of the results of the reference standard?** Yes. The MED-SAIL administrator was not aware of the capacity determination at the time of assessment. **If a threshold was used, was it pre-specified?** Not applicable. The research was intended to develop and validate a new tool (MED-SAIL), hence it was not possible to pre-specify the threshold. **Were the methods for performing the test described in sufficient detail?** Yes. The authors report that training of administrators took place and that administrators had access to a training manual. They also describe scoring criteria.	daily living and instrumental activities of daily living indicates greater dependence. **Were the reference standard results interpreted without knowledge of the results of the index test?** Not reported. **Was the interval between index test and reference standard appropriate?** No. Not reported. **Did all patients receive the same reference standard? Did all patients get the diagnostic test *and* the reference standard?** Yes. **Were all patients included in the analysis?** Yes. **Are the sensitivity and specificity and/or likelihood ratios presented or are the results presented in such a way that we can work them out?** Yes. Accuracy of MED-SAIL as a screening tool was determined by examining sensitivity, specificity, and Receiver Operating Characteristic analysis. The authors provided a metrics associated with potential cut points for MED-SAIL scoring, including sensitivity, specificity, negative predictive value, and positive predictive value across the range of possible MED-SAIL scores. In the discussion section, the authors report that they identified a mean MED-SAIL cut-off score of 5.0 across 2 scenarios to	**Were service users involved in the study?** Yes. A series of 5 focus groups were conducted with community-based health and social service providers in the development of MED-SAIL scenarios. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. The study population is older adults and the guideline specifies people above 16 years whose capacity to make decisions about care needs to be assessed. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Outpatient geriatrics clinic located in a community-based hospital. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Does the index test, its conduct, or interpretation differ from the review question?** No. The review question does not specify any tool, it takes into account all tools that assess the decision-making capacity in adults. **Does the target condition as defined by the reference standard**	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	maximise sensitivity. **How sure are we about the results, consequences and cost of alternatives performed?** Yes. Appropriate statistical tests applied and confidence interval mentioned. **Is the disease status of the tested population clearly described? (spectrum bias)** Yes. Participants have moderate to advanced cognitive impairment, clinically important functional declines, but mild to no depressive symptoms. The comprehensive capacity assessment clinic determined that 25% (N =12) of the participants had no capacity, 71% (N = 35) had partial capacity, and 4% (N =2) had full capacity.	**match the question?** Yes. The target condition is a diverse group whose decision-making capacity about care needs to be assessed. **Can the test be applied to your patient or population of interest?** Yes. The test MED-SAIL, a brief screening tool could be used to identify older adults with impaired capacity for remaining safe and independent in their current living environment. MED-SAIL is useful tool for health and social service providers in the community for the purpose of referral for definitive capacity evaluation. **Does the study have a UK perspective?** No. The study was conducted in the United States.	

7. Moye J, Karel MJ, Edelstein B et al. (2007) Assessment of capacity to consent to treatment. Clinical Gerontologist 31: 37–66

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The study reports on the development of a tool to assess capacity to consent to treatment. The authors also present statistical data in an attempt to determine reliability and validity of the tool. **Methodology:** Diagnostic accuracy study. The study has been critically appraised using a checklist for diagnostic accuracy studies (a modified version of the QUADAS-2 tool), as recommended in the NICE methods manual.	**Is the reference standard likely to correctly classify the target condition?** Yes. The Assessment of Capacity to Consent to Treatment interview is evaluated through comparison with cognitive test performance scores, clinician ratings, and differences in scores between patients where some degree of impairment is likely (people with dementia and schizophrenia) and a 'healthy' comparison group. None of these are considered to be a gold standard	**Does the study's research question match the review question?** Yes. The study reports on the development of a tool to assess capacity to consent to treatment. The authors also present statistical data in an attempt to determine reliability and validity of the tool. **Has the study dealt appropriately with any ethical concerns?** Yes. The study was approved by an Institutional Review Board and written informed consent/assent was sought.	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Was a consecutive or random sample of patients enrolled? No. The authors do not report whether the sample was enrolled consecutively or randomly; however, there is no indication that this is the case. A range of inclusion criteria are reported. **Was a case-control design avoided?** No. The study sample was comprised of 2 groups – individuals with a clinical diagnosis of dementia or schizophrenia and a '... healthy comparison group...' (p46). **Did the study avoid inappropriate exclusions?** Partly. To be included in the comparison group, potential participants were required to attain a score no lower than 26 on the mini mental state examination (Folstein et al. 1975). **Were the index test results interpreted without knowledge of the results of the reference standard?** Partly. The order in which tools were administered is not clear from the narrative, particularly in relation to the mini mental state examination. **If a threshold was used, was it pre-specified?** Not applicable. **Were the methods for performing the test described in sufficient de-**	comparison for assessment of capacity to make a treatment decision and it is unclear why the authors did not choose to use a tool such as the MacArthur Competence Assessment Tool for Treatment. **Were the reference standard results interpreted without knowledge of the results of the index test?** Partly. The order in which tools were administered is not clear from the narrative. **Was the interval between index test and reference standard appropriate?** Partly. The timescales over which the various tools and assessments were administered are unclear from the narrative. **Did all patients receive the same reference standard? Did all patients get the diagnostic test *and* the reference standard?** Yes. All participants with dementia or schizophrenia who received the diagnostic test also received all comparison tests. **Were all patients included in the analysis?** No. For certain comparisons (i.e. comparison of Assessment of Capacity to Consent to Treatment interview capacity ratings with clinician ratings of capacity), only a limited number of participants data were used.	**Were service users involved in the study**? No. Service users were not involved in the design of the study. **Is there a clear focus on the guideline topic?** Yes. The study focuses on capacity to consent to treatment. **Is the study population the same as at least one of the groups covered by the guideline**? Partly. The Assessment of Capacity to Consent to Treatment tool was designed to be used with cognitively 'abnormal' individuals (i.e. people with dementia or schizophrenia). It is unclear how or in what regards assessment of decisional capacity for people with either of these conditions differs from those who are cognitively 'intact'. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Does the index test, its conduct, or interpretation differ from the review question?** No. The index test is Assessment of Capacity to Consent to Treatment interview which supports assessment of treatment decision-making capacity.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
tail? Yes. The assessment of capacity to consent to treatment interview follows a protocol and an example is provided with the paper.	**Are the sensitivity and specificity and/or likelihood ratios presented or are the results presented in such a way that we can work them out?** No. **How sure are we about the results, consequences and cost of alternatives performed?** Partly. The failure to examine sensitivity and specificity or to use a more widely known comparator such as the MacArthur Competence Assessment Tool for Treatment suggest that the authors conclusions regarding the value of the Assessment of Capacity to Consent to Treatment interview should be treated with caution. **Is the disease status of the tested population clearly described?** No. Only limited details are provided regarding the characteristics of participants in the dementia and schizophrenia groups.	**Does the target condition as defined by the reference standard match the question?** Yes. The reference standards used in the study also included ratings of capacity to make treatment decisions. **Can the test be applied to your patient or population of interest?** Partly. It is unclear whether those who administer the interview require any training, or whether any costs are associated with the tool. **Does the study have a UK perspective?** No. The study was conducted in the United States.	

8. Sugano K, Okuyama T, Lida S et al. (2015) Medical decision-making incapacity among newly diagnosed older patients with haematological malignancy receiving first line chemotherapy: a cross-sectional study of patients and physicians. PLoS ONE 10: e0136163

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The purpose of this study was to identify the frequency of decision-making incapacity among newly diagnosed older patients with haematological malignancy receiving first-line chemotherapy, to examine factors associated with incapacity and	**Describes what was measured, how it was measured and the results?** Yes. The following outcome measures were used – frequency of incapacity; factors associated with incompetency: univariate analysis; factors associated with incompetency:	**Does the study's research question match the review question?** Partly. The study's research question is about identifying the frequency of decision-making incapacity and to examine factors associated with incapacity and to assess physicians' perceptions of patients' decision-making	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
assess physicians' perceptions of patients' decision-making incapacity. **Methodology:** Cross-sectional – survey. **Research design clearly specified and appropriate?** Yes. **Objectives of the study clearly stated?** Yes. The purpose of this study was to identify the frequency of decision-making incapacity among newly diagnosed older patients with haematological malignancy receiving first-line chemotherapy, to examine factors associated with incapacity and assess physicians' perceptions of patients' decision-making incapacity. **Clear description of context?** Yes. The introductory section clearly describes the existing literature and systematic reviews in the area and also explains the importance of the research topic. **References made to original work if existing tool used?** Yes. The validity and reliability of the Structured Interview for Competency Incompetency Assessment Testing and Ranking Inventory have been established in Japanese oncology settings. The authors utilised a modified version of this method, consistent with their previous study. Inter-rater reliability between the independent evaluations of	logistic regression analysis; physicians' recognition of patient incompetency. Details of statistical analysis and results of each outcome measure was reported. **Measurements valid?** Yes. The authors report that the evaluation of patient competency was performed using validated structured interviews. Inter-rater reliability was also confirmed in the study. Furthermore, depression and cognitive function were assessed by an international validated tool. The validity and reliability of the SICIATRI (Structured Interview for Competency Incompetency Assessment Testing and Ranking Inventory) have been established in Japanese oncology settings. The current study utilised a modified version of this method, consistent with their previous study. Inter-rater reliability between the independent evaluations of the two psychiatrists was rigorously examined in a subsample of 23 consecutive patients. The inter-class correlation coefficient was found to be sufficient (0.72, *p* <.01). The Patient Health Questionnaire - 9 was administered to assess patient's depression; the validity of the Japanese version has been verified. The Mini Mental State Examination (Folstein et al. 1975) was used to evaluate the current severity of cognitive impairment of the patients and the Japanese version of the Mini Mental State Examination has been validated.	incapacity. The review question is about effective interventions, tools, aids and approaches in supporting the assessment of mental capacity including the views and experience. **Has the study dealt appropriately with any ethical concerns?** Yes. The study was approved by the Institutional Review Board and Ethics Committee of Nagoya City University Graduate School of Medical Sciences, Japan, and was conducted in accordance with the principles laid down in the Helsinki Declaration. Written consent was obtained from each eligible patient after a thorough explanation of the purpose and method of the study. When the participants could not understand the contents of the study protocol fully, both the patients' oral consent and surrogates' written consent were obtained. **Were service users involved in the study?** No. Not reported. **Is there a clear focus on the guideline topic?** Partly. The guideline focuses on assessment of mental capacity, specifically focus on effective interventions, tools, approaches in supporting assessment of mental capacity and the views and experience. The study focuses on identifying the frequency of decision-making incapacity and to examine factors associated with incapacity.	

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
the 2 psychiatrists was rigorously examined in a subsample of 23 consecutive patients. The inter-class correlation coefficient was found to be sufficient (0.72, *p* <.01). The Patient Health Questionnaire - 9 was administered to assess patient's depression; the validity of the Japanese version has been verified. The Mini Mental State Examination was used to evaluate the current severity of cognitive impairment of the patients and the Japanese version of the Mini Mental State Examination has been validated. **Reliability and validity of new tool reported?** Yes. The authors used a modified version of the Structured Interview for Competency Incompetency Assessment Testing and Ranking Inventory-Revised, consistent with their previous study. Inter-rater reliability between the independent evaluations of the 2 psychiatrists was rigorously examined in a subsample of 23 consecutive patients. The inter-class correlation coefficient was found to be sufficient (0.72, *p* <.01). **Survey population and sample frame clearly described?** Yes. The study subjects were older patients with haematological malignancy admitted for inpatient treatment. Eligibility criteria – newly histopathologically diagnosed malignant lymphoma or multiple myeloma; 65 years of age or	**Measurements reliable?** Yes. The validity and reliability of the Structured Interview for Competency Incompetency Assessment Testing and Ranking Inventory have been established in Japanese oncology settings. The current study utilised a modified version of this method, consistent with their previous study. Inter-rater reliability between the independent evaluations of the 2 psychiatrists was rigorously examined in a subsample of 23 consecutive patients. The inter-class correlation coefficient was found to be sufficient (0.72, *p* <.01). The Patient Health Questionnaire - 9 was administered to assess patient's depression; the validity of the Japanese version has been verified. The Mini Mental State Examination was used to evaluate the current severity of cognitive impairment of the patients and the Japanese version of the Mini Mental State Examination has been validated. **Measurements reproducible?** Partly. The validity and reliability of the Structured Interview for Competency Incompetency Assessment Testing and Ranking Inventory-Revised have been established in Japanese oncology settings. Therefore the reproducibility to other settings need to be tested. Depression and cognitive function were assessed by international validated tool and it could be reproducible.	**Is the study population the same as at least one of the groups covered by the guideline?** Yes. The guideline population is all people aged 16 years or over whose capacity to make specific decisions about care needs to be assessed. The study subjects were 65 years of age or older with haematological malignancy newly diagnosed who has to take decisions about treatment. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Partly. The guideline focuses on assessment of mental capacity, with a specific focus on effective interventions, tools, approaches in supporting assessment of mental capacity. The study focuses on identifying the frequency of decision-making incapacity and to examine factors associated with incapacity as well as the accuracy of physicians' recognition of patients' decision-making incapacity. **Does the study have a UK perspective?** No. The study was conducted in Japan.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
older; informed about the cancer diagnosis. **Representativeness of sample is described?** Yes. Consecutive patients were recruited upon admission to the hospital prior to meeting with their primary physician to discuss the potential benefits and adverse effects of chemotherapy. **Subject of study represents full spectrum of population of interest?** Partly. Not adopting probability sampling methods suggests that the study sample may not represent the entire population and this study was conducted at a single tertiary institute. **Study large enough to achieve its objectives, sample size estimates performed?** Unclear. Sample size estimation not reported and the authors acknowledge that the sample size was small. **All subjects accounted for?** Yes. 114 subjects were included and all the subjects were accounted for in the analysis. **All appropriate outcomes considered?** Yes. Study outcomes were: frequency of incapacity; factors associated with incompetency; physicians' recognition of patient incompetency. **Response rate:** Response rate was	**Basic data adequately described?** Yes. Demographic data of subjects were described. **Results presented clearly, objectively and in enough detail for readers to make personal judgements?** Yes. Results of each outcome measure were clearly presented in text and in tables. **Results internally consistent?** Yes. There is internal consistency between the various outcome measures. **Data suitable for analysis?** Yes. Most of the data were quantitative in nature and subjected to statistical analysis. **Clear description of data collection methods and analysis?** Yes. The authors explained the procedure of data collection, tools used and analysis. **Methods appropriate for the data?** Yes. Statistical analyses were appropriate. **Statistics correctly performed and interpreted?** Yes. **Response rate calculation provided?** Yes. In this study, response rate was 100%. **Methods for handling missing data**		

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
100%, all the subjects responded to study measurements.	**described?** N/A. Not applicable as there was no missing data. **Difference between non-respondents and respondents described?** N/A. There were no non-respondents. **Results discussed in relation to existing knowledge on subject and study objectives?** Yes. Study results were discussed in relation to the existing literature. **Limitations of the study stated?** Yes. The authors acknowledged several limitations such as a small sample size, limits to the generalisability of the results, non-probability sampling, single study setting and inability to explore the specific influence of communication on decision-making incapacity. **Results can be generalised?** Partly. Some of the factors that limit generalisability include a small sample size, a population with only haematological malignancy, non-probability sampling, and single study setting. **Appropriate attempts made to establish 'reliability' and 'validity' of analysis?** Unclear. **Conclusions justified?** Yes.		

9. Brown PF, Tulloch AD, Mackenzie C et al. (2013) Assessments of mental capacity in psychiatric inpatients: a retrospective cohort study. BMC Psychiatry 13: 115

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To '… evaluate how frequently mental capacity is assessed in psychiatric inpatients, whether the criteria for determining capacity set out in the *Mental Capacity Act 2005* (MCA) are used in practice, and whether this has increased with the introduction of the MCA.' (p1). **Methodology:** Audit – the authors' extracted data from the South London and Maudsley NHS Foundation Trust Biomedical Research Centre Case Record Interactive Search. **Are the objectives of the audit clearly stated?** Yes. **The audit topic reflects a local service, speciality or national priority which merits evaluation and where care could be improved or refined through clinical audit**. Yes. The audit focuses on capacity assessments made during admission to a psychiatric ward. **The audit measures against standards.** Yes. The authors aim to determine the frequency with which psychiatric inpatients undergo assessments of mental capacity, and whether these meet the requirements set out in the Mental Capacity Act	**If a sample of the population was audited, the method for sampling is that which is best suited to measuring performance against the standards and is as scientifically reliable as possible.** Partly. The authors searched the trusts' database of patient records using the search term 'capacity', while this seems to be an appropriate approach, the authors note that this search was not able to access scanned documents that were attached to each patients records and it therefore seems likely that a substantial number of relevant records will have been excluded inappropriately. **Is the sample size sufficient to generate meaningful results?** Yes. **When necessary, the sample allows for adjustment for case mix?** N/A. **The audit uses pre-existing data sets where possible.** Yes. The authors extracted data from an existing database. **The data collection tool(s) and process have been validated.** No.	**Does the audit 'aim' match the review question?** Yes. The study aims to '… evaluate how frequently mental capacity is assessed in psychiatric inpatients, whether the criteria for determining capacity set out in the MCA are used in practice, and whether this has increased with the introduction of the MCA.' (p1). **Has the audit dealt appropriately with any ethical concerns?** Yes. The study was approved by an appropriate ethics committee. **Were service users involved in the design of the study?** No. **Is there a clear focus on the guideline topic?** Yes. The study focuses on practice in relation to the Mental Capacity Act. **Is the audit population the same as at least one of the groups covered by the guideline?** Yes. **Is the audit setting the same as at least one of the settings covered by the guideline?** Yes. **Does the audit relate to at least one of the activities covered by the guideline?** Yes.	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
(i.e. criteria used to determine capacity). **The audit standards are based upon the best available evidence.** Yes. The 'standards', which the authors measure are based on requirements set out in the Mental Capacity Act. **The audit standards are referenced to their source.** Yes. **The audit standards are expressed in a form that enables measurement.** Yes. The authors measure the frequency of capacity assessments and the proportion of those which meet Mental Capacity Act standards. **The patient group to whom the audit standards apply is clearly defined.** Yes. Individuals admitted to inpatient psychiatric settings in 1 large trust. **The audit standards take full account of patient priorities and patient-defined outcomes.** No. The study does not include patient defined/prioritised outcomes. **The timetable for the clinical audit is described, including timescales for completion and re-audit where necessary.** Yes. The study focuses on a 4-year period in which the Mental Capacity Act was implemented (2007).	**The data collection process aims to ensure complete capture of data.** Partly. The data collection technique would have ideally ensured a comprehensive dataset; however, the inability to access scanned documents attached to records seems likely to have excluded a significant number of records that may have been eligible. **Data are analysed, and feedback of the results is given so that momentum of the audit is maintained in line with the agreed timetable.** Yes. **Results of the clinical audit are presented in the most appropriate manner for each potential audience to ensure that the audit results stimulate and support action planning.** No. The findings only appear to have been reported in one paper. **The results are communicated effectively to all key stakeholders, including patients.** No. Communication of results appears to be limited to one paper. **The topic is re-audited to complete the audit cycle if necessary.** No. The authors do not discuss whether a re-audit is likely to take place. **Where recommended action has not been achieved in full, the topic**	**Are the audit measures relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
The methodology and data collection process is described in detail. Yes. The authors provide a reasonable level of detail in relation to their chosen methodology and data collection processes. **The methods used in the audit are recorded so that re-audit can be undertaken later in the audit cycle.** Yes.	**is re-audited at agreed intervals.** No. **The results of re-audit are recorded and disseminated appropriately, including to patients or people using services.** N/A. Re-audit not planned.		

10. Emmett C, Poole, Bond J et al. (2013) Homeward bound or bound for a home? Assessing the capacity of dementia patients to make decisions about hospital discharge: comparing practice with legal standards. International Journal of Law and Psychiatry 36: 73–82

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To '… comment on how assessments of residence capacity are actually performed on general hospital wards compared with legal standards for the assessment of capacity set out in the *Mental Capacity Act 2005* (MCA).' (p73). **Methodology**: Qualitative – focus groups and interviews (and an 'analysis' of key ward-based interactions and events) involving the whole range of health and social care professionals, people with dementia and their families. These included routine activities such as consultant-led ward rounds, MDT meetings, case conferences and discharge planning meetings, as well as more informal interactions. Patients' medical records	**Is the context clearly described?** Clear. The context in which data were collected is relatively well described. **Was the sampling carried out in an appropriate way?** Appropriate. The authors report that they used a purposive sampling strategy and a variable sampling matrix in order to recruit a diverse range of service users to the study. **Were the methods reliable?** Reliable. Data were collected by more than 1 method and the findings are discussed with reference to other studies. **Are the data 'rich'?** Mixed. The context in which data were collected are described relatively clearly; however,	**Does the study's research question match the review question?** Yes. The authors aimed to '… comment on how assessments of residence capacity are actually performed on general hospital wards compared with legal standards for the assessment of capacity set out in the Mental Capacity Act ...' (p73). **Has the study dealt appropriately with any ethical concerns?** Yes. The study received approval from a local ethics board and consent was provided by service users and practitioners involved in the research. **Were service users involved in the study?** No. Service users were not involved in the design of the study or interpretation of findings.	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
were also reviewed.' (p76). It is assumed that interviews were conducted with the same patients of whom case study analysis was undertaken; however, this is not clearly stated by the authors. **Is a qualitative approach appropriate?** Appropriate. The authors aimed to explore in-depth how decisions about mental capacity in relation to place of residence are made. **Is the study clear in what it seeks to do?** Clear. The authors clearly discuss the aims of the study and contextualise the study through reference to research focusing on mental capacity as well as the legal context. **How defensible/rigorous is the research design/methodology?** Defensible. The research design is appropriate and the authors present their rationale for taking this approach. They also provide detail on their sampling strategies and data collection/analysis techniques (however, only limited details are provided on site selection processes). **How well was the data collection carried out?** Appropriately. A clear description of the data collection and management processes are provided and these are appropriate to the research question.	details are limited. In particular, the narrative descriptions of practice provided by the authors overwhelms the data itself and therefore limits its usefulness to the NCCSC research question. **Is the analysis reliable?** Somewhat reliable. While the approach taken to data analysis is acceptable (constant comparative method), the authors do not report whether the data were themed and coded by more than 1 researcher and there is no indication that participant feedback was sought. **Are the findings convincing?** Somewhat convincing. While the findings are coherent and clearly presented, only a very small number of extracts from the original data are included. Much of the paper is given over to the authors' narrative description of practice and it is therefore difficult to have full confidence in their findings. **Are the conclusions adequate? Are the findings relevant to the aims of the study?** Somewhat adequate. While the conclusions are plausible and coherent, the decision to include only a small number of verbatim quotes from practitioners makes it difficult to have full confidence in the authors' interpretation of practice and the conclusions that they draw. In particular, the links between	**Is there a clear focus on the guideline topic?** Yes. The study focuses on assessments of mental capacity to decide on a place of residence after discharge from hospital. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
	the raw data and the authors' recommendation for a more specific test of capacity are not especially clear and while the NCCSC team has extracted this, the guideline committee should apply caution if this is considered in the process of drafting recommendations. In addition, the authors fail to discuss any limitations to the study or those associated with their chosen methodology.		

11. Manthorpe J, Samsi K, Rapaport J (2014) Dementia nurses' experience of the Mental Capacity Act 2005: A follow-up study. Dementia 13: 131–143

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
Study aim: This paper reports on the second stage of a research project in which interviews were used to follow-up with participants from the first stage. The '… overall aim of this part of the study was to explore participants' understanding, over time, their practice experience of the implementation of the MCA and their reflections of change in nursing practice. More specifically, this related to what challenges, if any, they faced in everyday practice and whether any expectations in relation to the MCA had been met.' (p133). **Methodology:** Qualitative – interviews. **Is a qualitative approach appropriate?** Appropriate. **Is the study clear in what it seeks**	**Is the context clearly described?** Unclear. The study does not provide a great deal of detail in relation to participants or the context in which they were working. We know that the interviews took place over the phone or in the workplace and there is some discussion of bias regarding this. **Was the sampling carried out in an appropriate way?** Not clear. The approach to sampling is not well described. It is not clear how many participants took part in the first interviews or how interviewees were selected. **Were the methods reliable?** Somewhat reliable. Only 1 interview was conducted per person, but findings are discussed in relation to other studies.	**Does the study's research question match the review question?** Partly. The study explores the experiences of dementia nurses in relation to the *Mental Capacity Act 2005*. **Has the study dealt appropriately with any ethical concerns?** No. Not reported. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. The focus is on dementia nurses experiences of the *Mental Capacity Act 2005*. These participants work with those who may lack mental capacity or lose capacity in the future. The study also describes how nurses work with carers. **Is the study population the same**	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
to do? Clear. This study follows on from another study (Samsi 2012) and the authors report that its aim was to gather the views and perspectives of dementia nurses regarding the *Mental Capacity Act 2005.* **How defensible/rigorous is the research design/methodology?** Defensible. The authors state that they aimed to explore participants understanding over time and their practice in relation to the *Mental Capacity Act 2005*. Participants were only interviewed once, which makes this difficult. This study can be viewed in tandem with its linked study, but the participants were not the same. Participants reflected on their practice in a single interview. The study rationalises its approach and sampling methods are well described. **How well was the data collection carried out?** Appropriately. Data collection methods are described in some detail. The study described the design of the semi-structured interviews and the issue of bias is discussed. Interviewers were intentionally selected on the basis that they had not interviewed participants in the earlier study. Data collection appears to have been systematic.	**Are the data 'rich'?** Mixed. The discussion is general and while some verbatim quotes are provided we do not learn in detail how many practitioners agreed on certain points. Overall the results lack detail. **Is the analysis reliable?** Reliable. Interviews were recorded and transcribed. They were analysed by 2 researchers and organised into themes using an iterative process. **Are the findings convincing?** Convincing. The findings appear coherent and themes are clearly presented. Some extracts from the interviews are presented. **Are the conclusions adequate?** Adequate.	**as at least one of the groups covered by the guideline?** Yes. People who may lack mental capacity. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Community settings. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

12. McDonald A, Dawson C, Heath B (2008) The impact of the Mental Capacity Act 2005 on social workers' decision making: a report for SCIE. Norwich: University of East Anglia

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors aimed to explore the '... impact of the Mental Capacity Act on assessments of capacity and best interests decision-making and their integration into record-keeping and care planning.' (p3). **Methodology:** Qualitative – semi-structured interviews in which interviewees were asked to describe examples from their practice in which an assessment of mental capacity was involved. The authors also made observations of practice. **Is a qualitative approach appropriate?** Somewhat appropriate. The study aims to explore the impact of the Mental Capacity Act on social work practice and a quantitative approach may have been a more appropriate means of evaluating the *impact* of the legislation. **Is the study clear in what it seeks to do?** Mixed. While the research objective of the study is reasonably clear the report as a whole lacks clarity. In particular, a significant proportion of the report provides a summary of the requirements of the Mental Capacity Act, and it is sometimes difficult to distinguish between this commentary, the authors' interpretation of participants' experiences, and the views of the interviewees themselves.	**Is the context clearly described?** Unclear. The authors do not describe the context in which interviews took place, and there is no consideration of context bias. **Was the sampling carried out in an appropriate way?** Not clear. No details on sampling methods are provided. **Were the methods reliable?** Not clear. No details on data collection are provided, making it difficult to assess whether the methods were reliable; and findings are not contextualised through reference to other studies. **Are the data 'rich'?** Poor. The authors do not provide details on the context in which data were collected and there is little consideration of diversity of perspective. **Is the analysis reliable?** Not clear/not reported. No details in relation to methods of analysis are provided. **Are the findings convincing?** Somewhat convincing. While the findings are reasonably convincing the report as a whole lacks clarity and coherence. It is often difficult to distinguish between the authors' commen-	**Does the study's research question match the review question?** Yes. The authors aimed to explore the '... impact of the Mental Capacity Act on assessments of capacity and best interests decision-making and their integration into record-keeping and care planning.' (p3). The study focuses on the practice of social workers that work with people with dementia. **Has the study dealt appropriately with any ethical concerns?** Yes. The study was approved by relevant ethics boards and interviewees were asked to sign consent forms. **Were service users involved in the study?** Yes. A reference group comprised of service users and carers was established to provide feedback on emergent findings. **Is there a clear focus on the guideline topic?** Yes. The study focuses on the impact of the Mental Capacity Act on social workers' practice in relation to assessments of capacity and making best interests decisions. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. The study sample is comprised of social workers who work with people with dementia.	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
In addition, findings related to assessment are also difficult to distinguish from those more general findings, and there is little consideration of the extant literature in relation to mental capacity and the Mental Capacity Act. **How defensible/rigorous is the research design/methodology?** Somewhat defensible. While a qualitative approach is to a certain extant appropriate to the research question, the authors do not discuss their rationale for taking such an approach, and they do not provide details on their site selection and interviewee sampling strategies. **How well was the data collection carried out?** Not clear/inadequately reported. The authors do not report any details in relation to data collection methods.	tary on the requirements of the Mental Capacity Act, their commentary on the experiences of the interviewees and the interviewees self-reported views. Extracts from the original data are minimal and do not always illustrate the finding that the authors wish to highlight. **Are the conclusions adequate?** Somewhat adequate. The conclusions drawn by the authors appear to be reasonable; however, links between the data and conclusions are often unclear. There is no discussion of the limitations of the study and findings in relation to assessment of capacity are not especially useful in relation to the objectives of this review question.	**Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes. The study was conducted in Norfolk.	

13. Murrell A and McCalla L (2016) Assessing decision-making capacity: The interpretation and implementation of the Mental Capacity Act 2005 amongst social care professionals. Practice 28: 21–36

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To explore how social care practitioners are carrying out capacity assessments and ultimately to provide an indication on how coherence (in assessing capacity) in practice can be maximised and the aims and principles of the *Mental Capacity Act 2005* upheld.	**Is the context clearly described?** Clear. The characteristics of the participants are clearly defined and context bias is considered. **Was the sampling carried out in an appropriate way?** Appropriate. Participants were purposively sampled to meet the requirements of the study –	**Does the study's research question match the review question?** Yes. Matches NCCSC review question 3.2 which seeks data about the experiences of practitioners about assessment of capacity to make decisions. **Has the study dealt appropriately**	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Methodology: Qualitative – semi-structured interviews. **Is a qualitative approach appropriate?** Appropriate. The research question seeks to illuminate subjective experiences of the assessment of decision-making capacity and therefore a quantitative approach would not have adequately addressed the question. **Is the study clear in what it seeks to do?** Clear. The purpose of the study is discussed including the aims and research question. There is detailed reference to the literature. **How defensible/rigorous is the research design/methodology?** Defensible. The design is appropriate to the research question and a clear rationale is given for using a qualitative approach, '… qualitative methods were employed for the purpose of this study, as this allowed for understanding the personal experiences and values of participants and how this may affect the implementation of the MCA.' (p25). There are clear accounts of the rationale/justification for the purposive sampling and the data collection and data analysis techniques. **How well was the data collection carried out?** Appropriately. Data collection methods were clearly described although no information on	namely that they were social care practitioners with experience of assessing capacity to make decisions under the *Mental Capacity Act 2005*. Sampling is therefore unlikely to adversely affect what respondents told researchers. **Were the methods reliable?** Somewhat reliable. Data were only collected via 1 method and reliability would have been improved if the researchers could have observed the practitioners while conducting assessments of decision-making capacity. Nevertheless findings are discussed in the context of existing literature which seems to concur with data gathered. **Are the data 'rich'?** Mixed. The contexts of the data (e.g. individual quotes) are not explicitly described but diverse perspectives do seem to have been explored. The detail and depth of the findings could have been more clearly demonstrated – the authors' own commentary dominates the presentation of data from the interviews. **Is the analysis reliable?** Somewhat reliable. The authors do not report that more than 1 researcher was involved in theming and coding transcripts/data therefore there is no evidence that different interpretations were explored/ discussed. In addition, participants do not appear to have	**with any ethical concerns?** Yes. The authors state that the '… research study was approved by a University Ethics Committee and the participating County Council in the southwest of England. The reflective approach ensured that the aims, objectives and assumptions of the research were transparent. This in turn upheld the utilitarian ethical principles of respect for persons, beneficence and justice (King and Horrocks 2010).' (p26). **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. Decision-making capacity under the Mental Capacity Act. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Decision-making capacity assessments. **Are the views and experiences reported relevant to the guideline?** Yes. Social care practitioners involved in the assessment of capacity to make decisions.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
the location of the interviews is provided. Appropriate data were collected to address the research question and record-keeping appears to have been systematic.	been given the opportunity to feed back on the transcripts or data. **Are the findings convincing?** Somewhat convincing. The findings are convincing, not least because they are presented alongside other research. However, they would have been more convincing if more abstracts from the original data had been included and there had been more discussion of the interview responses rather than the domination by the authors' own commentary. The data are nevertheless presented in themes and are therefore clear and coherent. **Are the conclusions adequate?** Somewhat adequate. There are clear links between data, interpretation and most of the conclusions although the researchers draw conclusions around the '… complex and subjective nature of risk assessment …' (p33), which don't seem to be explicitly underpinned by the study findings. Furthermore alternative explanations for the participant responses haven't clearly been explored and discounted. Nevertheless, the study does enhance understanding of the experience of social care practitioners in relation to assessing capacity to make decisions. The implications of the research are clearly defined and the authors are clear about the study limitations, namely the small-scale nature of the design.	**Does the study have a UK perspective?** Yes.	

14. Roy A, Sarus J, Roy A et al. (2011) Improving recording of capacity to consent and explanation of medication side effects in a psychiatric service for people with learning disability: audit findings. Journal of Intellectual Disabilities 15: 85–92

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors aimed to '… examine the practice of psychiatrists in a large learning disability service in recording capacity to consent to treatment and side effect discussion, and the impact of measures aimed at improving this.' (p85). **Methodology:** Audit – the authors describe their methodology as a '… retrospective case note audit …' (p87). **Are the objectives of the audit clearly stated?** Yes. **The audit topic reflects a local service, speciality or national priority which merits evaluation and where care could be improved or refined through clinical audit?** Yes. The study focuses on assessment of capacity and the recording of assessments. **The audit measures against standards.** Yes. The study measures performance against 3 standards; however, the origin of these is unclear. **The audit standards are based upon the best available evidence.** Unclear. The authors do not explain why these standards were identified	**If a sample of the population was audited, the method for sampling is that which is best suited to measuring performance against the standards and is as scientifically reliable as possible.** Yes. The authors report that they sampled records randomly (using a random number generator); however, given the likely caseload of the service it is disappointing that the authors did not. **Is the sample size sufficient to generate meaningful results?** Yes. At each stage of the cycle the authors randomly selected 26 sets of case notes from 1 of 6 teams. **When necessary, the sample allows for adjustment for case mix.** Unclear. **The audit uses pre-existing data sets where possible.** Yes. The authors extracted data from case notes. **The data collection tool(s) and process have been validated.** No. **The data collection process aims to ensure complete capture of data.** No. The authors focused on recording of capacity assessments.	**Does the audit 'aim' match the review question?** Yes. The authors aimed to '… examine the practice of psychiatrists in a large learning disability service in recording capacity to consent to treatment and side effect discussion, and the impact of measures aimed at improving this.' (p85). **Has the audit dealt appropriately with any ethical concerns?** No. The authors' narrative does not suggest that ethical issues were considered when designing the study. **Were service users involved in the design of the audit?** No. Service users were not involved in the design of the study. **Is there a clear focus on the guideline topic?** Yes. The study focuses on mental capacity assessments conducted in psychiatric learning disabilities services. **Is the audit population the same as at least one of the groups covered by the guideline?** Yes. **Is the audit setting the same as at least one of the settings covered by the guideline?** Yes.	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
or why they are important – the implicit assumption is that greater recording is preferable. **The audit standards are referenced to their source.** No. The authors do not report on the source of their chosen standards. **The audit standards are expressed in a form that enables measurement.** Yes. **The patient group to whom the audit standards apply is clearly defined.** Partly. The authors do not clearly define the population of interest except to note that they reviewed patient records from a learning disability service. **The audit standards take full account of patient priorities and patient-defined outcomes.** No. The authors make no reference to service user identified priorities or outcomes. **The timetable for the clinical audit is described, including timescales for completion and re-audit where necessary.** Yes. **The methodology and data collection process is described in detail.** Partly. Only limited details in relation to data collection are provided. **The methods used in the audit are recorded so that re-audit can be**	**Data are analysed, and feedback of the results is given so that momentum of the audit is maintained in line with the agreed timetable.** Yes. **Results of the clinical audit are presented in the most appropriate manner for each potential audience to ensure that the audit results stimulate and support action planning.** Partly. The audit appears to have only been published in article form. **The results are communicated effectively to all key stakeholders, including patients.** No. The authors do not describe how results were communicated. **The topic is re-audited to complete the audit cycle if necessary.** Yes. **Where recommended action has not been achieved in full, the topic is re-audited at agreed intervals.** Yes. **The results of re-audit are recorded and disseminated appropriately, including to patients or people using services.** No. The final results do not appear to have been disseminated to stakeholders in any other format.	**Does the audit relate to at least one of the activities covered by the guideline?** Yes. **Are the audit measures relevant to the guideline?** Yes. The study focuses on capacity assessments and the extent to which they are recorded. **Does the study have a UK perspective?** Yes. The study was conducted in England.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
undertaken later in the audit cycle. Partly. The methods are recorded, however these are not detailed.			

15. Shah A, Banner N, Newbigging K et al. (2009) The early experience of consultant psychiatrists in application of the Mental Capacity Act: issues for black and minority individuals. Ethnicities and Inequalities in Health and Social Care 2: 4–10

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors aimed to examine the experiences of consultant psychiatrists regarding the early implementation of the Mental Capacity Act. The findings reported in this paper focus specifically on equalities issues. **Methodology:** Survey – postal survey. **Objectives of the study clearly stated?** Yes. The authors clearly report their research aims. **Research design clearly specified and appropriate?** Yes. The research design is clearly outlined and this is appropriate. **Clear description of context?** Yes. The authors clearly describe the context in which the study took place (after the implementation of the Mental Capacity Act in late 2007) and this is supported by reference to appropriate research and guidance. **References made to original work**	**Measures for contacting non-responders?** Yes. Postcard reminders. **Describes what was measured, how it was measured and the results?** Yes. The authors clearly describe what they hoped to measure, how they measured it, and the results. **Measurements valid?** Unclear. The authors do not discuss the validity of the surveys they used. **Measurements reliable?** Unclear. **Measurements reproducible?** Yes. **Basic data adequately described?** Yes. The authors provide an appropriate level of detail. **Results presented clearly, objectively and in enough detail for readers to make personal judgements?** Yes. **Results internally consistent?** Yes. All results appear to have internal consistency.	**Does the study's research question match the review question?** Yes. The authors aimed to examine the experiences of consultant psychiatrists regarding the early implementation of the Mental Capacity Act. The findings reported in this paper focus specifically on equalities issues. **Has the study dealt appropriately with any ethical concerns?** No. **Were service users involved in the study?** No. There is no indication that service users were involved in the design of the study. **Is there a clear focus on the guideline topic?** Yes. The focus of the study is early experiences in relation to the Mental Capacity Act. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes.	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
if existing tool used? N/A. The researchers developed bespoke postal surveys. **Reliability and validity of new tool reported?** No. The authors do not discuss the reliability or validity of the surveys which they developed for this research programme. **Survey population and sample frame clearly described?** Partly. Details in relation to the survey population and the sampling frame are limited; however, the authors note that the Royal College of Psychiatrists database was used to identify relevant practitioners. **Representativeness of sample is described?** No. No data in relation to the characteristics of the sample are provided and it is therefore not possible to determine how representative the sample was. **Subject of study represents full spectrum of population of interest?** Unclear. As no details are provided on the sample or the extent to which it is representative, it is not possible to state whether the subject of the study represents full spectrum of population of interest. **Study large enough to achieve its objectives, sample size estimates performed?** Unclear. The authors do not report whether they performed	**Data suitable for analysis?** Yes. **Clear description of data collection methods and analysis?** No. The authors provide only limited details in relation to collection methods and analysis. **Methods appropriate for the data?** Yes. **Statistics correctly performed and interpreted?** NA. Statistical analysis not performed. **Response rate calculation provided?** Yes. **Methods for handling missing data described?** N/A. **Difference between non-respondents and respondents described?** No. Very few details are provided regarding the characteristics of respondents and the authors do not consider whether there were likely to be any differences between respondents and non-respondents. **Results discussed in relation to existing knowledge on subject and study objectives?** Yes. Findings are contextualised through reference to existing research and are considered in light of the study objectives. **Limitations of the study stated?**	**Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. The study reports on the experiences of consultant psychiatrists in the immediate aftermath of the implication of the Mental Capacity Act with a focus on equalities issues. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
sample size estimates. **All subjects accounted for?** N/A. **All appropriate outcomes considered?** Yes. The survey questions appear to be an appropriate means of determining how mental capacity assessments incorporate issues related to culture, ethnicity, or religion. **Response rate:** The response rate was low – for study 1, only 13% of potential participants responded. For study 2, only 29% responded.	Yes. **Results can be generalised?** No. Given the lack of information regarding the sample and the resulting difficulty in determining if the sample was representative the results are unlikely to be generalisable. **Appropriate attempts made to establish 'reliability' and 'validity' of analysis?** No. **Conclusions justified?** Yes. NB. Further detail regarding the methodology of this paper is provided in a paper by the same author also included for this review question: Shah A, Banner N, Heginbotham C et al. (2010) The early experience of Old Age Psychiatrists in the application of the Mental Capacity Act 2005: a pilot study. *International Psychogeriatrics* 22: 147–157.		

16. Shah A, Banner, N, Heginbotham C et al. (2010) The early experience of old age psychiatrists in the application of the Mental Capacity Act 2005: a pilot study. International Psychogeriatrics 22: 147–157

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To '… examine the experience of consultants in Old Age Psychiatry in the early implementation of the Mental Capacity Act pertaining to local policy and training in the application of the Mental Capacity Act, the assessment of decision-making ca-	**Describes what was measured, how it was measured and the results?** Yes. The authors are clear about what is being measured, and how and what results were collated via the survey. **Measurements valid?** Unclear. The	**Does the study's research question match the review question?** Yes. The experiences of consultant clinical psychologists in assessing decision-making capacity since the implementation of the Mental Capacity Act.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
pacity, the determination of best interests, and the use of the least restrictive option and restraint.' (p147). **Methodology:** Survey. **Research design clearly specified and appropriate?** Yes. **Objectives of the study clearly stated?** Yes. The study aimed to explore implementation issues with respect to the Mental Capacity Act**.** **Clear description of context?** Yes. Clear description with reference to supporting literature which highlights potential problems in the implementation of the Mental Capacity Act, including in relation to assessment of decision-making capacity. **References made to original work if existing tool used?** N/A. The researchers did not use an existing tool. They designed a questionnaire which was intended to examine certain aspects of the early implementation of the Mental Capacity Act. The chosen aspects are all supported by existing literature. **Reliability and validity of new tool reported?** No. Neither reliability nor validity were reported. **Survey population and sample frame clearly described?** Partly. The survey population in general is	questionnaire appears to have elicited the intended information although its validity is not formally measured. However, since this is a pilot study then, arguably, the study itself is a test of the validity of the instruments and overall study design. **Measurements reliable?** Partly. The only aspect of reliability that is relevant in this context is 'internal consistency'. Although the researchers do not specifically report on this, there are some questions (such as those about local training and policy concerning the Mental Capacity Act) which demonstrate internal consistency, for example similar answers being given about the 'presence of local Trust policy on capacity to consent', 'local trust policy on capacity to consent being used' and 'local trust policy on the implementation of the Mental Capacity Act'. **Measurements reproducible?** Partly. Although the authors describe the aspects of the Mental Capacity Act that the questionnaire was designed to address, they do not include the questionnaire, for example in an appendix to the paper. **Basic data adequately described?** Partly. It would have been beneficial to see data about the spread of respondents across Trusts.	**Has the study dealt appropriately with any ethical concerns?** Yes. Ethical approval was secured, although there are no details about which body granted approval. The researchers also used a method for the distribution and collection of questionnaires which ensured the anonymity and confidentiality of responses. **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. Assessment of decision-making capacity under the Mental Capacity Act. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Consultant clinical psychologists involved in assessing decision-making capacity. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
not described although the authors provide a clear description of the sampling frame, which is based on the Royal College of Psychiatrists' database (with some accuracy checking to add any consultants not already on the list). **Representativeness of sample is described?** No. **Subject of study represents full spectrum of population of interest?** Unclear. This is not reported although we might assume that the Royal College of Psychiatrists' list is representative. **Study large enough to achieve its objectives, sample size estimates performed?** Unclear. Sample size estimates were not performed. **All subjects accounted for?** No. There were 52 usable responses to the survey but not all subjects are accounted for – in any of the descriptive statistics. **All appropriate outcomes considered?** N/A. The questions relate to experiences and views rather than outcomes. **Measures for contacting non-responders?** A reminder was sent to those who had not responded within 6 weeks.	**Results presented clearly, objectively and in enough detail for readers to make personal judgements?** Yes. **Results internally consistent?** Yes. Although there is no reflection on this by the authors, responses appear to be consistent. **Data suitable for analysis?** Yes. But only descriptive statistics. **Clear description of data collection methods and analysis?** Yes. **Methods appropriate for the data?** Yes. Thematic analysis for the qualitative data and descriptive statistics for the categorical responses are appropriate. **Statistics correctly performed and interpreted?** Yes. Simple descriptive statistics are correctly interpreted. **Response rate calculation provided?** Yes. 29% but only 27% of responses were usable. **Methods for handling missing data described?** No. **Difference between non-respondents and respondents described?** No. **Results discussed in relation to existing knowledge on subject and**		

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Response rate: 29% – although only 27% were usable.	**study objectives?** Yes. **Limitations of the study stated?** Partly. The authors discuss the low response rate and possible implications and explanations. Other limitations identified by this critical appraisal are not highlighted. **Results can be generalised?** No. Findings should certainly not be generalised beyond England and Wales and even within those countries, they should be generalised with great caution because of the low response rate and consideration about the reasons for non-response. **Appropriate attempts made to establish 'reliability' and 'validity' of analysis?** Unclear. None are reported. **Conclusions justified?** Partly. The conclusions seem justified in the context of the findings and the supporting literature although doubt is cast on them in light of the low response rate.		

17. Walji I, Fletcher I and Weatherhead S (2014) Clinical psychologists' implementation of the Mental Capacity Act. Social Care and Neurodisability 5: 111–130

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To explore the experiences of clinical psychologists in implementing the Mental Capacity Act. This involves exploring their work with a range of client groups where	**Is the context clearly described?** Clear. The characteristics of the participants and settings in which they implement the Mental Capacity Act are very clearly defined. Interviews	**Does the study's research question match the review question?** Partly. The study examines the experiences of psychologists in imple-	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
they may have been involved in assessments of mental capacity, best interests decisions, deprivation of liberty safeguards, and general applications of the Mental Capacity Act in different contexts. Other aims reported are to '… identify elements of best practice within the sample, provide accounts of comparable experiences for other clinical psychologists, and identify factors that improve competence and confidence when implementing the MCA.' (p115). **Methodology:** Qualitative – in depth interviews with thematic analysis of transcripts. **Is a qualitative approach appropriate?** Appropriate. The study aimed to illuminate subjective experiences and a qualitative approach is appropriate. The authors also explain that because this was a new area of study, an exploratory stance needed to be taken, and the use of thematic analysis enabled a rich description of the data. **Is the study clear in what it seeks to do?** Clear. The rationale for the research and an explicit statement of the research question and aims are provided. **How defensible/rigorous is the research design/methodology?** Defensible. The qualitative design and thematic analysis is appropriate to	alone were conducted and the only additional observation work was carried out to improve the researcher's knowledge rather than to triangulate the interview findings. Interviews were conducted with psychologists working in a number of settings which demonstrates that context bias has been considered. **Was the sampling carried out in an appropriate way?** Appropriate. The sampling method, which was appropriate for answering the research question does not appear to introduce a risk of bias or influence on the respondents. The research aimed to explore the experiences of psychologists in implementing the Mental Capacity Act with different client groups and this is appropriately reflected in the sample. **Were the methods reliable?** Somewhat reliable. The methods do examine what they claim to – psychologists' subjective experiences – but the data would have been strengthened had the researchers conducted observations of practice which would have enabled triangulation with interview data. **Are the data 'rich'?** Mixed. The contexts of the data are clearly described and diversity of perspective has certainly been explored. Although there are a number of direct quotations the study would have benefitted from the	menting the Mental Capacity Act generally. It includes but is not solely focused on the conduct of capacity assessments. **Has the study dealt appropriately with any ethical concerns?** Yes. The authors report that the '… study was reviewed by the Faculty of Health & Medicine Research Ethics Committee and approved by the University Research Ethics Committee at Lancaster University.' (p116). **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. It covers (but is not solely focused on) experiences of conducting capacity assessments. **Are the views and experiences reported relevant to the guideline?** Yes. The experiences of psychologists in the implementation of the Mental Capacity Act including the	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
the research question and this rationale is clearly explained. The sampling is purposive and designed to address the research question. In this sense the sampling strategy is theoretically justified. **How well was the data collection carried out?** Appropriately. Data collection methods (interviews) are clearly described and judging by the emerging themes and supporting quotes, it appears that appropriate data was collected to answer the research question – although our confidence in this would be strengthened had the authors included a copy of the interview schedule. Data collection and record-keeping were systematic – they were audio-recorded and transcribed by the researcher.	presentation of further detail and depth to help understand psychologists' experiences. **Is the analysis reliable?** Somewhat reliable. The reliability of the data analysis is somewhat undermined by the transcripts having been themed by only 1 researcher – although the supervisor listened to and provided feedback on the recording of the first interview and reviewed the final themes, this did not provide an opportunity to discuss different interpretations of all the interview data and resolve any differences of opinion. In addition, there is no evidence that participants fed back on the transcripts/or emerging themes. **Are the findings convincing?** Convincing. The findings are clearly presented and appear to be internally coherent. Extracts from the original data are included (although more material would have been beneficial) and the data are always well referenced. **Are the conclusions adequate?** Adequate. There are clear links between data, interpretation and the conclusions and the conclusions themselves seem plausible and coherent. The study certainly enhances understanding of the research topic since it is the first to focus on the experiences of clinical psychologists. Finally, the implications of the research	conduct of capacity assessments. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	are clearly defined and there is adequate discussion of the study limitations, for example that none of the psychologists could provide the perspective of people working in acute mental health or forensic settings.		

18. Williams V, Boyle G, Jepson M et al. (2014) Best interests decisions: professional practices in health and social care. Health and Social Care in the Community 22: 78–86

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To explore professional practice in relation to best interests decision-making. The study has been included for review question 3 as it also provides information on practice relating to assessment of mental capacity. **Methodology:** Qualitative – interviews (telephone and face to face). **Is a qualitative approach appropriate?** Appropriate. The authors aimed to understand professional practice in relation to the Mental Capacity Act **Is the study clear in what it seeks to do?** Clear. The authors clearly discuss the aim of their research and contextualise this by references to existing literature. **How defensible/rigorous is the research design/methodology?** Defensible. The design of the study is appropriate to the research question;	**Is the context clearly described?** Unclear. Only minimal details are provided in relation to characteristics of participants and data collection context. Context bias is not considered by the authors. **Was the sampling carried out in an appropriate way?** Somewhat appropriate. Although the sampling strategy is on the whole appropriate, it should be noted that the sample was self-selecting (managers were asked to alert their staff to the project). In addition, only minimal detail in relation to the selection of the 4 areas from which the sample was drawn is provided. **Were the methods reliable?** Reliable. Data were collected using more than 1 method and these were appropriate to the research question. The findings of the research are discussed alongside the findings of similar studies.	**Does the study's research question match the review question?** Partly. The authors' objective was to explore professional practice in relation to best interests decision-making; however, the paper also provides information on practice relating to assessment of mental capacity. **Has the study dealt appropriately with any ethical concerns?** Yes. The study received approval from relevant ethics committees and written consent to participation was provided. **Were service users involved in the study?** No. Service users were not involved in the design of the study. **Is there a clear focus on the guideline topic?** Yes. The study focuses on professional practice related to the best interests principle of the Mental Capacity Act. **Is the study population the same**	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
however, the rationale for this approach is not presented very clearly. However, the authors also provide clear accounts of their sampling and data collection/analysis strategies and the rationale for these. **How well was the data collection carried out?** Somewhat appropriately. Data collection methods are reasonably well described and these are appropriate to the research question; however, detail is relatively sparse.	**Are the data 'rich'?** Mixed. Only limited details in relation to contexts of the data are provided, and it is difficult to understand whether the diversity of perspectives have been explored. **Is the analysis reliable?** Not clear/not reported. The authors do not report whether data were coded by more than 1 researcher or whether participants were given the opportunity to feedback on the data. **Are the findings convincing?** Somewhat convincing. The findings are coherent, address the research question, and are clearly presented; however, only a small number of extracts from the original data are presented. **Are the conclusions adequate?** Adequate. The findings are relevant to the aims of the project, the conclusions are plausible and the authors clearly consider the limitations associated with the study.	**as at least one of the groups covered by the guideline?** Yes. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes. The study was conducted in England.	

Research question 4. Best interests decision-making for those who have been assessed as lacking the mental capacity to make a specific decision:

- 4.1 – What interventions, tools, aids and approaches are effective and cost-effective in supporting best interests decision-making? No studies located.
- 4.2 – What are the views and experiences of people who may lack mental capacity, their families and carers and others interested in their welfare on the acceptability of interventions, tools and approaches to support best interests decision-making?

Effectiveness data

NB. No studies applicable to the UK context were located for question 4.1

Views and experiences data

1. Dunn MC, Clare ICH, Holland AJ (2010) Living 'a life like ours': support workers' accounts of substitute decision-making in residential care homes for adults with intellectual disabilities. Journal of Intellectual Disability Research 54: 144–160

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors aimed to gain an understanding of the process of substitute decision-making in day-to-day residential support of people with intellectual disabilities; however, it should be noted that the authors do not specifically frame their findings in the context of best interests decisions (as defined by the Mental Capacity Act). **Methodology:** Qualitative – interviews and observation of practice. **Is a qualitative approach appropriate?** Appropriate**.** The authors aimed to understand the processes by which support workers make substitute decisions – a qualitative approach is an appropriate means of doing so. **Is the study clear in what it seeks**	**Is the context clearly described?** Not clear. Only minimal details are provided in relation to the settings in which interviews were conducted and the characteristics of participants; and the authors do not specifically discuss the possibility of context bias in relation to the interview phase of the study. **Was the sampling carried out in an appropriate way?** Inappropriate. None of the participants had received training in relation to the Mental Capacity Act and the best interests principle. **Were the methods reliable?** Somewhat reliable. Data were collected using more than 1 method; however, it is not always clear that the chosen methods investigate what they claim to.	**Does the study's research question match the review question?** Partly. The authors aimed to gain an understanding of the process of substitute decision-making in the day-to-day residential support of people with intellectual disabilities. However, they do not frame their findings in the specific context of the best interests principle of the Mental Capacity Act. **Has the study dealt appropriately with any ethical concerns?** Partly. A local NHS research ethics committee approved the study; however, no details on consent procedures for practitioner interviewees are reported. **Were service users involved in the study?** No. Service users were not involved in the design of the study.	**Overall assessment of internal validity:** − **Overall assessment of external validity:** +

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
to do? Mixed. The authors provide a relatively clear description of their objectives and make adequate reference to the literature; however, they do not have a clearly defined research question and it is sometimes unclear how the findings they present relate to those objectives. **How defensible/rigorous is the research design/methodology?** Defensible. The design is appropriate to the research question, and the authors provide a clear rationale for their methodological approach as well as relatively clear accounts of their sampling, data collection and data analysis techniques. **How well was the data collection carried out?** Appropriately. The data collection methods are clearly described, are appropriate to the research question and appear to be systematic**.**	**Are the data 'rich'?** Poor. Very few details are provided in relation to the contexts of the data, there is little illustration of the detail or diversity of perspective and content, and there is no comparison of data or findings from the 3 different sites. **Is the analysis reliable?** Not clear/not reported. The authors do not report whether more than 1 researcher themed and coded transcripts or data and there is no indication that participants were invited to provide feedback on the data. **Are the findings convincing?** Convincing. The findings are supported by extracts from the original data and they are clearly presented and internally coherent. **Are the conclusions adequate? Inadequate.** The links between the data, the authors' interpretation of these and their conclusions are not always clear; and there is little consideration of the study's limitations. Although the authors draw a number of conclusions in relation to best interests decisions and make many recommendations on this basis, it is not at all clear how they have generated these recommendations when they do not clearly frame their findings in the context of best interests decisions (as defined in legislation), and their interviewees had not had	**Is there a clear focus on the guideline topic?** Yes. The study focuses on everyday substitute decision-making in the context of residential care. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Support workers of people with intellectual disabilities. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	training in relation to the requirements of the Mental Capacity Act.		

2. Emmett C, Poole M, Bond J, et al. (2014) A relative safeguard? The informal roles that families and carers play when patients with dementia are discharged from hospital into care in England and Wales. International Journal of Law, Policy and the Family 28: 302–320

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors aimed to explore the informal role of relatives of people with dementia in best interests decisions made regarding discharge from hospital and to determine whether they '… fulfil an effective safeguarding role when decisions are made to discharge older patients with dementia from hospital either back home or into long-term care.' (p304). **Methodology:** Qualitative – interviews, focus groups and observation. **Is a qualitative approach appropriate?** Somewhat appropriate. The researchers aimed to understand the role of relatives in best interests decisions made regarding place of discharge and whether they are an effective 'safeguard'/challenge to professional opinion. A mixed-methods approach may have been more appropriate for this purpose. **Is the study clear in what it seeks to do?** Clear. The authors provide a relatively clear description of their objectives and include references to relevant literature.	**Is the context clearly described?** Clear. The characteristics of the participants and settings are well defined, and observations were made in a variety of circumstances and based on interviews with a range of people, however there is only minimal consideration of context bias. **Was the sampling carried out in an appropriate way?** Appropriate. The authors provide a clear description of their sampling techniques and these appear to be appropriate to their objectives. **Were the methods reliable?** Reliable. The data were collected by more than 1 method and are appropriate to the research objectives. The findings are contextualised through reference to the wider literature. **Are the data 'rich'?** Mixed. While the contexts of the data are relatively well described there is only limited exploration of the diversity of perspective and the detail and depth of the data. Although the authors state that they aimed to explore the differences between cases these distinctions are	**Does the study's research question match the review question?** Yes. The authors aimed to explore the informal role of relatives of people with dementia in best interests decisions made regarding discharge from hospital and to determine whether they '… fulfil an effective safeguarding role when decisions are made to discharge older patients with dementia from hospital either back home or into long-term care.' (p304). **Has the study dealt appropriately with any ethical concerns?** Yes. Approval for the study was provided by a regional ethics committee and written consent was sought from participants (for those participants determined to be unable to provide written consent, the authors report that '… personal and nominated consultee agreement was obtained …' (p305). **Were service users involved in the study?** No. Service users were not involved in the design of the study. **Is there a clear focus on the guideline topic?** Yes. The study focuses on best interests decisions regarding	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
How defensible/rigorous is the research design/methodology? Somewhat defensible. The authors provide relatively clear accounts of their rationale for sampling and data collection; however, some aspects of the data analysis process are slightly unclear. **How well was the data collection carried out?** Appropriately. The data collection methods are described relatively clearly and appear appropriate to address the research question.	not always clearly made in the narrative. **Is the analysis reliable?** Somewhat reliable. It appears that more than 1 researcher analysed the data; however, the description of the data analysis process is somewhat unclear and there is no explanation of how differences were resolved, or any indication that participants were invited to give feedback on transcripts/data. In addition, the authors report that they 'synthesised' data originating from each source into a 'case study' to illustrate '… decision-making processes relating to judgments on capacity and discharge.' (p307). Only minimal details are provided in relation to this synthesis and it is therefore difficult to have confidence in this stage of the analysis. **Are the findings convincing?** Somewhat convincing. The findings are clearly presented and coherent and are supported by a reasonable number of extracts from the original data. **Are the conclusions adequate?** Somewhat adequate. The conclusions drawn by the authors are plausible and coherent and relevant to the aims of the study; however, the links between the data, the authors' interpretation of the data, and the conclusions are sometimes slightly unclear. The authors only briefly mention the	place of discharge for people with dementia. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. People with dementia. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes. The study was conducted in England.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	limitations associated with their chosen design.		

3. Harris D and Fineberg IC (2011) Multidisciplinary palliative care teams' understanding of Mental Capacity Act 2005 'best interest' determinations. International Journal of Palliative Nursing 17: 20–25

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To explore multidisciplinary palliative care teams' implementation of the concept of best interests as stated in the *Mental Capacity Act 2005*. **Methodology:** Qualitative – semi-structured interviews. **Is a qualitative approach appropriate?** Appropriate. The study explores beliefs and attitudes about the Mental Capacity Act and its concept of best interests in the decision-making of health and social care professionals. A qualitative approach is an appropriate means of doing so and it enables an in-depth exploration of a topic about which little is known. **Is the study clear in what it seeks to do?** Clear. The study aims are clearly stated and the methodology is well described. **How defensible/rigorous is the research design/methodology?** Somewhat defensible. The development of interview guides and the duration of interviews are not described	**Is the context clearly described?** Clear. The characteristics of participants and setting were described. **Was the sampling carried out in an appropriate way?** Somewhat appropriate. Participants were recruited via each teams' nurse manager, who expressed support for the research but were not eligible for participation themselves because they do not participate in the teams' clinical decision-making. **Were the methods reliable?** Somewhat reliable. The method of developing the interview guide and the conduct of interviews are not described in sufficient detail and data collection and coding was on the whole the responsibility of a single researcher (although a second researcher coded a sub-set of data). The process by which themes were developed is not clear. **Are the data 'rich'?** Mixed. The data provide themes, descriptions and verbatim quotes.	**Does the study's research question match the review question?** Yes. The review question relates to best interests decision-making and the study focuses on multidisciplinary palliative care teams' implementation of the concept of best interests. **Has the study dealt appropriately with any ethical concerns?** Yes. Appropriate NHS Research Ethics and Primary Care Trust Research Governance approval was granted for the study. Each participant provided written consent and was informed that there was no obligation to take part. **Were service users involved in the study?** No. Only health and social care professionals were involved. **Is there a clear focus on the guideline topic?** Yes. The study has a clear focus on the topic of decision-making and mental capacity. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Health	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
in detail. The researcher who conducted the interviews was also responsible for coding (although a sub-set of the data was coded by another researcher) and there is insufficient detail regarding how themes were developed and validated. **How well was the data collection carried out?** Somewhat appropriately. The semi-structured interview guide is not described in sufficient detail, and the duration of the interview and the number of sessions are not reported. Participants do not appear to have been invited to comment on data/findings.	**Is the analysis reliable?** Somewhat reliable. One researcher did most of the analysis, though a second researcher coded a sub-set of data. The authors do not describe how the themes were validated and whether participants or another researcher were involved. **Are the findings convincing?** Convincing. **Are the conclusions adequate?** Adequate.	and social care professionals in palliative care. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. The research was conducted at an NHS community service in the northwest of England where health and social-care professionals provide palliative care services to terminally ill patients. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The study relates to best interests decision-making. **Are the views and experiences reported relevant to the guideline?** Yes. The views and experiences presented relate to understanding of the Mental Capacity Act and the concept of best interests as reported by health and social care professionals working in palliative care teams. **Does the study have a UK perspective?** Yes. Conducted at a NHS community service in the northwest of England.	

4. Manthorpe J, Samsi K, and Rapaport J (2012) When the profession becomes personal: dementia care practitioners as family caregivers. International Psychogeriatrics 24: 902–910

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To present interview data from dementia care professionals with family experiences of dementia	**Is the context clearly described?** Clear. Yes, the study was conducted in the context of the *Mental Capacity*	**Does the study's research question match the review question?** Yes. The study focuses on dementia	**Overall assessment of internal validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
and their reflections on decision-making frameworks. **Methodology:** Qualitative – interviews with dementia care practitioners regarding their role as family caregivers. **Is a qualitative approach appropriate?** Appropriate. A qualitative approach is an appropriate means of capturing the reflections of dementia care professionals with experience of caring for a family member with dementia regarding their experiences and expectations of the Mental Capacity Act decision-making frameworks. **Is the study clear in what it seeks to do?** Clear. Study aims are clearly reported and the methodology is well described. **How defensible/rigorous is the research design/methodology?** Defensible. The researchers provide adequate justification for the chosen sampling process. They attempted to recruit a representative sample by developing a sampling frame of potential organisations to recruit participants. There is also a clear description of the data collection process including details such as time, place and mode of interview. Data analysis was conducted using thematic analysis and this process is explained in detail.	*Act 2005* and aspects of findings related to this are clearly described as such. **Was the sampling carried out in an appropriate way?** Appropriate. A purposive sampling frame of potential organisations from which to recruit participants was drawn up to reflect the many roles of dementia care practitioners in primary and social care (excluding medical practitioners). Data collection took place in the southeast of England, including London, and organisations providing dementia services in community health and social care were contacted. **Were the methods reliable?** Reliable. All interviews were recorded with permission and transcribed. A coding framework was developed for thematic analysis. Identified concepts, themes, and consistencies in the text were added iteratively to the coding framework, and analysis continued until no new themes emerged from the data. The lead author was blind to the job role and other participant characteristics; this reduced the risk of stereotypes of gender or occupation influencing categorisation. **Are the data 'rich'?** Rich. The data includes narratives and descriptions provided by a range of participants. The context was clearly described, a diversity of perspective was captured	care professionals with family experiences of caring for a person with dementia and their reflections on the decision-making framework specified in the Mental Capacity Act. **Has the study dealt appropriately with any ethical concerns?** Yes. As part of the study was an audit, ethical permissions were not required from the National Health Service, but some local government bodies required research governance approval. Ethical permissions were received for contacts with patients, carers, and service users (reported elsewhere; see Manthorpe et al. 2011). **Were service users involved in the study?** No. **Is there a clear focus on the guideline topic?** Yes. The study focuses on dementia care professionals with experience of caring for a family member with dementia and their reflections on the decision-making framework specified in the Mental Capacity Act. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Dementia care practitioners. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. Organisations providing dementia services in	**Overall assessment of external validity:** +

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
How well was the data collection carried out? Appropriately. The authors describe their data collection methods in detail including information regarding mode (face to face, telephone), duration, and recording techniques as well as the content of the interviews.	and data were compared and contrasted. **Is the analysis reliable?** Reliable. A coding framework was developed for thematic analysis. Identified concepts, themes, and consistencies in the text were added iteratively to the coding framework, and analysis continued until no new themes emerged from the data. The lead author was blind to the job role and other participant characteristics; this reduced the risk of stereotypes of gender or occupation influencing categorisation. **Are the findings convincing?** Convincing. Findings were clearly presented, internally coherent and addressed the research question. Extracts from the original data were included with reference to different participants. **Are the conclusions adequate?** Adequate. The conclusions were clearly linked to the findings and are coherent.	community health and social care. **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes. The study was conducted in England.	

5. Ramasubramanian L, Ranasinghe N, Ellison J (2011) Evaluation of a structured assessment framework to enable adherence to the requirements of Mental Capacity Act 2005. British Journal of Learning Disabilities 39: 314–320

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors aimed to '… explore the quality, thoroughness and practice of how mental capacity and issues around consent, best interests	**If a sample of the population was audited, the method for sampling is that which is best suited to measuring performance against**	**Does the audit 'aim' match the review question?** Yes. The authors aimed to '… explore the quality, thoroughness and practice of how mental capacity and issues around consent,	**Overall assessment of internal validity:** − **Overall assessment of external validity:**

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
and final care plan decisions were assessed and documented in a specialist learning disabilities unit and to develop and evaluate a structured assessment framework to act as a guideline to help adhere to the requirements of the Mental Capacity Act.' (p316). **Methodology:** Audit – review of minutes from Best Interests Group meetings and patient notes. **Are the objectives of the audit clearly stated?** Yes. **The audit topic reflects a local service, speciality or national priority which merits evaluation and where care could be improved or refined through clinical audit?** Yes. Adherence to the Mental Capacity Act in a specialist inpatient unit for people with learning disabilities. **The audit measures against standards.** Yes. The audit measures adherence to the Mental Capacity Act. **The audit standards are based upon the best available evidence** Partly. The audits measures were developed by collating recommendations made in a range of legislation and policy documents. **The audit standards are referenced to their source.** Yes.	**the standards and is as scientifically reliable as possible.** Unclear. **Is the sample size sufficient to generate meaningful results?** No. The audit examined records relating to 20 people with learning disabilities. **When necessary, the sample allows for adjustment for case mix.** Unclear. **The audit uses pre-existing data sets where possible.** Yes. **The data collection tool(s) and process have been validated.** No. **The data collection process aims to ensure complete capture of data** Yes. **Data are analysed, and feedback of the results is given so that momentum of the audit is maintained in line with the agreed timetable.** Partly. **Results of the clinical audit are presented in the most appropriate manner for each potential audience to ensure that the audit results stimulate and support action planning.** Unclear. **The results are communicated effectively to all key stakeholders, including patients.** No. The results	best interests and final care plan decisions were assessed and documented in a specialist learning disabilities unit and to develop and evaluate a structured assessment framework to act as a guideline to help adhere to the requirements of the Mental Capacity Act.' (p316). **Has the audit dealt appropriately with any ethical concerns?** Partly. The research and audit department of the local trust approved the study and data protection procedures were followed. **Were service users involved in the design of the audit?** No. There is no indication that service users were involved in the design of the study. **Is there a clear focus on the guideline topic?** Yes. The study focuses on practice related to mental capacity and issues of consent. **Is the audit population the same as at least one of the groups covered by the guideline?** Yes. People with a learning disability. **Is the audit setting the same as at least one of the settings covered by the guideline?** Yes. **Does the audit relate to at least one of the activities covered by the guideline?** Yes.	++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
The audit standards are expressed in a form that enables measurement. Yes. **The patient group to whom the audit standards apply is clearly defined.** Yes. **The audit standards take full account of patient priorities and patient-defined outcomes.** No. The authors make no reference to service user identified priorities or outcomes. **The timetable for the clinical audit is described, including timescales for completion and re-audit where necessary.** Yes. **The methodology and data collection process is described in detail** Partly. The authors provide only minimal detail regarding their methodology and data collection processes. **The methods used in the audit are recorded so that re-audit can be undertaken later in the audit cycle** Partly. Some of the standards used may be open to interpretation and it is not clear how it was determined from each set of notes that practitioners had '… looked into each question in the checklist and considered all aspects of the Act before the decision was made.' (p317). It is therefore unclear whether this research into adherence could be reliably replicated.	appear to have only been communicated to the trust's audit committee and via the publication of this paper. There is no indication that the results were communicated to patients. **The topic is re-audited to complete the audit cycle if necessary.** Unclear. There is no indication that the authors intend to carry out a re-audit. **Where recommended action has not been achieved in full, the topic is re-audited at agreed intervals** Unclear. There is no indication that the authors intend to carry out a re-audit. **The results of re-audit are recorded and disseminated appropriately, including to patients or people using services.** Unclear. It is not clear whether a re-audit will take place.	**Are the audit measures relevant to the guideline?** Yes. The audit assesses adherence to the Mental Capacity Act. **Does the audit have a UK perspective?** Yes. The study was conducted in England.	

6. Redley M, Clare ICH, Luke L et al. (2009) Mental Capacity Act (England and Wales) 2005: The emergent Independent Mental Capacity Advocate (IMCA) service. British Journal of Social Work 40: 1812–1828

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The aim of the evaluation was to ascertain whether an Independent Mental Capacity Advocate service could protect the interests of adults who lack capacity and are without family or friends, and are faced with a potentially life-changing decision. In addition, the authors sought to identify and understand any practical difficulties that Independent Mental Capacity Advocates might face following the introduction of the statutory service. **Methodology:** Mixed methods – quantitative data describing the number and types of referrals to the pilot Independent Mental Capacity Act service, and qualitative interview data capturing key stakeholders' experiences and perceptions of Independent Mental Capacity Advocate casework. **Qualitative component:** Qualitative interview data capturing key stakeholders experiences and perceptions of Independent Mental Capacity Advocate casework. **Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question?** Yes. Interviews were used to capture key	**Quantitative component:** Quantitative findings describing Independent Mental Capacity Advocate referrals, clients and casework. **Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed-methods question)?** Yes. In total, 436 referrals were made to the pilot service, of which 249 referrals involving 231 clients met all the criteria for eligibility and were included in the study. **Is the sample representative of the population under study?** Unclear. The authors included 249 referrals (involving 231 clients) which met all the criteria for eligibility out of a total of 436 referrals made to the pilot service. **Are measurements appropriate (clear origin, or validity known, or standard instrument)?** Yes. Quantitative data were collected by asking each participating advocacy organisation to complete a 22 item checklist describing each individual referred. The items on the checklist were discussed and piloted with representatives from each of the 7 organisations, and practitioners responsible for its completion were given face-to-	**Does the study's research question match the review question?** Yes. The study focuses on the Independent Mental Capacity Advocate service. **Has the study dealt appropriately with any ethical concerns?** Yes. The NHS Cambridge Research Ethics Committee granted ethical approval for the evaluation. **Were service users involved in the study?** Yes. For the quantitative data, a checklist was used and the items on the checklist were discussed and piloted with representatives from each of the 7 organisations participating in the study. **Is there a clear focus on the guideline topic?** Yes. The study focuses on the Independent Mental Capacity Advocate service, the objective of which is to ensure that the views of adults who lack capacity to make potentially life-changing health and social care decisions are represented to substitute decision-makers. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. Participants included people with compromised capacity, health and social	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
stakeholders experiences and perceptions of Independent Mental Capacity Advocate casework and Independent Mental Capacity Advocate services. **Is the process for analysing qualitative data relevant to address the research question?** Yes. Interview data were examined for content and emergent themes were identified and coded. **Is appropriate consideration given to how findings relate to the context, such as the setting, in which the data were collected?** Partly. Findings were discussed based on the type of referrals, age group of clients, health conditions, etc. **Is appropriate consideration given to how findings relate to researchers' influence; for example, though their interactions with participants?** Unclear.	face guidance in its use. **Is there an acceptable response rate (60% or above)?** Yes. 249 referrals from 231 clients were included for data collection and all of them were analysed. **Is the mixed-methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed-methods question?** Yes. The quantitative data describe the number and types of referrals to the pilot service, and qualitative interview data captured key stakeholders' experiences and perceptions of Independent Mental Capacity Advocate casework, which is relevant to address the research question. **Is the integration of qualitative and quantitative data (or results) relevant to address the research question?** Yes. The researchers integrated quantitative and qualitative findings together where appropriate. **Is appropriate consideration given to the limitations associated with this integration, such as the divergence of qualitative and quantitative data (or results)?** Yes. The purpose of qualitative data was to report only the successes and challenges of	care practitioners and people from advocacy organisations. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. The study was conducted at Independent Mental Capacity Advocate organisations. **Does the study relate to at least one of the activities covered by the guideline?** Yes. The study focuses on Independent Mental Capacity Advocate services for people who may lack capacity to make decisions. **Are the views and experiences reported relevant to the guideline?** Yes. The qualitative interview data captured key stakeholders' experiences and perceptions of Independent Mental Capacity Advocate casework, which is very much relevant to the guideline. **Does the study have a UK perspective?** Yes. England.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
	Independent Mental Capacity Advocate casework in general, not the subjective experience of individual interviewees and this limitation is acknowledged by the researchers.		

7. Samsi K and Manthorpe J (2013) Everyday decision-making in dementia: findings from a longitudinal interview study of people with dementia and family carers. International Psychogeriatrics 25: 949–961

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: To explore the experiences of people with dementia and their family carers in relation to everyday decision-making, how decisions are negotiated, and how experiences changed over time. **Methodology:** Qualitative – face-to-face interviews conducted every 3 to 4 months over a 1-year period. **Is a qualitative approach appropriate?** Appropriate. The authors aimed to explore the experiences of people with dementia and their family carers in relation to everyday decision-making and a qualitative approach is the most appropriate means of doing so. **Is the study clear in what it seeks to do?** Clear. The authors provide a clear description of their objectives and make appropriate references to existing literature on the subject. **How defensible/rigorous is the research design/methodology?** Defensible. The design is appropriate to	**Is the context clearly described?** Not clear. Although the authors provide some information in relation to the characteristics of participants, and the settings in which data were collected, this is not very detailed and the authors do not specifically discuss context bias. **Was the sampling carried out in an appropriate way?** Appropriate. The sampling methods were appropriate and unlikely to introduce bias; however, it should be noted that people with dementia who were unable to consent to an interview were excluded from the project. **Were the methods reliable?** Somewhat reliable. Data were not collected using more than 1 method; however, the authors do discuss their findings in the context of other studies on the subject. **Are the data 'rich'?** Poor. The authors provide only minimal details in relation to the context of the data and	**Does the study's research question match the review question?** Partly. The authors aimed to explore the experiences of people with dementia and their family carers in relation to everyday decision-making, how decisions are negotiated, and how experiences changed over time. The study does not specifically focus on the act of making a best interests decision on behalf of someone who has been determined to lack capacity, but does include findings relating to the wider concept of best interests and how carers of people with dementia incorporate this into their caring duties. **Has the study dealt appropriately with any ethical concerns?** Yes. An ethics board approved the study and consent was sought from participants. The authors excluded individuals who were unable to consent to an interview at the first stage of the study. **Were service users involved in the**	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
the aims of the study and relatively clear accounts of the sampling, data collection and data analysis techniques are provided. **How well was the data collection carried out?** Somewhat appropriately. The data collection methods are appropriate to the research objectives; however, the description of this process lacks detail.	the findings do not clearly demonstrate the diversity of perspective and content or its detail and depth. A reasonable number of verbatim quotes are provided but these do not always clearly support the point being made by the authors. **Is the analysis reliable?** Somewhat reliable. The data appear to have been analysed by more than 1 researcher; however, only minimal details are provided on the data analysis stage and it is not clear how disagreements were resolved. There is no indication that participants were asked to provide feedback on data or transcripts. **Are the findings convincing?** Convincing. The reporting is coherent and clearly presented and extracts from the original data are included. **Are the conclusions adequate?** Somewhat adequate. The conclusions are plausible and coherent; however, the links between the data, the authors' interpretations of the data and their conclusions are sometimes unclear and there is only a very brief reference to the limitations associated with the design of the study.	**study?** No. Service users were not involved in the design of the study. **Is there a clear focus on the guideline topic?** Yes. **Is the study population the same as at least one of the groups covered by the guideline?** Yes. People with dementia and their family carers. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes **Does the study relate to at least one of the activities covered by the guideline?** Yes. **Are the views and experiences reported relevant to the guideline?** Partly. The study focuses on the experiences of people with dementia and their family carers in relation to everyday decision-making. While this is not always specifically in the context of best interests decisions made on behalf of someone who has been deemed to lack capacity, the study does provide some information relevant to NCCSC review question 4 on best interests decision-making. **Does the study have a UK perspective?** Yes. The study was conducted in England.	

8. Sorinmade O, Strathdee G, Wilson C et al. (2011) Audit of fidelity of clinicians to the Mental Capacity Act in the process of capacity assessment and arriving at best interests decisions. Quality in Ageing and Older Adults 12: 174–179

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The authors aimed to '... evaluate health professionals' fidelity to the Mental Capacity Act (MCA) principles on determining mental capacity and arriving at best interests decisions in the care of individuals found to lack the relevant decision-making capacity.' (p174). **Methodology:** Audit – review of patient records provided by Community Mental Health Teams/psychiatrists and geriatricians working at a local hospital. **Are the objectives of the audit clearly stated?** Yes. **The audit topic reflects a local service, speciality or national priority which merits evaluation and where care could be improved or refined through clinical audit.** Yes. The study focuses on adherence to the principles of the Mental Capacity Act in relation to mental capacity assessments and best interests decisions. **The audit measures against standards.** Yes. The study measures adherence to the principles of the Mental Capacity Act. **The audit standards are based upon the best available evidence.** Partly. The authors examine adherence to principles outlined in the	**If a sample of the population was audited, the method for sampling is that which is best suited to measuring performance against the standards and is as scientifically reliable as possible.** No. The authors asked practitioners to provide records meeting their criteria (patients found to lack capacity to make decisions regarding place of residence, finances or treatment in the last two years). Given the point at which the audit took place (two years after implementation of the Mental Capacity Act) and lack of familiarity with its principles, it is possible that relevant records may have been missed. In addition, auditing all records from each service would have been a more comprehensive means of examining fidelity to the principles of the Mental Capacity Act. **Is the sample size sufficient to generate meaningful results?** Unclear. The authors were only provided with 68 records in total, which for a 2-year period is a relatively small sample. **When necessary, the sample allows for adjustment for case mix.** Unclear. **The audit uses pre-existing data sets where possible.** Yes. The authors extracted data from case notes.	**Does the audit 'aim' match the review question?** Yes. The authors aimed to '... evaluate health professionals' fidelity to the Mental Capacity Act (MCA) principles on determining mental capacity and arriving at best interests decisions in the care of individuals found to lack the relevant decision-making capacity.' (p174). **Has the audit dealt appropriately with any ethical concerns?** No. The narrative does not report on the consideration of ethical issues. **Were service users involved in the design of the audit?** No. Service users were not involved in the design of the study. **Is there a clear focus on the guideline topic?** Yes. The study focuses on mental capacity assessments and best interests decisions in psychiatric services. **Is the audit population the same as at least one of the groups covered by the guideline?** Yes. **Is the audit setting the same as at least one of the settings covered by the guideline?** Yes. **Does the audit relate to at least one of the activities covered by the guideline?** Yes.	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Mental Capacity Act. **The audit standards are referenced to their source.** Yes. The standards are drawn from the Mental Capacity Act. **The audit standards are expressed in a form that enables measurement.** Yes. **The patient group to whom the audit standards apply is clearly defined.** Partly. The authors do not clearly define their population of interest; however, they report that they requested records from psychiatrists working in Community Mental Health Teams providing support to working age adults, older adults and adults with learning disabilities. They asked the teams to provide records for patients who had been found to lack capacity to make a decision regarding their place of residence or their finances; and patients who had been found to lack capacity to consent to treatment. They also report that geriatricians working at the local hospital were asked to provide records; however, no further details on this are provided. **The audit standards take full account of patient priorities and patient-defined outcomes.** No. The authors make no reference to service user identified priorities or outcomes.	**The data collection tool(s) and process have been validated.** Unclear. The authors report that the audit tool was piloted to assess reliability and validity; however, no details are provided in relation to this. **The data collection process aims to ensure complete capture of data** No. The authors focused on assessments of mental capacity and best interests decisions. **Data are analysed, and feedback of the results is given so that momentum of the audit is maintained in line with the agreed timetable** Unclear. The authors do not provide details in relation to how findings were fed back to practitioners or the timescale of the audit. **Results of the clinical audit are presented in the most appropriate manner for each potential audience to ensure that the audit results stimulate and support action planning.** Partly. The findings only appear to have been published in article form. **The results are communicated effectively to all key stakeholders, including patients.** No. The authors do not describe how results were communicated; however, they report a number of recommendations and	**Are the audit measures relevant to the guideline?** Yes. The study focuses on the extent to which assessments of mental capacity and best interests decisions made in psychiatric services meet the requirements of the Mental Capacity Act. **Does the study have a UK perspective?** Yes. The study was conducted in England.	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
The timetable for the clinical audit is described, including timescales for completion and re-audit where necessary. Partly. The authors provide only limited details regarding the timescales over which the audit took place. **The methodology and data collection process is described in detail** Partly. The authors provide only limited details regarding data collection methods. **The methods used in the audit are recorded so that re-audit can be undertaken later in the audit cycle** Partly. The methods are recorded; however, only minimal details are provided.	the implementation of tools to address problems identified by their research. **The topic is re-audited to complete the audit cycle if necessary.** Partly. The authors state that the impact of the recommendations made (and tools implemented) will be reviewed after 12 months. **Where recommended action has not been achieved in full, the topic is re-audited at agreed intervals.** Unclear. **The results of re-audit are recorded and disseminated appropriately, including to patients or people using services.** Unclear.		

9. Williams V, Boyle G, Jepson M et al. (2012) Making Best Interests Decisions: People and processes. London: Mental Health Foundation

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
Study aim: The main aim of the study was to provide a picture of practice according to the main contexts and types of decisions being made (healthcare, personal welfare and property and affairs), and relating to different groups of individuals. Within this overall research goal, several questions were addressed – In which contexts are best interests decisions formulated, and for what groups of individuals?	**Quantitative component:** Quantitative – online survey. **Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed-methods question)?** Yes. Representative sample included for online survey. **Is the sample representative of the population under study?** Yes. Four areas selected had reasonably differentiated profiles, representing the	**Does the study's research question match the review question?** Yes. This study aimed to find out more about how best interests decisions are being made, how far the Code of Practice is followed, and how helpful it is in real-life situations. **Has the study dealt appropriately with any ethical concerns?** Yes. The research was approved by the Essex 2 Research Ethics Committee on 11 June 2010 (study REC refer-	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
- What is the range of current practice models for making best interests decisions, and is there any association between any of these models and particular contexts? - How is capacity being assessed, and what prompts such assessments? - How is extant decision-making by the person lacking capacity being facilitated? - What factors are taken into account by those who make best interests decisions, and how are these factors considered? - How are the personal views and beliefs of the person lacking capacity examined? - How are the views of relatives and carers, professionals and panel members weighted against the objective factors involved in weighing up outcomes of decisions? - What influence, if any, do resource allocation mechanisms have on the eventual outcome? - What challenges do professionals face when making best interests decisions? **Methodology:** Mixed methods - Multi-stage, mixed-methods project. - Stage 1 – online survey (reported in analytical report 1). The researchers aimed to recruit 400 people to participate in an online survey, and achieved 385.	spread of ethnicity, socio-economic status and living conditions across England and Wales. In each of the 4 geographical areas where the study took place, the authors aimed to talk with 20–25 participants, with an overall target of 70–100 interviews. They achieved 68 interviews, almost reaching the target, and were satisfied that sampling saturation had been reached. The 4 geographical areas in the study were very different in size and scope, but the final numbers from each site were fairly even. The aim was to obtain a spread of telephone interviews over the different decision-making contexts and the different types of impairment represented in the cases. The authors aimed to ensure that the sample of telephone interviews represented the whole range of possible decision types and impairments, and developed a sampling frame and attempted to recruit to particular gaps. **Are measurements appropriate (clear origin, or validity known, or standard instrument)?** Unclear. **Is there an acceptable response rate (60% or above)?** Yes. Stage 1 – online survey (reported in analytical report 1). The authors aimed to recruit 400 people to participate in an online survey, and achieved 385. **Is the mixed-methods research de-**	ence number: 10/H0302/23) after minor amendments. Following favourable ethical review, the study then sought, and gained Site Specific R and D approval from each of the NHS settings. As the study also took place in local authority settings, the researchers applied to gain the support of the Association of Directors in Adult Social Services (ADASS) research group. Confirmation of support from the research group was received on 10 August 2010 (ADASS code: Rg10-014). **Were service users involved in the study?** Yes. Prior to the study, 9 focus groups were conducted to inform the questions in the subsequent stages of the research, from the point of view of various 'key players' – the 3 groups, respectively for social care, health and property and affairs covered the professional perspective, but were not impairment specific. Participants for the groups were recruited because of their experience or views about the Mental Capacity Act. **Is there a clear focus on the guideline topic?** Yes. This study aimed to find out more about how best interests decisions are being made, how far the code of practice is followed, and how helpful it is in real-life situations. **Is the study population the same**	

Internal validity – approach and sample.	Internal validity – performance and analysis.	External validity.	Validity ratings.
• Stage 2 – telephone survey (reported in analytical report 2). The target was 70–100 – 68 people took part. • Stage 3 – face-to-face interviews (reported in analytical report 3) We sought to recruit 20–25 'cases' to follow-up in more detail using face-to-face interviews, and achieved 25 cases. **Qualitative component:** Qualitative – telephone and face-to-face interviews. **Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question?** Yes. Telephone interviews with open-ended questions and face-to-face interviews with topic guide and in-depth exploration. **Is the process for analysing qualitative data relevant to address the research question?** Yes. Most interviews were audio-recorded and transcribed, while the remainder were recorded in written format. A systematic qualitative thematic analysis was carried out using a qualitative software package (NVivo). **Is appropriate consideration given to how findings relate to the context, such as the setting, in which the data were collected?** Yes. Data	**sign relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed-methods question?** Yes. In this research the survey findings were triangulated with telephone interview and face-to-face interview findings. **Is the integration of qualitative and quantitative data (or results) relevant to address the research question?** Yes. The authors aimed to collect both quantitative and qualitative data from the telephone interviews, in order to extract key themes relating to good practice and to conflicts and issues with best interests processes. One of the central goals in analysing this data was to start to identify processes and patterns in using the Mental Capacity Act, so that these could be explored further in the face-to-face interviews conducted at Stage 3. **Is appropriate consideration given to the limitations associated with this integration, such as the divergence of qualitative and quantitative data (or results)?** Unclear.	**as at least one of the groups covered by the guideline?** Yes. Study involves a wide range of professionals working with people who lack mental capacity. **Is the study setting the same as at least one of the settings covered by the guideline?** Yes. **Does the study relate to at least one of the activities covered by the guideline?** Yes. Study focuses on best interests decision-making. **Are the views and experiences reported relevant to the guideline?** Yes. **Does the study have a UK perspective?** Yes. Study conducted in the United Kingdom.	

Internal validity – approach and sample.	**Internal validity – performance and analysis.**	**External validity.**	**Validity ratings.**
were described considering the setting, participant's role and how the decision was made. **Is appropriate consideration given to how findings relate to researchers' influence; for example, through their interactions with participants?** Unclear.			

Findings tables

Research question 1. Planning in advance, including for people who experience fluctuating capacity (review 1):

- 1.1 – What interventions, tools, aids and approaches are effective and cost-effective in supporting advance planning for decision-making for people who may lack mental capacity in the future?
- 1.2 – What are the views and experiences of people who may lack mental capacity, their families and carers, practitioners and others interested in their welfare, on the acceptability of interventions, tools, aids and approaches to support planning in advance for decision-making?

1. Bravo G, Trottier L, Arcand M et al. (2016) Promoting advance care planning among community-based older adults: A randomized controlled trial. Patient Education and Counseling 99: 1785–1795

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To test '… whether a multimodal advance planning intervention (1) motivates community-based older adults to document their wishes regarding future healthcare and (2) guides proxies in making hypothetical health related decisions that match those of their relatives.' (p1786). **Methodology:** Quantitative – randomised controlled trial. **Country:** Canada. **Source of funding:** Canadian Institute of Health Research.	**Participants:** Service users and their families, partners and carers – a non-clinical community-based sample of older adults and their proxies. **Sample size:** total N = 235; intervention n = 118; control n = 117. **Intervention category:** Advance care planning – training and support for service users. • Description – An intervention to help older adults clarify and communicate their preferences in the event of incapacity so as to guide their proxy in making substitute decisions. • Delivered by – The first and third sessions were delivered by a senior social worker, while the second session was a group information session delivered by a retired teacher. • Delivered to – Older adults and their proxies.	Eighty per cent of those in the experimental group completed the booklet. There were no significant improvements in the proxy's ability to predict the older adult's wishes in the intervention group when compared to the control group. For the intervention group, agreement improved in vignettes about incurable brain cancer specifically (T0 score = 1.01, T2 score = 1.24, *p* = 0.001), and in combined health states overall (T0 score = 1.18, T2 = 1.26, *p* = 0.013). However these also improved similarly and significantly for controls. Those in the experimental group were highly satisfied with the intervention. They also reported few adverse side effects, with just one older adult experiencing some anxiety and two proxies reporting that the prospect of one day having to make difficult decisions for their loved one was upsetting.	**Overall assessment of internal validity: +** **Overall assessment of external validity: +**

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	- Duration, frequency, intensity, etc. – Three monthly sessions, totalling just over 4 hours. - Key components and objectives of intervention – To help older adults clarify and communicate their preferences for themselves and to their proxy, so their proxy can guide in the event of them losing capacity. End goal was the completion of a booklet designed for facilitating advance care planning. - Content/session titles – Session 1: Show dyad how difficult substitute decision-making can be, and start the process of clarifying and communicating preferences; session 2: To present a booklet developed to record preferences; session 3: To assist interested older adults in filling out the booklet. - Location/place of delivery – Participants own home and research centres. **Comparison intervention:** The control group received 3 monthly sessions of a health intervention program aimed to promote a healthy lifestyle. **Outcomes measured:** Service user related outcomes – hypothetical vignettes were used to elicit older adults' preferences and assess their proxy's ability to predict them. This concordance was the key outcome. Also numbers of completed advance care plans were measured.		

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Follow-up: Six months post-intervention. **Costs?** No. Cost information not reported.		

2. Elbogen E, Swanson J, Appelbaum P et al. (2007) Competence to complete psychiatric advance directives: effects of facilitated decision making. Law and Human Behavior 31: 275–289

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The researchers aimed to examine the '… clinical and neuropsychological correlates of performance on a measure to assess competence to complete PADs and investigates the effects of a facilitated PAD intervention on decisional capacity.' (p1). **Methodology:** Quantitative – randomised controlled trial. **Country:** United States. **Source of funding:** Government funded grant by the National Institute of Mental Health. Also funded by the MacArthur Foundation Research Network on Mandated Community Treatment.	**Participants:** Service users and their families, partners and carers – service users with mental illness that wanted to complete a Psychiatric Advance Directive. **Sample size:** total N = 419; intervention n = 213; control n = 206. **Intervention category:** Advance care planning – training and support for service users. • Description – Participants in the intervention group were offered to meet with a trained facilitator to create a psychiatric advance directive. The session was structured but flexible, giving directions and assistance. • Delivered by – Six trained research assistants, one with a master's degree and the others with bachelor's degrees. • Delivered to – Adults with mental health issues.	Before randomisation higher Decisional Competence Assessment Tool for Psychiatric Advance Directives scores were associated with IQ and also verbal memory, abstract thinking and psychiatric symptoms. In the area of 'competence to write a psychiatric advance directive' those in the intervention group showed no significant improvement in understanding domain, but showed significant improvement in the reasoning domain compared to controls (F(1, 368) = 8.65, $p < .01$). There was an increase in z-scores of 0.25 for those in the intervention group. The researchers considered that these effects may be influenced by participant's cognitive abilities. In a multivariate analysis participants in the intervention group with IQ below 100 that received the intervention had higher scored than those in the control group ($F_{1,\ 171} = 7.36$, $p < .01$). Their score increased by z-scores of 0.41. Participants with an IQ higher than 100 did not show a significant improvement in reasoning on these scores. Similarly to the competence to write, in the area of 'competence to make treatment decisions' those in the intervention group showed no significant improvement in understanding domain but showed significant improvement in	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	• Duration, frequency, intensity, etc. – A single structured session (Facilitated psychiatric advance directive intervention), made available for the participant. The Facilitated psychiatric advance directive intervention was structured but flexible to meet the individual's needs and requests. • Key components and objectives of intervention – Structured but flexible session to provide orientation to psychiatric advance directives, as well as direct assistance that may be necessary for patients with mental illness to complete a legal psychiatric advance directive. • Location/place of delivery – Not clearly stated – the authors' report that participants were living in the community; however, it is not clear whether they were called, visited at home, or met in a clinical setting. **Comparison intervention:** Participants in the control group received written materials – the standard support usually offered. The materials described psychiatric advance directives and included copies of the standard forms in North Carolina, as well as a referral to a free helpline. **Outcomes measured:** Service user related outcomes – competence to complete psychiatric advance directives was measured using the Decisional Competence Assessment Tool for Psychiatric	the reasoning domain compared to controls ($F_{1, 355} = .30$, $p < .05$). Again those with IQ below 100 had a far higher improvement in reasoning (increased z-score of .16), higher compared to controls ($F_{1, 164} = 3.75$, $p < .05$). When looking only at those with an IQ of over 100 the difference between intervention group and control was again now non-significant. In a narrative summary of their findings the authors report that at '… one-month follow-up, participants in the intervention group showed more improvement on the Decisional Competence Assessment Tool for Psychiatric Advance Directives than controls, particularly among participants with pre-morbid IQ estimates below the median of 100. The results suggest that PAD facilitation is an effective method to boost competence of cognitively impaired clients to write PADs and make treatment decisions within PADs, thereby maximising the chances their advance directives will be valid.' (p1).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Advance Directives. This is a briefer version of another tool. It assesses 2 competencies– 'competence to write a psychiatric advance directive' and 'competence to make treatment decisions.' Each area has an 'understanding' domain (e.g. understand the pros and cons of hospital treatment) and a 'reasoning' domain (e.g. reason about how hospital treatment would affect their lives). **Follow-up:** One month follow-up. **Costs?** No.		

3. Pearlman R, Starks H, Cain K et al. (2005) Improvements in advance care planning in the Veterans Affairs System: results of a multifaceted intervention. Archives of Internal Medicine 165: 667–674

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To evaluate the effectiveness of an advance care planning intervention utilising counselling alongside the 'Your life, your choices' workbook. **Methodology:** Quantitative – randomised controlled trial. **Country:** United States. **Source of funding:** Voluntary/Charity – Department of Veterans Affairs	**Participants:** Service users and their families, partners and carers – users of Veteran's Affairs centres primary healthcare services aged 55 of over. **Sample size:** total N = 248; intervention n = 119; control n = 129. **Intervention category:** Advance care planning – an educational and motivational intervention. • Description – An advance care planning workbook called 'Your Life, Your Choices' was the start point for the intervention. Participants in the intervention group received this workbook	The intervention led to better agreement between patients and care providers on the patient's preferences. Higher agreement was found for: Treatment preference agreement: intervention = 58%; control = 48%; $p < 0.01$. Values: intervention = 57%; control = 46%; $p < 0.01$. Personal beliefs: intervention = 61%; control = 47%, $p < 0.01$. However, the intervention only improved agreement between patients and their proxies in the domain of personal beliefs (intervention = 67%; control = 56%; $p < 0.01$). At follow-up participants that received the intervention	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Research aims.	**PICO (population, intervention, comparison, outcomes).**	**Findings.**	**Validity ratings.**
Merit Review grant.	to use, postcard prompts, and a 30-minute session with a social worker to review their progress with the workbook and answer their questions, and a prompt for their care providers to discuss with them. • Delivered by – Resources and prompts were arranged by the study coordinator. The sessions were delivered by social workers because of their familiarity with assisting with advance directives. • Delivered to – Users of Veteran's Affairs centres primary healthcare services aged 55 of over. • Duration, frequency, intensity, etc. – The workbook was 52-pages long. Support sessions were half an hour long. Social workers were given 4.5 hour training sessions on the workbook. • Key components and objectives of intervention – The authors report that the workbook is comprised of 3 parts; the first of which '… contains case stories written to convey basic information and motivate persons in pre-contemplation and contemplation stages of change to engage in ACP behaviours. The second part contains 4 subsections, including (1) exercises to elicit values about quality of life and other relevant issues; (2) a glossary describing health states that may cause decisional incapacity, life-sustaining treatments, and palliative care; (3) documents for recording	were more likely to have discussed advance care planning with their care providers (intervention = 64%; control = 38%; $p < 0.001$). They were also more likely to have an advance care plan filed in their medical record (intervention = 48%; control = 23%; $p < 0.001$).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	health state ratings and treatment preferences; and (4) advice about communicating with family members and healthcare providers.' (p668). - Location/place of delivery – Participants' own homes and a Veterans Affairs' clinic. **Comparison intervention:** The control group were posted the hospitals 8-page advance directives packet – included a living will and forms for durable power of attorney for healthcare. **Outcomes measured:** Service user related outcomes – participants completed a questionnaire that assessed their values, personal beliefs, and preferences for treatment. Family member proxies and care providers were also asked what they thought were the patients' preferences - to assess concordance. Patients were also assessed on quality of life and physical health using the 12 Item Short-Form Health Survey, and mental health using the CES Depression scale. Reports of discussions, and number of living wills filed in medical records, were also monitored. **Follow-up:** Four months after the first visit. **Costs?** Not reported.		

4. Seal M (2007) Patient advocacy and advance care planning in the acute hospital setting. Australian Journal of Advanced Nursing 24: 29–36

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: This study aimed to '… to explain the role of patient advocacy in the Advance Care Planning process.' (p30). **Methodology:** Mixed methods – a prospective quasi-experimental (non-randomised) controlled trial, complemented with semi-structured focus groups. **Country:** Australia. **Source of funding:** Not reported.	**Participants:** Professionals/practitioners – nurses. **Sample size:** • Intervention: Pre-test n = 82 returned forms. Post-test n = 74 returned forms. About 72% of the staff team were present during both surveys. • Control: Pre-test n = 81 returned forms. Post-test n = 69 returned forms. About 67% of the staff team were present during both surveys. • Focus groups – Eighteen nurses from 6 of the 8 wards involved in the trial attended the pre-intervention session, and 3 from 3 of the 4 pilot wards attended the post-intervention session. **Intervention category:** Advance care planning training and framework for nurses. • Description – The Respecting Patient Choices Program (RPCP) is an intervention to improve patient-advocacy. It uses '… a framework of educative, patient information, safety and quality systems and policy support for advance care planning, along with equipping mainly nurses, through a comprehensive 2-day training course, with skills and resources to facilitate the process.' (p31). • Delivered to – The wards involved in the first phase of the intervention's implementation served as the pilot	Fostered patient advocacy: For the question 'In my work environment I am encouraged to ensure patients understand and can make informed choices about their end-of-life treatment' a significant difference emerged for the intervention group at follow-up. 84% of nurses agreed compared to 49% at baseline ($\chi^2 = 0.001$ $p < 0.05$), and compared to 42-55% at follow-up in controls ($\chi^2 = 0.145$, $p < 0.05$). Quality end-of-life assurance: For the question 'In practice I am able to uphold the end-of-life wishes of patients' a significant difference emerged for the intervention group at follow-up. 73% of intervention group nurses agreed compared to 54% at baseline ($\chi^2 = 0.016$ $p < 0.05$), and compared to 54% at follow-up in controls ($\chi^2 = 0.670$, $p < 0.05$). Associated job satisfaction: For the question 'I experience job satisfaction because in practice I can deliver appropriate end-of-life care' a significant difference emerged for the intervention group at follow-up. 67% of intervention group nurses agreed compared to 47-53% at baseline ($\chi^2 = 0.026$ $p < 0.05$), and compared to 47-53% at follow-up in controls ($\chi^2 = 0.658$, $p < 0.05$). Other findings on the state of end-of-life care: Across all times and conditions 77–87% of nurses agreed that 'prolonging the dying process with inappropriate measures is nursing's most disturbing ethical issue'. Also 98–100% of nurses across times and conditions stated that 'respect for patient self-determination at end-of-life was important', and 94–96% said that delivering quality end-of-life care should give Job satisfaction (94–96%).	**Overall assessment of internal validity:** – **Overall assessment of external validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	group – and second phase wards served as the control group. - Location/place of delivery – On ward. **Comparison intervention:** Those in the comparison group were being cared for in wards in which the intervention had not yet been introduced. **Outcomes measured:** - Service user related outcomes – a 5-point Likert scale was developed to quantitatively assess nurse's feelings towards 2 service user related areas – 1) Fostered patient advocacy – how much they felt the environment encouraged patient advocacy. 2) Quality end-of-life assurance – meaning how much they felt patients were getting a 'good death' - Service outcomes – a third outcome was measured also on a 5-point Likert scale – the nurses own 'associated job satisfaction' **Follow-up:** The nurses were given a questionnaire to fill out and return anonymously at baseline and again 6 months after implementation. **Costs?** Not reported.		

Views and experiences data

5. Ashton S, Roe B, Jack B et al. (2014) End of life care: The experiences of advance care planning amongst family caregivers of people with advanced dementia – a qualitative study. Dementia 15: 958–975

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The researchers aimed to '… explore the experiences of ACP among family caregivers of people with dementia.' (p961). **Methodology:** Qualitative – semi-structured in-depth interviews. **Country:** United Kingdom. **Source of funding:** No financial support received for the research.	**Participants:** Service users and their families, partners and carers – family carers of people with advanced dementia. **Sample size:** N = 12.	Family carers reported that advance care planning – • Was "… a planned, yet occasionally informal discussion with the senior nurse …" (p964). • Could be an uncomfortable experience, and some were not sure what advance care planning was – "I wasn't sure what she meant at first and thought it was some sort of agreement to stop any treatment. But Xxxxx explained it to me that it was to find out what XXX would have preferred at the end of his life. I must say I was a bit upset at first to be talking about this. I did not want XXX to think I wanted him to die but he didn't know anyway. It did feel a bit uncomfortable." (Participant, p964). • "It was to try and decide what would be the best course of action if she became very ill and was going to die. There is no point in pretending that is what they did not mean, although I can see why some people would find this very difficult..." (Participant, p964). Most family carers reported that advance care planning was appropriate for people with advanced dementia and welcomed the opportunity to be involved in end-of-life care decisions as they felt it was their responsibility to protect their vulnerable relatives – "I think the advance plan is good for people with dementia otherwise everybody just guesses what the person wants as they often cannot speak. My XXX could not talk or communicate towards the end he just smiled sometimes and looked lost." (Participant, p965). "I would say, it removed a lot of the uncertainty... all of a sudden you'll be faced with a decision, it would be at a time perhaps when you're not emotionally prepared for it. At least if you've planned it.... it helped. I discussed what	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		was going to happen, how best end of life can be dealt with in terms of making her life as easy as possible really." (Participant, p965). Participants also reported that discussions were an opportunity rather than something negative, allowing them to confront important and inevitable decisions that had to be made as the resident deteriorated – "One thing the advance plan has done is that it has given me the opportunity to really think about my aunt and what she was like. How she would think of how things have turned out and if she wants to be kept alive for as long as possible... I suppose I can only do the best I can and hope I am doing the right things and making the best decisions, but really no one prepares you for this burden." (Participant, p965). "I wonder about doing the right thing as I did not have a lot of contact with her up until she became ill so I try and think about what she would have wanted ... I suppose you just have to do the best you can." (Participant, p965). Family carers appreciated the benefits of having open and honest discussions with the care staff about advance care planning at end-of-life and reported that when treatment is futile their relations with advanced dementia should not be distressed by active interventions – "We talked about drips and tubes and pain relief… We talked about if withholding treatment would make her suffer." (Participant, p965). "I think there was a reasonable discussion about the physical side effects, when it got to the stage where she (Mum) refused food or fluids, what would happen from a physical point of view and from a medical point of view without obviously horrendous intervention." (Participant, p965).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		An important feature of advance care planning discussions was the desire for death, if inevitable, to come sooner rather than later, and the need to make sure the personal history and personality of the person is kept alive to the end. The relationship that family caregivers and the resident had developed with the care staff in the nursing home was reported to be very important. In summary, family carers of people with advanced dementia reported that advance care planning was relevant and welcomed the opportunity to be involved in end-of-life care decisions and discuss the issues of advance care planning openly and honestly with the care staff though they found it could be an uncomfortable experience. The advance care planning discussion allowed the family carers to confront important and inevitable decisions that had to be made as their loved one's condition deteriorated. 'Dying with dignity', the need to ensure the personal history and personality of the person to be kept to the end were reported to be important in advance care planning discussion, also the issues of complex nursing and medical interventions to relieve suffering or prevent undue distress in the dying person. Family caregivers need encouragement to ask the right questions during advance care planning to discuss the appropriateness of nursing and medical interventions at the end of life.	

6. Bisson J, Hampton V, Rosser A et al. (2009) Developing a care pathway for advance decisions and powers of attorney: qualitative study. British Journal of Psychiatry 194: 55–61

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To '… develop a care pathway for advance decisions and	**Participants:**	Only the findings from the modelling phase are extracted here. The qualitative methods in the modelling phase produced findings that were grouped into 5 themes.	**Overall assessment of internal validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
powers of attorney using Huntington's disease as an exemplar.' (p55). The researchers aimed to address a number of issues specifically: '… when should advance decisions and lasting power of attorney be discussed; how should information regarding advance decisions and lasting power of attorney be delivered and by whom; how should capacity to execute an advance decision or lasting power of attorney be determined; and can a care pathway that is acceptable to service users and clinicians be developed. (p55). **Methodology:** Qualitative. The study uses qualitative methods to develop a care pathway for advance decision-making. Only the first part of the study is relevant to NCCSC review question 1. **Country:** United Kingdom. **Source of funding:** Not reported.	• Service users and their families, partners and carers – The study interviewed 2 people with symptoms of Huntington's disease, 1 person who carried the Huntington's gene and 1 carer. • Professionals/practitioners – Five practitioners working with people with Huntington's disease, and 2 advisors working with the Huntington's disease association (a legal professional and a medical ethicist). **Sample size:** Total N = 13 (3 services users, 1 carer and 9 practitioners).	Information and method of delivery – Service users expressed confusion about the nature of advance decision-making and powers of attorney, people said that they wanted clear information in either verbal or written format. Interviewees considered information on Huntington's disease to be important. Particularly about treatment and locations of specialist facilities to help with planning. Informants said that a leaflet and a verbal explanation would be useful. "The Huntington's Disease Association leaflet was actually the best one of all. It gave a lot of information but it's not too in-depth either." (Participant, p60). Location and individuals involved – some interviewees preferred to discuss their conditions at home and others in a clinical setting. A good relationship with the practitioner and good communication were important. "I think it would be comfortable if it was made less like a hospital appointment. It's not a hospital appointment. It is something very important to us." (Participant, p60). "It helped that we know him. I wouldn't have wanted someone I didn't know. It made it easier. We have a rapport with him." (Participant, p60). Timing and duration of the process – professionals were reluctant to introduce the idea of discussing advance planning, because of a concern regarding the potential to cause distress. Service users were much more positive about talking about advance planning early. Because of increased autonomy. The duration of the process, it was felt, should be flexible. Allowing several sessions to decide and also a 2-week 'cooling off' period.	**Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		"In order for the individual to have the most control, the discussion should take place earlier. The earlier the better really." (Participant, p60). "I think if I had symptoms, then I'd be panicking to rush this thing through." (Participant, p60). Form of Documentation – interviewees recommended simple and easy to follow decision forms to record advance planning. They should include personal statements and wishes. Informants reported that the topics that the form should detail were: "Lifesaving treatments, percutaneous endoscopic gastrostomy feeding, location of future care, capacity assessment, witness details and a distribution list." (Participant, p56). Other important elements were a – "… summary sheet for patient files, and checklists for education, completion and review were considered important" (Participant, p56). "I would say it should be a standardised document and additional information could be filled in by speaking to the person. I'd say that was the easiest way to do it." (Participant, p60).	

7. Manthorpe J, Samsi K, and Rapaport J (2014) Dementia nurses' experience of the Mental Capacity Act 2005: a follow-up study. Dementia 13: 131–143

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: This paper reports on the second stage of a research project in which interviews	**Participants:** Professionals/practitioners – dementia nurses. **Sample size:** N = 15.	The nurses all reported that they were involved in providing advice to carers about lasting power of attorney provisions in relation to their relatives. Nurses advised carers of the "practical and financial risks" (p137) of not doing so.	**Overall assessment of internal validity:** + **Overall assessment of**

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
were used to follow-up with participants from the first stage. The overall aim of was '… to explore participants' understanding, over time, their practice experience of the implementation of the MCA and their reflections of change in nursing practice. More specifically, this related to what challenges, if any, they faced in everyday practice and whether any expectations in relation to the MCA had been met'. (p133). **Methodology:** Qualitative. **Country:** United Kingdom. **Source of funding:** Not reported.		Nurses had recruited solicitors to speak to carer groups and at an Alzheimer's Cafe. Nurses said that advising on the Mental Capacity Act was a key part of their role – "We always talk about dementia being sort of like a long-term condition and the person would get progressively more unwell and trying to put your house in order before it gets to a stage where they lose capacity, because dementia has the ability to rob people of their capacity the longer and the more progressive it is." (p137) 30% of respondents said that encouraging end-of-life planning was part of their role. Some nurses felt that carers would be informed of end of life planning from their attendance at "carer education programmes" (p137); this belief was thought to limit their intervention on end-of-life care. Nurses said that by the time the referral came to them the condition was advanced beyond advanced planning and carers were making best interests decisions. Nurses reported that resuscitation was the most common decision discussed along with the move in residential care. Two nurses said that they had been encouraged to talk to carers about the advance planning part of the Mental Capacity Act. Nurses reported making statement of wishes in nursing notes. General practitioners were sometimes party to these wishes but not always. Documents around advance planning were not common and one nurse said that statements were usually verbal which led to uncertainty around care wishes later.	**external validity:** ++

8. Poppe M, Burleigh S, Banerjee S (2013) Qualitative evaluation of advanced care planning in early dementia (ACP-ED). PLoS ONE 8: e60412

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To explore the acceptability of discussing advance care planning with people with memory problems and mild dementia shortly after diagnosis. **Methodology:** Qualitative – interviews. **Country:** United Kingdom. **Source of funding:** Voluntary/Charity – funded by Guy's and St Thomas' Charity with support from the King's College Hospital Charity and South Lon-don and Maudsley NHS Foundation Trust Charitable Funds.	Participants: • Service users and their families, partners and carers: People with early dementia and carers of people with dementia. • Professionals/practitioners – staff members of memory clinics. **Sample size:** People with early dementia (n = 12) and their carers (n = 8), staff member of memory clinics and mental health team (n = 6).	Patients motivation for advance care planning – • Concerns regarding their memory loss and wanting to plan for a time when they could no longer look after themselves. (p2). • Wanted to discuss preferences for the future as a means of self-protection, because of a dispute with a family member, who was questioning the patient's capacity to make decisions. Having made his preferences for future care known, now felt more secure. (p2). Patients found the advance care planning discussion to be a positive and helpful experience and were satisfied overall – "I was glad to have told her what I wanted." (Participant, p3). "They covered everything I wanted to know and the questions they asked were the right questions." (Participant, p3). Advance care planning discussions gave patients time to think about the future, and they felt relieved, less worried and were reassured after discussing their preferences. They also felt it important that their family and professionals knew their preferences for the future. "I suppose really it was the wisest thing to do because there is no use leaving things like that too long before things are going to get worse … I would rather know what I am doing … so if anything happens now they all know what I want and … saves me worrying about it." Patients reported that discussing the future could be dispiriting and difficult without knowing what the future would bring Carers found advance care planning to be a positive experience as it prompted discussions about the future with the	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		patient or other family members, and it was helpful to find out the patient's wishes and to have a written record of it, so that everyone knew that this was what the patient wanted. To be able to make a decision that would reflect the patient's wishes was a relief. "The social worker doesn't know mum and doesn't know us and whereas we are actually quite a close knit family and we are very lucky because we can actually make those decisions and think yeah that isn't actually what mum would want, what she would want is x, y, z." (Participant, p3). Some carers found advance care planning difficult, not knowing what the future would bring. They felt that it was important that the advance care planning documents be reviewed regularly in case of changing preferences, and suggested that advance care planning documentation be communicated to other relevant health service providers with the patient's consent. They also felt that service providers should receive training in order to understand the process of advance care planning and associated documentation and the relevant advance care planning documentation. Both patients and carers reported that they felt that advance care planning should only be discussed if it was the person's choice and if they were ready for the discussion. Staff reported that advance care planning could be challenging for a number of reasons – • End-of-life care was the most challenging aspect of advance care planning as this topic could cause anxiety in patients, especially if this led in to discussions regarding assisted suicide. • Some carers were upset by the topic but felt it important to discuss this while the patient was able to	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		make such a decision, particularly if their family did not share the patient’s views about end-of-life care. • The uncertainty regarding the disease trajectory of dementia made it difficult for patients to plan for the future. • A perceived lack of patient understanding regarding dementia also reportedly made advance care planning discussions more difficult, especially when discussing the patient’s living situation and the anxiety and distress patients tended to experience at the thought of being admitted to a care home. Views on the Advanced Care Planning in Early Dementia tool – • Staff, patients and carers believed that all relevant issues were covered in the Advanced Care Planning in Early Dementia tool. • Staff found the structure of the tool useful to guide them in the discussion. The tool was open-ended which provided flexibility to generate further questions, but this open-endedness could also be a disadvantage if a patient was vague. • Staff who had not yet conducted any advance care planning discussions themselves were unsure how to initiate the discussion with those patients who had not raised the issue themselves, but saw the tool as a potential way of facilitating this. Timing of the discussion – • Patients, carers and staff agreed that advance care planning should be discussed sooner rather than later. • Staff found it difficult to pinpoint a specific time in the dementia pathway for discussing advance care planning, but the general consensus was that the opportunity to discuss advance care planning should be offered to patients soon after diagnosis when patients had time to think about the diagnosis, when they were	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		still in contact with the service, and where they were still able to make decisions about preferences for the future. Discussing advance care planning at the point of diagnosis might be too stressful – “It’s very difficult because when is the best time? I often think ....once you just had the diagnosis, had time to digest it a bit, consider what that might mean to them and then maybe a month after that or something, that might be a good time.......because it’s too overwhelming I think.” (Participant, p3). • Some patients and carers felt that the timing of the discussion should depend on individual circumstances and whether they were ready to discuss advance care planning. The memory services could advise on the right time of the discussion based on the results of their assessments and their experience with dementia progression. Barriers to advance care planning reported by staff – • Some patients and carers had difficulties in accepting the diagnosis of dementia and others were reportedly not yet willing to discuss advance care planning. • Some patients worried that by discussing advance care planning they would no longer be allowed to make decisions. • Staff felt that it was important to give patients and carers detailed information about advance care planning before the discussion so that patients would not feel threatened and so they could decide whether to proceed. • Family dynamics were identified as a potential barrier, for example, where there was disagreement over the patients’ readiness for advance care planning discussions – “I think the client would have been quite open to the discussion but the daughter was quite, that wasn’t somewhere that she wanted to do and she was, so we didn’t. (Participant, p3).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		• Some staff were concerned that discussing advance care planning would be time consuming and suggested that there was a lack of capacity to do so, particularly when it was likely that more than one session might be required. Facilitators of advance care planning reported by staff – • Building a good relationship with the patient and the patient's family as the patient would be more open to discuss advance care planning if they knew and trusted the person delivering it. • Good training and refreshers would improve staff's confidence about facilitating advance care planning discussion. Staff felt that it was important for practitioners who discussed advance care planning to – • Have knowledge about dementia, knowledge about available resources and knowledge of one's own limitations as key skills and competencies for discussing advance care planning. • Feel confident when discussing advance care planning and having experience in dealing with difficult conversations increased their confidence – "I think it does draw on quite a complex set of clinical skills as well in terms of having difficult conversations and knowing that actually it's OK to push these conversations and not to back off these conversations … whereas I think because I've had a bit more experience, I persisted with the conversation even though it's upsetting and difficult. "(Participant, p4). • Understand how to conduct the discussion in a sensitive way and to be able to listen and let the patient guide the discussion as much as possible. • Be open minded and not judgemental of patients' wishes.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		- Have good communication skills and the ability to manage conflict.	

9. Robinson L, Dickinson C, Bamford C et al. (2013) A qualitative study: professionals' experiences of advance care planning in dementia and palliative care, 'a good idea in theory but ...' Palliative Medicine 25: 401–408

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors report that the '… aim of this study was to examine critically the views and experiences of a wide range of professionals, clinical and non-clinical, on ACP in 2 clinical areas, dementia and palliative care, where professionals may be more likely to introduce it due to a future loss of mental capacity and the presence of a terminal illness.' (p402). **Methodology:** Qualitative – focus groups and individual interviews. **Country:** United Kingdom. **Source of funding:** Government – National Institute of Health Research.	**Participants:** Professionals/practitioners. Specialist palliative care professionals (consultants, clinical nurse specialists), family physicians/general practitioners, community nurses and allied health professionals, old-age psychiatrists, mental health nurses and, social workers, ambulance service, solicitors, voluntary sector professionals. **Sample size:** Ninety-five participants. Specialist palliative care professionals (consultants, clinical nurse specialists) n = 5; Family physicians/general practitioners n = 10; Community nurses and allied health professionals n = 17, old-age psychiatrists n = 10; Mental health nurses and allied health professionals n = 22; Social workers n = 6; Ambulance service n = 15; Solicitors n = 3; Voluntary sector n = 7.	Value and usefulness of advance care planning. Many participants described advance care planning as positive in theory but difficult to carry out – "I think the whole concept of advance care planning is a really good idea but … it's one thing having a good idea, it's another thing actually putting it into practice." (Participant, p402). Some participants felt that issues like end-of-life care were difficult to discuss with people, but that it was positive to help people resolve fears. Some people questioned the usefulness of advance care planning and the feasibility of reflecting patient choices. They also said that delivering on patient preferences would be challenging. Dementia specialists said that advance care planning duplicated person-centred care measures already in place. Concern that advance care planning would be a 'tick-box' exercise. Because advance care planning a legal requirement, or a quality indicator of a service. "One of the huge worries is that advance care planning is going to be used as a target that in nursing homes all residents … and/or people with dementia will have an advance care plan before they lose capacity … I think if we start doing that that would make the whole thing much worse." (Participant, p403).	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		Delivering patient choice and outcomes – • The difficulty for different professionals to deliver preferences. • Other appropriate care is not available, and so there are no other options: "But the reality is where else can that person be managed? They can't be. So somebody might well end up seeing their days out somewhere like that and it wouldn't be the family's first choice, it wouldn't be my first choice, but there's no other place for that person to go." (Participant, p403). • Ambulance staff found it difficult to adhere to wishes. Dealing with Do Not Resuscitate orders and balancing patient wishes with family wishes. • Patient wishes may change over time: "We ended up taking the patient to hospital even though the care plan stated no removal to hospital, the daughter overruled it and at 4 or 5 o'clock in the morning I'm not there to argue, I'll just do what I want to do for the patient and that's what exactly happened. However, later that day the doctor in the hospital who got her to sign this form rang the ambulance service to register a complaint." (Participant, p404). Defining advance care planning and legal issues – • Confusion around the legal status of an advance care planning and what was included. • Professionals were most confident around Lasting Powers of Attorney and most confused about the content of Advance Decision to Refuse Treatment orders. • Professional showed a lack of knowledge of the Mental Capacity Act. • Professionals interchanged terms like advance directives, do not resuscitate orders and living wills. "I get confused about the terminology about advance care	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		and advance directive and that and one's legally binding and one isn't and it all becomes a bit of a blur." (Participant, p404). • Professional concerned about litigation if they contravened patient wishes in an advance care planning document. • Palliative care specialist and solicitors most confident regarding legal implications. • Professionals reported Advance Decision to Refuse Treatment orders could be seen as not 'valid or applicable' and therefore not enacted. • Professionals questioned how to make advance care planning documents 'valid and applicable'. • "It was a document that had been written about 3 years ago of some-one who had motor neurone who was having a fit … staff were saying we don't want any investigations, no look we've got this; but actually when you looked at it, it was so non-specific or it wasn't legally binding." (Participant, p406). Health and social care interviewees reported confidence in discussing Lasting Powers of Attorney in relation to property and affairs. They saw signposting to legal advice as part of their role. "We'll mention it [LPA], we'll give them information leaflets and then at the end of the day it's the solicitor who actually has to do it." (Participant, p404). Lasting Powers of Attorney for health and welfare was not discussed frequently with people who may lack mental capacity. • Knowledge of the Mental Capacity Act varied between professionals. • Knowledge of the Mental Capacity Act was seen to underpin advance care planning practice.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		• Palliative care specialists, solicitors and old age physiatrists have the most knowledge of the Mental Capacity Act. • Primary concern related to assessing capacity to complete an advance care plan. • No single group considered assessment their responsibility. • Old age physiatrists had confidence in assessment; they believed that general practitioners might be better placed to do this because of personal relationships. • Professionals said they regularly made judgements about capacity, but doing so formally in relation to an advance care plan was daunting. “We’re always making some kind of assessment of capacity whenever you do something or making a decision with a patient. When you’re formally asked to do it just scares the living daylights out of all GPs. And it’s just the legal involvement.” (Participant, p404). Practicalities of implementing advance care planning – • Professional uncertainty in relation to implementing advance care planning, in relation to the following factors: ○ Who is responsible? ○ Supporting documents ○ When to instigate an advance care planning ○ The costs of an advance care planning. Roles and Responsibilities – Debate among professionals as to who should take overall responsibility for the advance care planning – “Nobody knows what to do or whose role it is to do it, how they’re going to do it and I think it’s just something that’s overlooked …” (Participant, p405). • Many participants felt they lacked the skills to implement advance care planning.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		• This was true whether they had received training or not. • Palliative care specialists, solicitors, community nurses and some doctors were more likely to see advance care planning as part of their professional responsibilities. • Others said that it was either outside of their remit or that they didn't have enough time, training or resources. "When looking at Advance Care Planning the commissioners have to make a decision about whether this is our business because within psychiatry of old age service I don't think it is our business." (Participant, p405). Some professional felt it was part of specialist dementia roles and other felt that responsibility should be shared among professionals. "I think also it depends on what is the advanced decision? Is it related to finances where there might be more as a solicitor? Or maybe, I don't know, a nurse, a dementia adviser … It's probably not only one role …" (Participant, p405). Documentation – • The variety of documents used for advance care planning caused confusion. • Professionals weren't sure they were transferable to other care settings. • Different professionals used different forms for advance care planning. • The forms were criticised because they couldn't always capture individual contexts. "These are kind of forms which are following A, B C, it's like this linear pro-cess isn't it and accounting for every	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		eventuality.” (Participant, p405). • Some professional used their notes, like nurses, which were not available to other professionals. • Others did not formally record advance care planning discussions. “People actually want to talk but they don’t necessarily want to write it down … it can be a stumbling block …” (Participant, p405). Timing of advance care planning – • Delays caused by a lack of clarity about who should complete the advance care planning. • Delays led to plans not being in place by the time a person lost capacity. “So she needed to make a decision about whether she would be PEG fed at some point and by the time that was a reality the family were left to make that decision for her. And she had said anecdotally that she wanted the least intervention possible, but then nothing was documented …” (Participant, p405). Some professionals described cues to gauge whether someone was interested in advance care planning, these were – • Talking generally about the future. • Asking if someone liked to plan ahead. • For those with dementia planning ahead was much harder to gauge, the right time for advance care planning was not clear. “It’s actually now on our assessment document but it’s actually not the right time with the vast majority of patients. There are 2 questions with a tick box saying have you made an advance request or an advance decision it never	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		comes out right if you ask those questions at that point." (Participant, p405). The timing of Advance Decision to Refuse Treatment orders was an issue, there were problems with knowing if they remained relevant as treatment changed. "Looking at advance decisions a little way down the line you have no idea what information was available to the individual when they decided not to have the particular treatment." (Participant, p406). Financial costs of Lasting Powers of Attorney – • Costs were seen as a potential barrier to people using Lasting Powers of Attorney. • Families may not want to pay, even though a person had capacity. "It costs over £400 to get a lasting power of attorney. And it costs £800 to £1000 if you do it via a solicitor. So a lot of people are put off with actually going through that process because of the cost of it." (Participant, p406).	

10. Samsi K, Manthorpe J, Rapaport P (2011) 'As people get to know it more': experiences and expectations of the Mental Capacity Act 2005 amongst local information, advice and advocacy services. Social Policy and Society 10: 41–54

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors report that they aimed to explore the views and experiences of local Age Concern staff in relation to their knowledge and understanding of the *Mental Capacity Act 2005*.	**Participants:** Professionals/ practitioners – Age Concern staff. **Sample size:** N = 9.	<u>Understanding of the Mental Capacity Act</u> – Informants had gained knowledge though the Age Concern information network. This included information about changes to Enduring and Lasting Powers of Attorney, the role of Independent Mental Capacity Advocates and changes to legal definitions of mental capacity. Few had detailed knowledge of the Act and only 1 had made a referral to an Independent Mental Capacity Advocate service.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Methodology: Qualitative. **Country:** United Kingdom. **Source of funding:** National Institute of Health Research.		"My knowledge is very limited just regarding issues of powers of attorney, appointees and donors being made for people not able to carry out their decisions, so it's the application of the Act rather than the legislation and articles related to it." (Participant, p46). The staff saw the Independent Mental Capacity Advocate service as valuable for those who did not have the support of family members. Some staff were critical of the Lasting Power of Attorney registration system. Staff felt it may discourage people due to complexity and price. "One of the disadvantages, I think, is the cost of the LPA. People before would think about (the previous) EPA because it didn't cost much and they would go along with it, now a lot of people are just saying 'no, I am just going to leave it'." (Participant, p47). Staff felt that some people who had Lasting Powers of Attorney were unclear regarding their role and that this led to problems with advocacy. The role of training Staff had experienced training in the Mental Capacity Act, which they had found useful. Some commented that it had given them confidence drawing up Lasting Powers of Attorney, and knowing when to deal with a query themselves or refer to a legal practitioner. The impact of the Mental Capacity Act on perceived organisational role – Age Concern staff said that they provided information that was valuable to older people. Workers said they sign posted people for advance planning and encouraged the drawing up of Lasting Powers of Attorney. They often sign-posted people to solicitors.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		Frequent enquiries – Enquires about Lasting Powers of Attorney were the main query from the public. Callers were signposted to more specialist agencies or told to contact a solicitor. "We now have found a special department within social services for that, but in respect of the other parts of the MCA we would just signpost to services that could help in setting systems into place for wills and LPAs." (Participant, p48). Participants said that social workers had made enquiries about decisions around moving people with dementia to more appropriate care. "We have had people in nursing homes who need to go to the EMI (dementia specific) type places, we have had queries from social workers sending the people to us saying you know, 'we need to help them moving' and we have to explain that this – not us – that is when an IMCA should be involved …" (Participant, p48). Role of Age Concern – Age Concern provided expertise and experience and information to older people. The study indicates that the service was a useful resource to help with planning and that the staff had more time to help other services. The service also offered independent advocacy and had links with other organisations for signposting. "When people come in, we spend time with them, in other organisations they are time-restricted, they only have so long for interviews or to deal with people, whereas we will spend time." (Participants, p49). Predictions/expectations of the Mental Capacity Act in relation to older people – Participants said that they hoped that the Mental Capacity Act would encourage people to plan. Staff said that demand for information and advice was	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		likely to rise. Staff said that new Lasting Powers of Attorney and Independent Mental Capacity Advocate powers were significant but it was uncertain whether older people with dementia would use the Mental Capacity Act to make future plans. Some people were thought to be unaware of the act, this was thought to be a barrier to planning. Age Concern staff felt that older people were reluctant to face the changes ahead and address legal arrangements. “I think some might, some won’t, some people assume they can carry on, it is like making a will, most people don’t take out a LPA until the end, I think it is a difficult thing to come to terms with if you are losing your capacity …” (Participant, p50). Some staff said that they hoped the Mental Capacity Act would encourage people with worries about their future to make plans. The service received lots of enquires about Lasting Powers of Attorney. “I think that things like advance directives (decisions), greater emphasis on making decisions early and making sure that they are incorporated into binding agreements, I think will become much more part of everyday life for the majority of people far more than ever in the past, and in that sense legislation should be enabling and again in that sense the MCA is making things easier for people.” (Participant, p50). The barriers to future planning that participants identified included – lack of information, poor legal literacy and limited public awareness. Services were seen as a way to spread information and encourage people to start using the Mental Capacity Act. “I think it will be used by older people and certainly as	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		older people become more aware of it, and possibly social services will be passing information on, which may mean that more people become aware and will use it." (Participant, p50).	

11. Sinclair J, Oyebode J, Owens R (2016) Consensus views on advance care planning for dementia: a delphi study. Health and Social Care in the Community 24: 165–174

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To investigate consensus views of how advance care planning should be explained and carried out with people with dementia. **Methodology:** Survey – delphi methods using 3 rounds of questionnaire surveys. **Country:** United Kingdom. **Source of funding:** Not reported.	**Participants:** • Service users and their families, partners and carers – People with dementia and their family carers. • Professionals/practitioners – Policy makers, psychiatrists. **Sample size:** Total N = 17. • Three policy-makers • Six old age psychiatrists • One people with dementia • Seven family members	Items achieving consensus across 80% (range 80–100%) Delphi panel members about what, when, with whom and how to address advance care planning with dementia. (p170). 1. What do you think that an advance care plan for a person with dementia should include? (p170) a. Financial planning b. Power of attorney (financial) c. Whatever the person wants it to include d. Power of attorney (wellbeing) e. Planning for end-of-life care f. What care is available on the NHS g. Preferences for place of death h. Preferences for place of care i. Treatment/medication preferences j. Advance directives for refusal of treatment Items reaching consensus after Round 3: a. General principles by which they have made decisions throughout their lifetime. b. Religious views and beliefs. 2. At what point should advance care planning be discussed with a person with dementia? (p170) When they wish to have the discussion. Items reaching consensus after Round 3.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		After the person has come to terms with the diagnosis. 3. How should the issue of advance care planning be explained to a person with dementia? (p170) a. The explanation has to be tailored to the individual. b. That it is not known what their future will hold but that there are certain possibilities and if these were to occur how they would want them to be dealt with. c. That we want to know what is important to them. d. That, because of diminishing capacity, decisions are better made at an early stage. e. That it makes it easier for families and health professionals to act in a way they would have wanted. f. That the process enables some element of control to be retained. g. By stressing that they might not need it but it would help if advance care planning was discussed. 4. Who should be involved in advance care planning with a person with dementia? (p170) a. Spouses. b. Anyone the person with dementia decides they want to be involved. c. Children. Items reaching consensus after Round 3 a. Primary carers b. Close friends Items *not* reaching consensus, concerning what, when, how and who should be involved in advance care planning with people with dementia. (p171) 1. What do you think that an advance care plan for a person with dementia should include? a. The cost of care. b. Specific aspects of care (e.g. how often they like to have their hair washed, how they like their tea). c. Any available medical trials.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		2. At what point should advance care planning be discussed with a person with dementia? (p171) a. As soon after diagnosis as possible. b. Not at initial diagnosis. c. When they start to become a burden. 3. How should the issue of advance care planning be explained to a person with dementia? (p171) a. The need for it, particularly in terms of Lasting Power of Attorney over finance and property, needs to be explained. b. That it will ensure their wishes and preferences will always be considered during any care planning/treatment process. c. The explanation will be no different for a person with dementia than for any other person. 4. Who should be involved in advance care planning with a person with dementia? (p171) a. Siblings. b. General practitioners. c. Clinicians from psychiatric services. d. Any medical professionals who may be involved in implementing any future care. e. Advocacy services. 5. Consensus (over 80%) items on why so few people with dementia take part in advance care planning (advance care planning). (p171) a. The time required. b. It is left too late until the person with dementia has lost the capacity to have the discussion. Items reaching consensus after Round 3: a. It isn’t being offered. b. They do not realise the urgency of it. c. The belief that it is someone else’s job. d. Not a priority for patient, carer and health professionals	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		because of dealing with crises and current problems. 6. Items *failing* to achieve consensus regarding why so few people with dementia take part in advance care planning. (p172) a. Reluctance on the part of professionals to discuss it for fear of causing anxiety/distress. b. Staff lack confidence and adequate communication skills. c. Professionals fear not being able to answer questions. d. Paternalistic view. e. Clinicians and carers may be worried that a patient will make unrealistic demands that they will not be happy to implement. f. They feel they're coping anyway. g. They would rather deal with the situation in a crisis. h. Families do not want the person to have to think about the future. i. A denial of future needs. j. Neither patients nor clinicians think to discuss it. k. Most patients do not have a community psychiatric nurse and there are not enough resources for this. l. They are not of much practical use apart from the areas covered by law (i.e. Mental Capacity Act, an area overseen by the Office of the Public Guardian). m. Late diagnosis. From closed questions, there was consensus that advance care planning is important to the future care of a person with dementia and that telling a person they have dementia is essential before a discussion on their future care needs can take place, but only 61% (carers and psychiatrists) agreed or strongly agreed that all people with dementia should have an advance care plan. This suggests a possible tension between family carers and some old age psychiatrists in this respect. Some reported the need to give choice and one wrote: "Many patients show no interest in this and are happy for the family and professionals to	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		make these decisions on their behalf." (p169). To summarise, the consensus reached in this study was that: 1. When – the best time to discuss advance care planning was when the person has come to terms with the diagnosis of dementia and feels ready to engage in the discussion. This respects the person's personal choice and autonomy and the person has the right to choose whether to pursue advance care planning or not. 2. What – advance care planning needs to prioritise discussing financial aspects, power of attorney, planning for end-of-life care. 3. Who – advance care planning needs to include spouses. 4. How – advance care planning explanation needs to be tailored to the individual concerned, how decisions are better made at an early stage, while the person still maintains control and have ideas of what is important to them. It will also make it easier for families and health professionals to act in a way the person would have wanted. There was consensus that the process should be couched in terms of 'certain possibilities', due to the uncertain future relating to the natural progression of the disease of dementia. Advance care planning may not be needed but would be helpful to discuss it. Low uptake of advance care planning by people with dementia – clinicians carrying main responsibility – 'It isn't being offered', 'the belief that it is someone else's job' and 'the time required'.	

12. Wilson E, Seymour J, Perkins P (2010) Working with the Mental Capacity Act: findings from specialist palliative and neurological care set-tings. Palliative Medicine 24, 396–402

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors aimed to explore '… staff perspectives on, and experiences of working with, the new MCA guidelines. The study took place in 3 palliative and 3 specialised neurological care centres run by a national charity and situated across England.' (p396). **Methodology:** Qualitative – interviews and focus groups. **Country:** United Kingdom. **Source of funding:** Voluntary/Charity. Sue Ryder Care.	**Participants:** Professionals/ practitioners. Staff worked with individuals with the following conditions: multiple sclerosis, Huntington's disease and acquired brain injury in the neurological centre and advanced cancer in palliative care. **Sample size:** N = 26.	Documentation – Participants used a checklist, what was kept in the person's notes, which signposted any advance care planning decisions and discussions. This was seen as simple and prompted checks for advance care planning records. Staff said that they did not agree with the terminology related to the Court Appointed Deputy, which had unfamiliar terminology and was difficult to convey to families and service users. Many interviewees said that they did not have confidence explaining the options relating to advance care planning. "I think the Court of Protection appointed deputy, I think that's something that is something that I wouldn't have the knowledge to explain." (Participant, p400) ". . . you can't really just go 'have you got a Lasting Power of Attorney?' if you don't feel comfortable that you know what that means ..." (Participant, p400) This lack of confidence stopped staff from discussing advance care planning with patients: "I mean I don't know the difference really between lasting and enduring [power of attorney]." Interviewer: "So then how do you explain that to a relative?" "Yeah, I mean I really don't, I mean I've looked at the forms . . . and there's another one that goes on the pile [of paperwork to do], look at that later..." (Participant, p400). One team interviewed had solved the issue of unfamiliar terminology by developing a leaflet explaining the key terms: "We do actually have a little information sheet for patients	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		that we could give to them to take away and talk through with their family if they want to start, . . . And it's just very brief about what it is really, I mean 'what is advance decisions' but also, and 'Lasting Power of Attorney', but it's also around advance care planning." (Participant, p401). Staff interviewed said that they had missed training or had not been training via a useful method, or felt they lacked training. Staff were unsure who was responsible for initiating the advance care planning process. They were also unsure about how to complete the documents. The staff in the neurological centre had more confidence but those in palliative care did not know whether it was a nursing or medical responsibility. "Sometimes they didn't get done because the doctors didn't do them, but latterly the doctors have said that they feel it should be with the admission from the nurses' point of view, that the nurses should do it, but I think there's still this, it's sort of a little bit grey area of whose responsibility actually is it to do that form, and they do get missed a lot." (Participant, p400). When to initiate advance care planning was also a point of uncertainty and when to complete the documentation. Staff reported that advance care planning was meant to start when a person was admitted. Some staff said that this was not felt to be appropriate, because: – Other issues need to be discussed at admission – Too much paperwork – Questions from carers and patients about the Mental Capacity Act that needed expertise to answer. Some staff said that sensitivity was needed to discuss difficult topics – "I believe that documentation's an ongoing process and you don't always gather all the information in	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		one visit. I do sometimes think you have to stop and ask, who are we doing this for, you know, and if you go into a patient and their agenda's totally away from discussing mental capacity, then maybe that's not the time to go there." (Participant, p400). Most staff said that the introduction of advance care planning documents had not changed their working practice a great deal because: – They were dealing with these types of issues previously – But the Mental Capacity Act did formalise and structure discussions about future care. "I think they were very good at doing that anyway but it gives them a firm concrete documentation rather than just oh well I heard her say this. Yeah, you've got a lot more clout." (Participant, p401).	

Research question 1. Planning in advance, including for people who experience fluctuating capacity (review 2):

- 1.1 – What interventions, tools, aids and approaches are effective and cost-effective in supporting advance planning for decision-making for people who may lack mental capacity in the future?
- 1.2 – What are the views and experiences of people who may lack mental capacity, their families and carers, practitioners and others interested in their welfare, on the acceptability of interventions, tools, aids and approaches to support planning in advance for decision-making?

Effectiveness data

1. Borschmann R, Barrett B, Hellier JM et al. (2013) Joint crisis plans for people with borderline personality disorder: feasibility and outcomes in a randomised controlled trial. British Journal of Psychiatry 202: 357–364

Research aims.	**PICO (population, intervention, comparison, outcomes).**	**Findings.**	**Validity ratings.**
Study aim: To '… examine the feasibility of recruiting and retaining adults with borderline personality disorder to a pilot RCT investigating the potential efficacy and cost-effectiveness of using a joint crisis plan …' (p357). **Methodology:** Quantitative – randomised controlled trial. **Country:** United Kingdom. **Source of funding:** Other – Medical Research Council.	**Participants:** Service users and their families, partners and carers – Eighty-eight adults with borderline personality disorder participated in the study, 46 were assigned to the treatment group and 42 to the control group. **Sample characteristics:** - Age – All participants were aged 18 or older. The mean age at randomisation of participants in the study was 35.8 years (SD 11.6). Mean age of the 'treatment' group – treatment as usual or treatment as usual + joint crisis plan was 36.1 (SD 12.37). Mean age of the control (treatment as usual/treatment as usual) group was 35.6 (SD 11.1). - Gender – From the whole sample, 17 (19.3%) were male and 71 (80.7%) were female. From the treatment as usual group 7 (16.7%) were male and 35 (83.3%) were female. From the treatment as usual + joint crisis plan group 10 (21.7%) were male and 36 (78.3%) were female.	<u>Self-harm</u> – For the treatment as usual group n at baseline was 42 and at six-month follow-up was 36. For the joint crisis plan + treatment as usual group's self-harm data, n at baseline was 46 and at 6-month follow-up was 36. At baseline 42 (100%) of treatment as usual group had self-harmed; at follow-up it 20 reported that they had done so (55.6%). At baseline 46 (100%) of joint crisis plan + treatment as usual group had self-harmed; at follow-up 25 reported that they had done so (69.4%). The OR for self-harming for joint crisis plan + treatment as usual v treatment as usual was 1.86 (95% CI 0.53 to 6.51 and *p* = 0.33). At baseline for the treatment as usual group, in terms of self-harm frequency (episodes) the mean was 56.2 with SD 102.2, and median 5.5 with IQR 47. At follow-up mean was 20.3 with SD 67.0, and median was 1 with IQR 3.5. At baseline for the joint crisis plan + treatment as usual group, in terms of self-harm frequency (episodes) the mean was 51.2 with SD 126.4, and median 6 with IQR 37. At follow-up mean was 20.6 (SD 89.7, median = 2, IQR = 7.0). The rate ratio of frequency of self-harm for joint crisis plan + treatment as usual v treatment as usual was 0.74 (95% CI 0.34 to 1.63, *p* = 0.46). Data for secondary outcomes are provided for treatment as usual v joint crisis plan + treatment as usual at baseline and	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	• Ethnicity – From the whole sample, 1 (1.1%) was Asian, 9 (10.2%) were black, 65 (73.9%) were white, 7 (8.0%) were mixed, and 6 (6.8%) were 'other'. From the treatment as usual group 1 (2.4%) was Asian, 3 (7.1) were black, 31 (73.8%) were white, 4 (9.5%) were mixed, and 3 (7.1%) were 'other'. From the treatment as usual + joint crisis plan group, 9 (0.0%) were Asian, 6 (13.0%) were black, 34 (73.9%) were white, 3 (6.5%) were mixed, and 3 (6.5%) were 'other'. • Religion/belief – Not reported. • Disability – From the whole sample, 42/88 (47.7%) were described as permanently sick or disabled. From the treatment as usual group, 22/42 (52.4%) were described as permanently sick or disabled. From the joint crisis plan + treatment as usual group, 20/46 (43.5%) were described as permanently sick or disabled. • Long-term health condition – Alcohol Use Disorders identification Test scores were as follows: of the whole sample, 39 (44.3%) scored <8, 44 (15.9%) scored 8-15, and 35 (39.8%) scored >15. Of the treatment as usual group, 20 (47.6%) scored <8, 5 (11.9%) scored 8-15, and 17 (40.5%) scored >15. Of the joint crisis plan + treatment as usual group, 19 (41.3%) scored <8, 9 (19.6%) scored 8-15, and 18 (39.1%) scored >15. Depression, measured using the Hospital	follow-up, with mean, standard deviation and n, for the following where highest score means best outcome (data to calculate effect sizes not available, definitions provided here are taken from the report). Working alliance with practitioners (Working Alliance Inventory Client self-report instrument for measuring the perceived quality of working alliance between client and practitioner, with higher scores indicating a more positive perception of alliance, range 12–84) – For treatment as usual at baseline n = 33, mean 63.36 (SD 17.92); at follow-up n = 30, 60.47 (15.92). For joint crisis plan + treatment as usual at baseline n = 38, 58.47 (SD 18.50); at follow-up n = 33, 58.85 (SD 16.75). Working Alliance Inventory Therapist (range 12–84) – for treatment as usual at baseline n = 37, 61.27 (SD 11.10); at follow-up n = 25, 62.96 (10.74). For joint crisis plan + treatment as usual at baseline n = 40, 63.68 (SD 8.72); at follow-up n = 29, 64.66 (SD 10.87). Satisfaction with services - Client Satisfaction Questionnaire (measure of participants' level of satisfaction with treatment received, with higher scores indicating a higher level of satisfaction with services) (range 4–32): for treatment as usual at baseline n = 37, 18.62 (SD 1.53); at follow-up n = 36, 19.64 (SD 1.33). For joint crisis plan + treatment as usual at baseline n = 41, 19.85 (SD 1.46); at follow-up n = 37, 19.97 (SD 2.0). Well-being measured using the Warwick–Edinburgh Mental Well-Being Scale (a measure of subjective mental well-being over the preceding 2 weeks and focuses entirely on positive aspects of mental health. Higher scores indicate a higher level of well-being, range 14–70) – for treatment as usual at baseline n = 23, 31.74 (SD 10.14); at follow-up n = 35, 35.26 (SD 10.26). For joint crisis plan + treatment as usual at baseline n = 26, 29.65 (SD 11.09); at follow-up n =	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Anxiety and Depression Scale (depression subscale) was scored as follows: of the whole sample 14 (15.9%) scored <8, 16 (18.2%) scored 8-10, and 58 (65.9%) scored >10. Of the treatment as usual group, 6 (14.3%) scored <8, 10 (23.8%) scored 8-10, and 26 (61.9%) scored >10. Of the joint crisis plan + treatment as usual group, 8 (17.4%) scored <8, 6 (13.0) scored 8-10, and 32 (69.6%) scored >10. 100% of participants met 'diagnostic criteria for Borderline Personality Disorder (according to DSM-IV-TR criteria and measured using the Structured Clinical Interview for DSM-IV (SCID-II) – Borderline Personality Disorder subsection)' (p357). - Sexual orientation – Not reported. - Socioeconomic position – From the whole sample, 10 (11.4%) were in paid work, 36 (40.9%) were not working, and 42 (47.7%) were described as permanently sick or disabled. From the treatment as usual group, 4 (9.5%) were in paid work, 16 (38.0%) were not working, and 22 (52.4%) were described as permanently sick or disabled. From the joint crisis plan + treatment as usual group, 6 (13.0%) were in paid work, 20 (43.5%) were not working, and 20 (43.5%) were described as permanently sick or disabled. **Sample size:** - Total N = 88.	36, 34.33 (SD 11.40). Depression measured using the Hospital Anxiety and Depression Scale – Depression, 0–21) – for treatment as usual at baseline n = 42, 11.76 (SD 4.30); at follow-up n = 34, 10.47 (SD 3.54). For joint crisis plan + treatment as usual at baseline n = 46, 11.78 (SD 4.98); at follow-up n = 35, 10.20 (SD 4.96). Anxiety measured using the Hospital Anxiety and Depression Scale, 0–21) – for treatment as usual at baseline n = 42, 14.48 (SD 5.55); at follow-up n = 36, 12.94 (SD 4.55). For joint crisis plan + treatment as usual at baseline n = 46, 14.46 (SD 4.07); at follow-up n = 37, 14.57 (SD 3.83). Data is also provided for treatment as usual v joint crisis plan + treatment as usual at baseline and follow-up, with mean, standard deviation and n, for the following where lowest score means best outcome: Work and Social Adjustment Scale (a self-report instrument to assess impaired functioning, with higher scores indicating a higher level of impairment, 0–40) – for treatment as usual at baseline n = 42, 26.95 (SD 7.36); at follow-up n = 36, 26.06 (SD 7.98). For joint crisis plan + treatment as usual at baseline n = 46, 27.02 (SD 6.46); at follow-up n = 36, 25.81 (SD 8.94). Treatment Experience Scale (assesses the perceived level of coercion experienced by service users during hospital admission, 0–45) – for treatment as usual at baseline n = 42, 16.52 (SD 2.75); at follow-up n = 36, 16.0 (SD 3.07). For joint crisis plan + treatment as usual at baseline n = 46, 17.04 (SD 2.97); at follow-up n = 37, 17.68 (SD 3.09). Service Engagement Scale (self-report scale, completed by the participant's treating clinician – in this trial typically a	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	• Intervention – 46 were in the joint crisis plan + treatment as usual group. Eight were 'lost to follow-up' and 1 died, leaving 37 who could be analysed for primary outcomes. • Control – 42 were in the 'treatment as usual' or control group. 6 were 'lost to follow-up' and 1 died, leaving 36 who could be analysed for primary outcomes. Intervention category: Advance care planning – Joint crisis plan. • Description – Participants were randomly allocated either to a group who would continue to receive usual treatment, or to a group who developed an individualised joint care plan, which was in place alongside usual treatment. The joint crisis plan is 'a written document containing a mental health service user’s treatment preferences for the management of future crises. It is drafted a week after the service user is sent a blank template, which has a list of some topics that could be considered for inclusion in the joint crisis plan, e.g. ‘Positive things I can do in a crisis’, ‘Specific refusals regarding treatment during a crisis’, ‘Practical help in a crisis’ and ‘Useful telephone numbers’ (p358). 'The service user develops the joint crisis plan in collaboration with their treating clinician at a meeting that is facilitated by an independent mental health	care coordinator or key worker – to measure the participant’s level of engagement with community mental health services. Higher scores reflect a greater level of difficulty engaging with services, range 0–42) – for treatment as usual at baseline n = 34, 10.41 (SD 7.14); at follow-up n = 25, 10.88 (SD 5.62). For joint crisis plan + treatment as usual at baseline n = 38, 9.82 (SD 6.04); at follow-up n = 30, 8.63 (SD 6.11). The study reported, for the secondary clinical outcomes, that treatment differences ‘… were considered in a fully adjusted model. No significant differences ($p < 0.05$) were found between the treatment as usual and joint crisis plans + treatment as usual …’ (p362). The authors nevertheless state that their successful engagement with people who have bipolar disorder in advance planning for crises does have clinical implications, as previous research has shown joint crisis plans can 'promote self-determination and empowerment among service users' and they may 'facilitate stronger relationships between service users and providers' (p 363). Resource use – Resource use and cost-effectiveness data have been reviewed by the economist and presented separately in the papers reporting the review of economic evidence. Standardised mean differences between groups at 6 months follow-up have been calculated by the review team. *Working alliance with practitioners*	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	practitioner' (p357). After the joint crisis plan was agreed with the service user, with other people chosen/invited by the service user (e.g. family and friends, advocates, key workers) able to participate in the meeting, a typed version of the plan was circulated within 24 hours to everybody specified by the participant. The aim of the study was to investigate the potential for recruiting people with BPD to trials of joint crisis plan, and collect data about how effective and cost-effective using a joint crisis plan was on participants' self-harming behaviour. The primary outcome that was measured was the proportion of participants reporting self-harm after 6 months. The following secondary clinical outcomes were measured at baseline and 6-month follow-up, using appropriate instruments: depression and anxiety; working alliance between client and practitioner; satisfaction with services; engagement with services; wellbeing; social functioning; perceived level of coercion experienced by service user during hospital admission, health-related quality of life; and resource use. - Delivered by – The joint crisis plans were drawn up at a meeting between the service user and their care co-ordinator, which took place a week after service users had been sent a blank template of a joint crisis plan which did, however, suggest some topics that could be included, e.g. 'Positive things I can do in a crisis', 'Specific	Working Alliance Inventory Client (WAI-C, instrument for measuring the perceived quality of working alliance between client and practitioner, self-reported by client, with higher scores indicating a more positive perception of alliance, range 12–84) - participants in the intervention group had lower scores than those in the control group, however this difference was not significant d = –.099, 95% CI –0.59 to 0.39. Working Alliance Inventory Therapist (WAI-T, instrument for measuring the perceived quality of working alliance between client and practitioner, self-reported by practitioner, range 12–84) - participants in the intervention group had higher scores than those in the control group, however this difference was not significant d = 0.15, 95% CI –0.37 to 0.69. *Satisfaction with services* Client Satisfaction Questionnaire (CSQ - measure of participants' level of satisfaction with treatment received, with higher scores indicating a higher level of satisfaction with services, range 4–32) - participants in the intervention group had higher scores than those	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	refusals regarding treatment during a crisis', 'Practical help in a crisis' and 'Useful telephone numbers' (p358). - Delivered to – All participants were 18 or older, had BPD, had self-harmed in the last 12 months, were under a community mental health team and living in the community, and were able to consent in writing. None were currently an in-patient, had a primary diagnosis of a psychotic illness, and all had to be able to read and write in English and give informed, written consent. Out of 133 referrals, 88 were eligible and agreed to participate. - Duration, frequency, intensity, etc. – Participants were measured at a baseline date and then again after 6 months. - Key components and objectives of intervention – The intervention involved drawing up a joint care plan that specified in writing what the person wanted to highlight as important considerations in the event of crisis. This was circulated to the people and agencies who would be involved with them at the time of crisis. The aim was to ensure that they received the appropriate intervention at the time of crisis, and to provide the person with some stability. The aim was to address the response of people with BPD to instability in emotions and relationships, which can be frequent crises and acts of self-harm, which are a strong predictor of completed suicide.	in the control group, however this difference was not significant d = 0.19, 95% CI – 0.27 to 0.65. *Wellbeing* Warwick–Edinburgh Mental Well-Being Scale (WEMWBS, measure of subjective mental well-being over the preceding 2 weeks and focuses entirely on positive aspects of mental health. Higher scores indicate a higher level of wellbeing. Range 14–70) - participants in the intervention group had lower scores than those in the control group, however this difference was not significant d = –.086, 95% CI – 0.55 to 0.38. *Depression* Hospital Anxiety and Depression Scale – Anxiety (HADS-A, lower scores indicate lower levels of depression) - participants in the intervention group had lower scores than those in the control group, however	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Comparison intervention: Treatment as usual. **Outcomes measured:** Service user related outcomes – self-harm frequency and episodes; in-patient mental health nights; in-patient physical health nights; out-patient appointments; accident and emergency attendances; general practitioner contacts; contacts with the Community Mental Healthcare Team; community healthcare contacts; community advice contacts. **Follow-up:** Follow-up took place 6 months after randomisation. **Costs?** Economic evaluation – full or partial – Please see economic evidence tables and narrative summary for details on costs and resource use.	this difference was not significant d = –.06, 95% CI –0.53 to 0.41. Anxiety Hospital Anxiety and Depression Scale – Depression (HADS-D, lower scores indicate lower levels of anxiety) - participants in the intervention group had higher scores than those in the control group, however this difference was not significant d = .39, 95% CI – 0.08 to 0.85. Social functioning Work and Social Adjustment Scale (WSAS: self-report instrument to assess impaired functioning, with higher scores indicating a higher level of impairment, 0–40) - participants in the intervention group had lower scores than those in the control group, however this difference was not significant d = –.030, 95% CI –0.49 to 0.43. Perceived coercion	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		Treatment Experience Scale (TES: assesses the perceived level of coercion experienced by service users during hospital admission, 0–45) - participants in the intervention group had higher scores than those in the control group, however this difference was not significant d = 0.55, 95% CI 0.078 to 1.01. *Engagement with services* Service Engagement Scale (SES: self-report scale, completed by the participant's treating clinician – in this trial typically a care coordinator or key worker – to measure the participant's level of engagement with community mental health services. Higher scores reflect a greater level of difficulty engaging with services) (range 0–42) - participants in the intervention group had lower scores than those in the control group, however this difference was not significant d = –.038, 95% CI –0.92 to 0.15. The study reported for these secondary clinical outcomes, that "… treatment differences were considered in a fully adjusted model. No significant differences ($p < 0.05$) were found between the treatment	

Research aims.	**PICO (population, intervention, comparison, outcomes).**	**Findings.**	**Validity ratings.**
		as usual and joint crisis plans + treatment as usual." (p362).	

2. Jones L, Harrington J, Barlow CA et al. (2011) Advance care planning in advanced cancer: can it be achieved? An exploratory randomized patient preference trial of a care planning discussion. Palliative and Supportive Care 9: 3–13

Research aims.	**PICO (population, intervention, comparison, outcomes).**	**Findings.**	**Validity ratings.**
Study aim: The authors aimed to determine '… the acceptability and feasibility of a patient preference randomized controlled trial of an intervention to facilitate planning for end-of-life care?' (p4) and the most appropriate outcomes to assess the effectiveness of this intervention. **Methodology:** Quantitative – randomised controlled trial. **Country:** United Kingdom – London. **Source of funding:** Voluntary/Charity – Dimbleby Cancer Care.	**Participants:** Service users and their families, partners and carers – patients with advanced cancer. **Sample characteristics:** • Age – Whole sample: mean 61.64 (SD 10.71); Preference cohort (advance care planning): mean 61.95 (11.03); Preference cohort (usual care): 67.71 (7.89); Randomised cohort (advance care planning): 58.57 (8.11); Randomised cohort (usual care): 60.21 (13.29). • Gender – Whole sample: 39 male (51.3%); 37 female (48.7%) Preference cohort (advance care planning): 10 male (47.6%); 11 female (52.4%) Preference cohort (usual care): 7 male (50.0%); 7 female (50.0%) Randomised cohort (advance care planning): 12 male (57.1%); 9 female (42.9%) Randomised cohort (Usual care): 10 male (50.0%); 10 female (50.0%). • Ethnicity – Whole sample: 70 white (92.1%); 2 black Caribbean (2.6%); 4	The mean differences (and standard errors) between baseline and follow-up, when patients' preferences were measured on a visual analogue scale scored from -5 (strong preference not to receive the advance care planning intervention) to +5 (strong preference to receive the advance care planning intervention) and 0 no preference either way, were as follows: Communication – • Communication overall: Randomised cohort (usual care) -2.4 (1.4); Randomised cohort (advance care planning) -1.4 (1.8); Preference cohort (usual care) 0.0 (0.8); Preference cohort advance care planning -0.5 (1.0); Combined (usual care) -1.3 (0.9); Combined (advance care planning) -0.9 (1.0). • Communication with professionals: Randomised cohort (usual care) -0.8 (0.7); Randomised cohort (advance care planning) -0.1 (0.6); Preference cohort (usual care) 0.2 (0.5); Preference cohort advance care planning -0.7 (0.8); Combined (usual care) -0.4 (0.5); Combined (advance care planning) -0.4 (0.5). • Communications with family and friends: Randomised cohort (usual care) -1.5 (0.8); Randomised cohort (advance care planning) -1.6 (1.1); Preference cohort (usual care) -0.6 (0.8); Preference cohort advance care planning 0.3 (0.6); Combined (usual care) -1.2 (0.6); Combined (advance care planning) -0.7 (0.6).	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	other (5.3%) Preference cohort (advance care planning): 20 white (95.2%); 1 black Caribbean (4.6%); 0 other (0.0%) Preference cohort (usual care): 13 white (92.8%); 0 black Caribbean (0.0%); 1 other (7.1%) Randomised cohort (advance care planning): 18 white (85.7%); 0 black Caribbean (0.0%); 3 other (14.3%) Randomised cohort (Usual care): 19 white (95.0%); 1 black Caribbean (5.0%); 0 other (0, 0%). • Religion/belief – Whole sample: 27 Christian (35.5%); 10 other (13.2%); 39 none (51.3%) Preference cohort (advance care planning): 7 Christian (33.3%); 5 other (23.8%); 9 none (42.9%) Preference cohort (usual care): 6 Christian (42.9%); 2 other (14.3%); 6 none (42.9%) Randomised cohort (advance care planning): 6 Christian (28.6%); 2 other (9.5%); 13 none (61.9%) Randomised cohort (Usual care): 8 Christian (40.0%); 1 other (5.0%); 11 none (55.0%) • Disability – Not reported. • Long-term health condition – All participants had advanced cancer. This was broken down by type of cancer as follows (figures given are as stated in Table 2 of the study, including some inconsistencies, e.g. e.g. pancreatic cancer in preference advance care planning cohort): Whole sample: lung 1 (1.3%); prostate 10 (13.0%); breast 6 (7.8%); renal 5 (6.5%); melanoma 5 (4.1%); lymphoma 3 (3.9%);	Discussion – • Discussion overall: Randomised cohort (usual care) 2.2 (3.1); Randomised cohort (advance care planning) 3.7 (2.3); Preference cohort (usual care) 0.3 (4.2); Preference cohort advance care planning 1.1 (2.9); Combined (usual care) 1.5 (2.5); Combined (advance care planning) 2.4 (1.9). Discussion with professionals: Randomised cohort (usual care) 2.2 (2.4); Randomised cohort (advance care planning) 2.3 (1.1); Preference cohort (usual care) 0.0 (2.4); Preference cohort advance care planning 1.2 (1.6); Combined (usual care) 1.4 (1.7); Combined (advance care planning) 1.7 (1.0). • Discussion with family and friends: Randomised cohort (usual care) -0.1 (1.1); Randomised cohort (advance care planning) 1.5 (1.4); Preference cohort (usual care) 0.3 (2.3); Preference cohort advance care planning 0.6 (1.5); Combined (usual care) 0.1 (1.1); Combined (advance care planning) 1.1 (1.0). Satisfaction – Satisfaction overall: Randomised cohort (usual care) 1.9 (1.1); Randomised cohort (advance care planning) 0.6 (1.5); Preference cohort (usual care) -0.2 (2.8); Preference cohort advance care planning -2.8 (1.8); Combined (usual care) 1.1 (1.2); Combined (advance care planning) -1.0 (1.2). Anxiety and depression – • Anxiety (measured using the Hospital Anxiety and Depression Scale) - Randomised cohort (usual care) -0.3 (0.7); Randomised cohort (advance care planning) 0.3 (0.5); Preference cohort (usual care) -0.1 (0.9); Preference cohort advance care planning -0.6 (0.5); Combined (usual care) -0.2 (0.6); Combined (advance care planning) -0.2 (0.3). • Depression (measured using the Hospital Anxiety and Depression Scale) – randomised cohort (usual care)	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	neuroendocrine 7 (9.1%); brain 4 (5.2%); bowel 11 (14.3%); multiple sites 3 (3.9%); other 6 (7.8%); colorectal 5 (6.5%); gynaecological 8 (10.4%); pancreatic 1 (1.3%); unknown 3 (3.9%) Preference cohort (advance care planning): lung 1 (4.8%); prostate 2 (9.5%); breast 1 (4.8%); renal 0 (0.0%); melanoma 0 (0.0%); lymphoma 2 (9.5%); neuroendocrine 2 (9.4%); brain 1 (4.8%); bowel 4 (19.1%); multiple sites 1 (4.8%); other 2 (9.5%); colorectal 2 (9.5%); gynaecological 2 (9.5%); pancreatic 0 (9.5%); unknown 1 (4.8%) Preference cohort (usual care): lung 0 (0.0%); prostate 1 (6.7%); breast 0 (0.0%); renal 2 (13.3%); melanoma 2 (13.3%); lymphoma 0 (0.0%); neuroendocrine 1 (6.7%); brain 0 (0.0%); bowel 3 (20.0%); multiple sites 2 (13.3%); other 2 (13.3%); colorectal 2 (13.3%); gynaecological 0 (0.0%); pancreatic 0 (0.0%); unknown 1 (6.7%) Randomised cohort (advance care planning): lung 0 (0.0%); prostate 3 (14.3%); breast 1 (14.8%); renal 1 (4.8%); melanoma 2 (9.5%); lymphoma 0 (0.0%); neuroendocrine 3 (14.3%); brain 2 (9.5%); bowel 2 (9.5%); multiple sites 0 (0.0%); other 2 (9.5%); colorectal 1 (4.8%); gynaecological 3 (14.3%); pancreatic 1 (4.8%); unknown 0 (0.0%) Randomised cohort (Usual care): lung 0 (0.0%); prostate 4 (20.0%); breast 4 (20.0%); renal 2 (10.0%); melanoma	1.1 (0.6); Randomised cohort (advance care planning) -0.4 (0.6); Preference cohort (usual care) 0.2 (0.9); Preference cohort advance care planning 0.6 (0.6); Combined (usual care) 0.7 (0.5); Combined (advance care planning) 0.1 (0.4). Data concerning treatment coefficients of ANCOVA models for effect of advance care planning intervention over usual care, adjusting for baseline score and cohort (in the combined models), with 95% confidence intervals and p values: <u>Communication</u> – • Communication – treatment with professionals: Randomised cohort Coef. 0.3, 95% CI −4.5 to 5.1, *p* = 0.896; Preference cohort Coef. -1.5, 95% CI −4.7 to 1.8, *p* = 0.363; Combined Coef. -0.6, 95% CI −3.5 to 2.3, *p* = 0.677. • Communication – treatment with family and friends: Randomised cohort Coef. 0.3, 95% CI −1.4 to 2.0, *p* = 0.734; Preference cohort Coef. −1.8, 95% CI −3.9 to 0.3, *p* = 0.087; Combined Coef. −0.6, 95% CI −1.9 to 0.7, *p* = 0.351. • Communication – treatment: Randomised cohort Coef. -0.3, 95% CI −3.2 to 2.6, *p* = 0.835; Preference cohort Coef. 0.1, 95% CI −1.9 to 2.2, *p* = 0.905; Combined Coef. −0.1, 95% CI −1.9 to 1.6, *p* = 0.872. • Discussion – treatment with professionals: Randomised cohort Coef. 1.3, 95% CI −6.4 to 9.0, *p* = 0.738; Preference cohort Coef. 2.2, 95% CI −4.7 to 9.1, *p* = 0.520; Combined Coef. 1.3, 95% CI −4.1 to 6.6, *p* = 0.640. <u>Discussion</u> – • Discussion – treatment with family/friends: Randomised cohort Coef. 0.0, 95% CI −5.0 to 5.1, *p* = 0.994; Preference cohort Coef. 2.9, 95% CI −1.0 to 6.8, *p* = 0.132; Combined Coef. 0.9, 95% CI −2.5 to 4.3, *p* = 0.612. • Discussion – treatment: Randomised cohort Coef. 1.2,	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	1 (5.0%); lymphoma 1 (5.0%); neuroendocrine 1 (5.0%); brain 1 (5.0%); bowel 2 (10.0%); multiple sites 0 (0.0%); other 0 (0.0%); colorectal 0 (0.0%); gynaecological 3 (15.0%); pancreatic 0 (0.0%); unknown 1 (5.0%) All patients in the trial had received a primary course of cancer treatment, but 'still had clinically detectable, active, progressive disease' (p5). • Sexual orientation – Not reported. • Socioeconomic position – Socioeconomic group (using the study's categories): Whole sample: high 37 (58.7%); middle 17 (27.0%); low 9 (14.3&) Preference cohort (advance care planning): high 13 (72.2%); middle 4 (22.2%); low 1 (5.6%) Preference cohort (usual care): high 3 (25.0%); 5 (41.7%); 4 (33.3%) Randomised cohort (advance care planning): high 11 (61.1%); middle 4 (22.2%); low 3 (16.7%) Randomised cohort (Usual care): high 10 (52.6%); middle 5 (26.3%); low 4 (21.1%). **Sample size:** • Total N = 77 (randomised cohort 42, preference cohort 35). • Intervention – randomised cohort 22, preference cohort 21. • Control – randomised cohort 20, preference cohort 14.	95% CI −2.2 to 4.5, *p* = 0.482; Preference cohort Coef. 0.0, 95% CI −4.3 to 4.2, *p* = 0.996; Combined Coef. 0.7, 95% CI −1.9 to 3.2, *p* = 0.611. <u>Satisfaction with treatment</u> – Randomised cohort Coef. −2.0, 95% CI −5.8 to 1.7, *p* = 0.273; Preference cohort Coef. −4.9, 95% CI −12.3 to 2.6, *p* = 0.190; Combined Coef. −3.1, 95% CI -6.6 to 0.5, *p* = 0.086. The intervention was at least 1 and up to 3 discussions with a trained care planning mediator. The primary outcome measured was degree to which participants had discussed advance care planning with care professionals and family and friends 8 weeks after baseline. Secondary outcomes measured included '… patient's (1) happiness with the level of communication with health professionals and family or friends, (2) satisfaction with healthcare, and (3) HADS anxiety and depression scores …' (p6). There was a total of 77 participants, which was divided into a randomised cohort (22 received advance care planning input + usual treatment, 20 usual treatment only) and a preference cohort (21 received advance care planning + usual treatment, 14 usual treatment only). Eighty-eight per cent completed to follow-up. With regard to the primary outcome, in the randomised cohort there was no difference between intervention and control groups in the level of discussion with health professionals about the future, but the intervention group was more likely to have discussed it with family and friends. In the preference cohort, there was no difference in the level of discussion with family and friends, but more discussion with health professionals. Combining the groups showed a higher level of discussion	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Intervention category: Advance care planning – advance care planning for patients with advanced cancer. • Description – The intervention involved the patient having a discussion for around 1 hour with 1 of 2 specially trained care planning mediators, who used a checklist of topics, which had been generated by the qualitative phase of the study. The topics were: 'Quality of care so far (to open up discussion); Feelings/concerns regarding the future; Communication with doctors and nurses; Communication with family and friends; Financial concerns/preparation of a last will; Death and dying/preferred place of care; Coping mechanisms; Views on resuscitation/future healthcare decisions; Reflection on advance care planning discussion/desire to complete another discussion' (p5). • Delivered by – The interviews were carried out by 2 advance care planning mediators who were both independent of the clinical teams involved with the patients. 'The first was a research nurse in oncology and palliative care who had been trained in the Department of Health's advanced communication skills course, and the second was an experienced palliative care physician. Both mediators were trained for the study using extensive role play. Neither mediator divulged the nature of their professional backgrounds to trial participants, nor did they at any time give clinical advice'	about the future overall within those who had the intervention. With regard to secondary outcomes, within the randomised cohort in terms of happiness and with communication no major trends emerged between the 2 groups at follow-up, after adjustment had been made for cohort and baseline scores. However, happiness with communication was lower in the advance care planning group than in the treatment group within the preference cohort at follow-up. They were less happy about communication with professionals, but not with family and friends. Combining the 2 cohorts showed that those assigned to the advance care planning group were less happy overall about communication. Satisfaction with healthcare was also lower for the advance care planning group in both cohorts, but with a greater effect in the preference cohort. In terms of anxiety and depression, there was little difference between the groups at follow-up.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	(p5). - Delivered to – In order to be eligible for inclusion, these cancer patients had to have had a primary course of treatment, but still have a 'clinically detectable, active, progressive disease' (p4–5). They had to be aged at least 18, have the capacity to give informed consent, not have a psychiatric diagnosis, have adequate English language skills, and have been judged medically well enough to participate by the health professional who referred them. - Duration, frequency, intensity, etc. – Each of the 40 patients receiving the intervention had an initial advance care planning session with the advance care planning mediator which lasted on average for about 1 hour, with the duration of this discussion varying between 25 minutes to 2 hours. Patients were also offered 2 follow-up sessions. Only 1 patient had both follow-up session, but 10 had 1 follow-up session. - Key components and objectives of intervention – The intervention consisted of at least 1 discussion with the advance care planning mediator. Discussions focused on patients' perceptions of their current situation, their communication with health professionals and significant others, and their hopes and fears for the future and about making future healthcare decisions' (p5). The objective was to		

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	explore the impact of these discussions on the patients, across 1 primary and 3 secondary measures. - Location/place of delivery – Baseline questionnaires were completed by patients at the clinics if this was possible, with alternative arrangements such as a home visit being used if that was not possible. Following this, the advance care planning patients were able to choose where and when they would be interviewed. **Comparison intervention:** The comparison group received usual treatment, i.e. they continued their usual hospital treatment, but without having any advance care planning interviews. **Outcomes measured:** service user related outcomes – - The primary outcome being measured was 'the degree to which participants had discussed end-of-life planning with primary and secondary care professionals, and family and friends' (p6). Also measured were 3 secondary outcomes: 'a patient’s (1) happiness with the level of communication with health professionals and family or friends, (2) satisfaction with healthcare, and (3) HADS anxiety and depression scores.' (p6). - Satisfaction with services – Satisfaction with healthcare is one of the secondary outcomes measured. Another		

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	is happiness with the level of communication with health professionals (as well as with family and friends). **Follow-up:** Follow-up interviews, where patients could be measured on the identified trial outcomes for comparison with pre-interview scores, took place 8 weeks after baseline. **Costs?** No.		

3. Thornicroft G, Farrelly F, Szmukler G et al. (2013) Clinical outcomes of Joint Crisis Plans to reduce compulsory treatment for people with psychosis: a randomised controlled trial. Lancet 381: 1634–1641

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The study reports on the CRIMSON (CRisis plan IMpact: Subjective and Objective coercion and eNgagement) trial, an '… individual level, randomised controlled trial that compared the effectiveness of Joint Crisis Plans with treatment as usual for people with severe mental illness. The joint crisis plan is a negotiated statement by a patient of treatment preferences for any future psychiatric emergency, when he or she might be unable to express clear views.' (p1634).	**Participants:** Service users and their families, partners and carers – 569 participants aged over 16 with a relapsing psychotic illness who had all had at least 1 psychiatric admission in the last 2 years. **Sample characteristics:** • Age – In the quantitative part of the study, the mean age of the whole sample was 39.8 (SD 11.9), with the mean age of the control group 39.6 (12.1) and of the treatment group 40.0 (11.8). The mean age of the care co-ordinators for this sample was 42 years. In the qualitative part of the study, the mean age of the patients was 39.2 (SD 9.6), and the mean age of the care co-ordinators was 43.8 (SD 8).	For the whole sample at follow-up: 20% of control group and 18% of treatment group had at least 1 compulsory admission. OR 0.90, 95% CI 0.59 to 1.38. *p* = 0.63. 29% control group and 29% of treatment group had at least 1 admission to hospital (compulsory or voluntary). OR 1.00, 95% CI 0.69 to 1.44. *p* = 0.63. The mean duration of compulsory admission for the control group was 20.6 (SD 73.4, median 0, range 0-600). For the treatment group the mean duration of compulsory admission was 22.3 (SD 72.0, median 0, range 0-507). OR was 2.21, 95% CI −10.01 to 14.43. For the mean (SD) *p* = 0.72. For the median (range *p* = 0.53). Mean duration of admission (compulsory or voluntary) for the control group was 26.4 (SD 76.2, median 0, 0-600). For the treatment group the mean was 29.5 (SD 75.7, median 0, range 0-507). OR was 3.04, 95% CI −9.72 to 15.81. For mean (SD *p* = 0.64. For median (range) *p* = 0.92. The mean number of admissions for the control group was	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Methodology: Mixed methods - randomised controlled trial, plus qualitative component. **Country:** United Kingdom. **Source of funding:** Other – Medical Research Council and the National Institute for Health Research.	• Gender – In the quantitative part of the study, of the whole sample 285 (50%) were male, in the control group 146 (51%) were male, and in the treatment group 139 (49%) were male. The care co-ordinators for this sample were 65% female. In the qualitative part of the study, 52% of patients, 58% of care co-ordinators and 75% of psychiatrists were female. • Ethnicity – In the quantitative part of the study, the ethnicities of the whole sample were: 353 (62%) white; 56 (10%) Asian or Asian British; 126 (22%) black or black British; 28 (5%) mixed; and 5 (1%) other. Seventy-one per cent of the care co-ordinators for this sample were white. In the control group 179 (63%) were white; 23 (18%) were Asian or Asian British; 65 (23%) were black or black British; 13 (5%) were mixed; and 3 (1%) were other. In the treatment group 174 (61%) were white; 33 (12%) were Asian or Asian British; 61 (21%) were black or black British; 15 (5%) were mixed; and 2 (1%) were other. Analysis was also carried out of a black subgroup of participants, which included those who had identified as black/black British (Caribbean), black/black British (African), black/black British (other), mixed (white and black Caribbean) or mixed (white and black African). This subgroup include 147 participants, of whom 75 were in the control group and 72 in the treatment group. In the	0.48, with SD 0.92, median 0 and range 0-6. For the treatment group the mean number of admissions was 0.51, with SD 1.01, median 0 and range 0-7. For mean (SD) *p* = 0.61. For median (range) *p* = 0.96. For perceived coercion, for the control group n = 245, mean = 2.33 (SD 1.68). For the treatment group n = 213, mean = 2.10 (SD 1.76). Mean difference = 0.23, 95% CI 0.08 to 0.55, *p* = 0.16. On service engagement scale (higher scores indicate lower engagement), where for control group n = 228, mean = 9.74 (SD 7.26). For the treatment group n = 202, mean = 10.05 (SD 7.15). Mean difference = 0.31, 95% CI −1.06 to 1.68, *p* = 0.65. Working Alliance Inventory – Client – scale, for control group n = 240, mean = 17.3 (SD 7.6) for treatment group n = 106, mean = 16.0 (SD 7.1). Mean difference = −1.29, 95% CI −2.67 to 0.09, *p* = 0.07. Working Alliance Inventory – Therapist scale, for control group n = 238, mean = 17.5 (SD 5.1). For the treatment group n = 208, mean = 17.1 (SD 5.2). Mean difference = −0.44, 95% CI −1.40 to 0.53, *p* = 0.37. For the black subgroup (control n = 72; intervention n = 66), at follow-up, 32% of the control group and 20% of the treatment group had at least one period of compulsory admission (OR 0.52, 95% CI 0.24 to 1.14, *p* = 0.10). Thirty-eight per cent of the control group and 27% of the treatment group had at least one admission, voluntary or compulsory (OR 0.63, 95% CI 0.30 to 1.29, *p* = 0.20). The mean duration in days of compulsory admission for the control group was 48.1 (SD 119.8, median 0, range 0-600). For the treatment group the mean was 31.8 (SD 95.4, median 0, range 0-507). The OR for mean (SD) was −16.32, with 95% CI −53.0 to 20.3 and *p* = 0.38. For median (range) *p* = 0.08. The mean duration in days of admission for the control	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	qualitative part of the study, 64% of patients were white, 32% were black, and 4% were Asian. • Disability – Not reported. • Long-term health condition – 100% of the patient participants in this study had been diagnosed as having a relapsing psychotic illness. Within the whole patient sample, 422 (74%) were diagnosed with schizophrenia spectrum disorder and 147 (26%) with affective disorder. Of the control group, 215 (75%) were diagnosed with schizophrenia spectrum disorder and 72 (25%) with affective disorder. Of the treatment group, 210 (74%) were diagnosed with schizophrenia spectrum disorder and 75 (26%) with affective disorder. In the whole sample, during the previous 2 years, 391 (69%) had had 1 hospital admission, 120 (21%) had had 2 admissions, and 58 (10%) had had 3 or more admissions. In the control group, 205 (72%) had had 1 hospital admission, 51 (18%) had had 2 admissions, and 28 (10%) had had 3 or more admissions. In the treatment group, 186 (75%) had had 1 hospital admission, 69 (24%) had had 2 admissions, and 30 (11%) had had 3 or more admissions. The mean duration of admissions in the previous 2 years, for the whole sample was 102 (SD 118), with median 59 and IQR 31-129. For the control group the mean was 105 with SD 126, median 55 and IQR 31-123. For the treatment group the mean was	group was 54.7 (SD 121.3, median 0, range 0-600). For the treatment group the mean was 36.3 (SD 57.8, median 0, range 0-507). OR for mean (SD) was −18.36, with 95% CI -55.66 to 18.94 and *p* = 0.33. For median (range) *p* = 0.17. The mean number of admissions for the control group was 0.64 (SD 1.15, median 0, range 0-6). The mean number of admissions for the treatment group was 0.58 (SD 1.24, median 0, range 0-7). The mean OR = 0.90 (95% CI 0.59 to 1.38, *p* = 0.64). For median (range) *p* = 0.31. There were no differences for the primary outcome between the control and intervention groups, either for the whole sample or for the black subgroup. The intervention group showed a modest improvement in therapeutic relationship, but this was the only secondary outcome measure that showed a difference. The authors report that these findings are at odds with previous studies of joint crisis plans, and considered possible explanations: the model may not have been adhered to in delivery (considered unlikely as the mean fidelity score was high); there could have been better crisis planning in the control group than at the time of earlier studies (also considered unlikely since assessment of crisis plans for participants considered them to be of poor quality); or clinician engagement at crisis planning meetings and afterwards could have been poor (considered to be supported by the findings that in 48% of cases there was not a specific meeting at which the joint crisis plan was formulated). The qualitative interviews provided some additional insights into this process. Qualitative data came from 12 focus groups and 37 individual interviews. Five focus groups were with patients only, 5 were with care co-ordinators only, and 2 were mixed. Attendance included 35 patients, 22 care co-ordinators and	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	100, with SD 112, median 66 and IQR 30-132. • Sexual orientation – Not reported. • Socioeconomic position – Educationally, the whole sample were categorised as: no formal qualification 153 (27%); school 291 (51%); vocational 52 (9%); and higher 71 (12%). The control group were categorised as: no formal qualification 67 (24%); school 158 (56%); vocational 22 (8%); and higher 37 (13%). The treatment group were categorised as: no formal qualification 86 (30%); school 133 (47); vocational 30 (11%); and higher 34 (12%). **Sample size:** • Total – total sample size for the qualitative part of the study was 569. Thirty-five of this group took part in focus groups and 15 in individual interviews. There were also 23 practitioners who took part in focus groups and 22 who took part in individual interviews. • Intervention – n = 285 were in the treatment group. • Control – n = 284. **Intervention category:** Advance care planning – joint crisis plans. • Description – The intervention involved patients aged over 16 who had a relapsing psychotic illness, and who had had at least 1 admission in the 2 previous years. They were randomly	one psychiatrist, who attended a mixed group. Individual interviews were conducted with 16 psychiatrists, 6 care coordinators and 15 patients. Quantitative data suggested there was no difference between the treatment/intervention group, who were provided with joint crisis plans in addition to usual treatment, and the control group, who received usual treatment, other than in the treatment group showing an improved therapeutic relationship between patient and clinician. The qualitative interviews confirmed the improved therapeutic relationship. Patients felt more respected by clinicians, and some clinicians 'seemed to gain a wider understanding of patients' views of care and presentation in a crisis' (p1638–9). However, a picture emerged from the interviews of joint crisis plans not being used as intended. A number of patients could not recall the joint crisis plan meeting as anything distinct from other care planning meetings they took part in. The report identified three barriers to implementing joint crisis plans, from the interviews: – Clinicians did not perceive the joint crisis plan meetings as being very different from usual care planning meetings. However, their descriptions of the joint crisis plan meetings indicated that they were clinician and not patient led. There was not enough demarcation from usual planning meetings, since 48% of joint crisis plan meetings took place in association with a Care Programme Approach meeting, the 'usual treatment' meeting. Clinicians were also doubtful about routine care planning generally, which they saw as 'a bureaucratic exercise with limited clinical benefit.' (p1639). Most clinicians '... failed to recognise that implementing the joint crisis plan required a change in the usual clinician-pa-	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	allocated into 2 groups: 1 continued to receive usual treatment; the other received usual treatment, but with the addition of a joint crisis plan. Outcomes for the 2 groups were compared, in terms of hospital admissions (how many, how long, whether compulsory). Secondary outcomes measured were perceived coercion, service engagement scale, WAIC (working alliance inventory – client) and WAIT (working alliance inventory – therapist). Outcomes related to admissions were also measured for the subgroup of black participants in the study. • Delivered by – Five senior mental health nurses, who were provided with a week's training and assessment in order to be joint crisis plan facilitators. • Delivered to – Eligibility criteria by which the 569 participants were chosen were: 'a relapsing psychotic illness; aged over 16; at least 1 psychiatric admission in the previous 2 years; and registered on Enhanced Care Programme Approach (i.e. the integrated mental healthcare system for those mental health service users with the most complex needs).' (p1635). • Duration, frequency, intensity, etc.- The 'treatment' for the intervention group was that they took part in 2 meetings organised by the joint crisis plan facilitators, who introduced the	tient relationship on their part, beginning with active discussion of treatment options and supporting patient choice both in the meeting and in implementation ...' (p1639). There seems to have been a lack of commitment to implementing the joint crisis plans in practice, as many patients complained about the agreed plans not being honoured, and '... only five of the 28 care coordinators reported referring to or using the joint crisis plan during the follow-up period ... (p1639). This was the case for patients from different ethnic groups.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	participants and their care co-ordinator to the principles of joint care planning. In attendance at these joint crisis plan meetings, other than the participants and the joint crisis plan facilitators, were the participant's care co-ordinator and psychiatrist. The presence of the joint crisis plan facilitators was seen as a crucial difference with other care planning meetings for participants, and was intended to facilitate free expression of their wishes for what treatment they should receive if the need arose. The purpose of the meetings was to draw up a plan that expressed the participants' wishes for how they wanted to be treated in the event of having a mental health crisis. The joint crisis plan facilitators contacted participants after 9 months, to check if they wanted to update the plan. Data about the participants was extracted at baseline and 18 month follow-up. - Content/session titles – There were 2 meetings at the start of the 'treatment' – preparatory and planning. At the preparatory meeting, attended by the participant and their care co-ordinator, the joint crisis plan facilitator explains the principles of joint crisis planning and introduces the joint crisis plan menu. The planning meeting is attended by these 3 plus the participant's psychiatrist. The participant could also invite a friend or relative – the aim of this and the involvement of the joint crisis plan co-ordinator is to		

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	give them as much confidence as possible to make their treatment wishes known and discuss them with the clinicians. The participant gives approval to the joint crisis plan after the meeting, and it is then disseminated to the participant, psychiatrist, care co-ordinator, and anybody else the participant nominates, as well as being placed on their electronic records. After 9 months, the joint crisis plan facilitator checks with the participant whether they want to update their plan. • Location/place of delivery – The location of these meetings is not specifically stated in the report but seems likely to have been a community mental health setting. **Comparison intervention:** Treatment as usual. **Outcomes measured:** Service user related outcomes – the primary outcome being measured was the proportion of participants forcibly detained in hospital (sectioned) under the Mental Health Act. Secondary outcomes measured were the proportion of participants admitted to psychiatric hospital, the length of stay on a psychiatric unit, self-rated perceived coercion, self- and clinician-rated therapeutic relationships, and clinician-rated patient engagement. These were measured for the whole group, and analysed for a subgroup of black participants.		

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Satisfaction with services – While there was not a measure of satisfaction with services, 2 of the secondary hypotheses being tested related to the participants' perceptions of coercion, and their rating of the therapeutic relationship with clinicians. **Follow-up:** There were 18 months between baseline and follow-up. The authors report that the '... median length of follow up was 557 days (18·5 months, range 3 months [death due to unrelated physical causes] to 36 months [difficulties locating participant]) ...' (p1637). **Costs?** No.		

Views and experiences data

4. Almack K, Cox K, Moghaddam N et al. (2012) After you: conversations between patients and healthcare professionals in planning for end of life care. BMC Palliative Care 11: 15

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The study explores with patients, carers and healthcare professionals if, when and how advance care planning conversations about patients' preferences for place of care (and death) were facilitated and documented. **Methodology:** Qualitative – exploratory case study design using retrospective audit and qualitative interviews. **Country:** United Kingdom. **Source of funding:** Voluntary/Charity – Mid Trent Cancer Network, a number of primary care trusts in Lincolnshire and the National End of Life Programme.	**Participants:** • Service users and their families, partners and carers – People with a range of conditions such as breast cancer, heart failure, kidney cancer, lung cancer, multiple sclerosis, prostate cancer, skin cancer, as well as a number of patients who had experienced a stroke. The sample also included the relatives of these patients. • Professionals/practitioners – Care co-ordinators, community matrons, district nurses, general practitioners, heart failure nurses, Macmillan managers, Macmillan nurses, practice managers, registered nurses, and specialist community nurses. **Sample characteristics:** • Age – patients median age = 75 years; relatives median age = 65 years. • Gender – patients 8 females, 10 males; nominated relatives 7 females, 4 males. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported.	<u>Awareness</u> – Of the 18 patients interviewed, 13 were cancer or heart failure patients. Of these, 9 had a degree of awareness. They reported that they had engaged in some level of conversation with both family carers and/or healthcare professionals about end-of-life care, although the depth, process and areas reported to have been addressed in these conversations varied. In a follow-up interview, the care home manager indicated that initiating conversations about residents' preferences for end-of-life care was rarely a priority, particularly when somebody was first admitted (unless they were identified as having a terminal illness at admission). <u>Preferred Place of Care document</u> – Only 2 patients had Preferred Place of Care documents in place that they were able to locate and show to the researcher; 2 patients were uncertain as to whether they had completed a Preferred Place of Care document; 1 patient knew that her preferences were recorded in her notes but had no Preferred Place of Care document. Thirteen patients did not have a Preferred Place of Care document and could not recall whether their preferences had been documented elsewhere. <u>Engagement in any significant communication about end-of-life care preferences</u> – Four participants appeared not to have engaged in any significant communication about end-of-life care preferences with either family members or healthcare professionals. A key factor appeared to be that at the time of interview these patients reported being at a stage where they didn't want to think too far ahead: "No, not at this time because I don't see myself as being	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Sample size: The study recruited 18 'cases' (patients n = 18; nominated relatives n = 11; and n = 15 healthcare professionals caring for the patient).	that far down the road yet, I'm still quite positive, well apart from when I'm feeling really ill." (Patient p5). However, the participant went on to acknowledge that ". . . at the end of the day we know it's serious . . . it's not going to have a good ending but I just think that you've got to carry on fighting . . ." (Participant, p5). One patient with heart failure reported some conversations with healthcare professionals during a period when he was seriously ill and required hospitalisation but he had not subsequently followed-up on these conversations: "I've been feeling pretty good now for about 2 or 3 months I suppose." When asked about whether future planning is seen as less important in periods of better health, the participant replied: "Oh yeah, I don't give them a thought. . ." (Participant, p5). When asked "Has anybody talked to you about where you want to be cared for? In terms of staying at home or, has anyone had those sort of conversations with you?" a patient with cancer replied: "No, no, not yet. No. I certainly want to stay at home. I'll be quite frank with you. If I'm going to die, I want to die at home; I don't want to die in hospital. And the family, I think, understand that." (Patient, p6). In a follow-up interview with the nominated healthcare professionals involved in the care of this patient (after his death), the practitioners recalled having difficulties in knowing how and when to initiate conversations with the patient regarding his preferences: "He never really, up until the very end, particularly considered himself to be palliative. Only near the end did he say 'I don't think I'm winning this' and that was the first indication I had that he was thinking along the lines of I'm going to die from this." (Participant, p6).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		Healthcare professionals' reports of discussions with patients about preferences for end-of-life care – There were sometimes difficulties in having conversations about end-of- life care with patients who did not consider themselves to be in need of palliative care: "… if you think they're coming towards end of life, with all the uncertainty around heart failure, you want to discuss that, but at the same time, you don't want to take away all their hope." (Participant, p6). Some professionals reported that they waited for patients or family carers to raise the issues themselves: "It's very much led by the patient; if they want to know . . . how they are doing whatever, and be guided intuitively by them really. There are some patients who will be very open and frank with you and use all the right words but there are others that will say to you or indicate I know where you're going with this and I don't want to hear." (Participant, p6). Judgments on timing included doing preparatory work and first building up a relationship with the patient and family – "It's important we've built up a rapport with the patient… and that's why we like early referrals so we get to know the person." (Participant, p7). Factors that influence if healthcare professional's initiate discussions about preferences for end-of-life care: • Level of experience and training in advanced communication skills. • Judgements regarding a patient's level of awareness/denial. • Reluctance of relatives to have these conversations. • Uncertainty of trajectory with long-term conditions (e.g. heart failure). Factors that influence when healthcare professional's initiate discussions about preferences for end-of-life care – • Patients initiate or ask for information.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		- Judgement on timing – don't want to concern patients/relatives too early (nor leave it too late). - Once preparatory work is carried out (getting to know the patient; planning what to say). - The need to follow policy guidelines on the need to identify patient preferences. Factors that influence how healthcare professional's initiate discussions about preferences for end-of-life care – - Taking a step-by-step approach. - Use of trigger questions. - Different choice of language, e.g. some healthcare professionals will use the words death and dying; some would not.	

5. Barnes K, Jones L, Tookman A et al. (2007) Acceptability of an advance care planning interview schedule: a focus group study. Palliative Medicine 21: 23–28

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors report that the '… aims of this phase I qualitative focus group study were (1) to explore the acceptability of an interview schedule, designed to encourage conversations regarding future care; and (2) to explore the suitability of such discussions and inquire about their possible timing, nature and impact.' (p23). **Methodology:** Qualitative – focus groups.	**Participants:** Service users and their families, partners and carers – patients attending a palliative care day unit at a hospice, oncology outpatients, members of Cancer Network groups, and relatives and carers. **Sample characteristics:** - Age – Age range = 32–80 years Median age = 60 years (52, 69). - Gender – 13 (59%) female and 9 (41%) male. - Ethnicity – 21 (95%) Caucasian. - Disability – Not reported. - Long-term health condition – 18 of the focus group participants (82%) were oncology patients at different stages	Prompting patients to think about issues – Some participants said that the questions in the interview schedule prompted patients to consider issues they may not have thought about before. They acknowledged that these issues worry them, and some may not want to deal with them, while others welcome a discussion and think about a course of action. "It's given me some food for thought...we do put things to the back of our mind... I have got some quite firm views about what I would want...I would like people to do what I want to have done." (Participant, p25). Timing of advance care planning – The majority of participants felt the most suitable time to discuss advance care planning would be following a recurrence of disease, or if treatment had not worked and the prognosis had become poor. Participants reportedly felt that it was better to avoid discussions around the time of diagnosis or during active	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Country: United Kingdom. **Source of funding:** Voluntary/Charity - Marie Curie Cancer Care.	of disease. Five patients were in remission (23%), 9 patients had recurrent disease (41%), and 4 patients were approaching the end of life (18%). The remaining 4 participants (18%) were relatives of hospice patients and a person who had cared for someone with cancer. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** N = 22.	treatment: "Had he asked me about living wills when I was first diagnosed, that would have just flipped me over the edge...it was hard enough to deal with the diagnosis." (Participant, p25). There was recognition that those with a limited life expectancy need time to plan and arrange things and the interview schedule was potentially useful in this respect. For some patients who had experienced a disease recurrence, it was hard to balance the everyday life with the need to consider end-of-life matters. Most participants felt that the opportunity to discuss these issues should be provided more than once to allow patients time to think through and address different issues in their own time, including the need to involve family and friends. Some participants felt that health professionals should take a more active role in inviting patients to have a discussion if appropriate, following regular assessments in relation to their prognosis and emotional state: "I think the problem with it being left up to the individual is that they may put it off and put it off. Because...everyone wants to hope that it won't be today." (Participant, p26). <ins>Recognising individuality</ins> – Participants emphasised the significance of treating patients as individuals. Some may be more willing while others not as comfortable talking through the issues in the schedule and this may be affected by their health condition or prognosis. <ins>Person conducting advance care planning discussion</ins> – The participants felt that discussion should be carried out by a trained person with excellent communication skills, who can provide accurate information and allow for discussion in an unhurried atmosphere. Most participants felt that their consultant would not be the right person because of	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		the constraints of time in clinical settings. Some participants felt that advance care planning discussions with their doctor might change the doctor-patient relationship. "I’m still at the stage where I go to my doctor for him to make me better, not to tell me how to die... If you’re going to go through these kinds of issues with your doctor... you may lose the hope that you have in your physician...that could be negative.” (Participant, p26). <u>Losing a sense of hope</u> – Some participants felt that talking about advance care planning may destroy all sense of hope. "I think it might actually destroy people’s hope.” (Participant, p27). "Hope can see people through diseases... (Addressing these issues) might smash that very delicate thing that can keep someone alive for much longer.” (Participant, p27). These comments emphasise the significance of ensuring that advance care planning discussions take into account the complex emotions patients may be experiencing. <u>Maintaining a sense of control</u> – Advance care planning discussions may enhance control by providing individuals with the opportunity to make end-of-life care choices. One relative suggested that for "… patients (at the hospice) ... to feel that they may have a choice, or some input to their environment, rather than those decisions being made for them...might allow them to feel more empowered and more in control.” (Participant, p27). <u>Advance directives</u> – There was anxiety and confusion about the legalities of advance directives, their connection to euthanasia and how and at what point they should be discussed with patients. Some participants were worried and said that there should be the opportunity to change what is written in an advance directive if a person wishes to change their mind in future.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		Effect of taking part in a focus group – For some participants, initiating discussion about end-of-life matters encouraged them to discuss their wishes for future care with their relatives.	

6. Barnes KA, Barlow CA, Harrington J et al. (2011) Advance care planning discussions in advanced cancer: analysis of dialogues between patients and care planning mediators. Palliative and Supportive Care 9: 73–79

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To explore the views of people with recurrent progressive cancer about advance care planning as an aid to consider, discuss, and plan their future care with health professionals. **Methodology:** Qualitative – discussion sessions with mediators. **Country:** United Kingdom – London. **Source of funding:** Voluntary/Charity – Dimbleby Cancer Care Fund.	**Participants:** Service users and their families, partners and carers – people with recurrent progressive cancer. **Sample characteristics:** • Age – Age range 42–78 years. • Gender – 19 (47%) female and 21 (53%) male. • Ethnicity – 36 (90%) white; 1 (2.5%) black Caribbean; 3 (7.5%) other. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Patients with recurrent progressive cancer, not known if their mental capacity is intact or fluctuating. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** N = 40.	Participants attended advance care planning discussion sessions, led by independent mediators with extensive clinical experience and were able to respond to patient cues, answer questions, and tailor discussions to the needs of the individual. A checklist of topic domains was introduced, including communication with health professionals and close persons, feelings about the future and the dying process, preferences for place of care, and making future healthcare decisions. In order to ensure that the intervention was primarily patient focused, participants were seen alone for the first discussion but close persons could be present at subsequent meetings according to patient wishes. Second and third discussions focused on the main topics, but also returned to themes from earlier discussions that required further attention. A maximum of 3 sessions were offered as part of the trial design, and information was available for participants who felt they had need of further future support. (p74) The main topics covered were: - quality of care so far (to open up discussion); feelings/concerns regarding the future; communication with doctors and nurses; communication with family and friends; financial concerns/ preparation of a last will; death and dying/preferences for place of death; coping mechanisms; views on resuscitation/future healthcare decisions; reflection on advance care planning discussion/desire to complete another discussion.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		Maintaining a Positive Attitude – The majority of participants acknowledged a possible deterioration in health, but were focusing on staying positive: "You have got to be positive … so I don't sort of dwell on it." (Participant, p75). Some participants wanted to think about the issues raised and make plans. Others were not ready but said they would address the issues at a more appropriate time. Some tried to remain positive by getting on with life as usual and not thinking too far ahead: "One has to discuss it at some stage, but discussing it early, I'm not sure is a good thing … I really don't want to think about it … I want to try and think positive." (Participant, p75). Maintaining Hope – Participants had hope for the future: "I'm just concentrating … on taking the … treatment' medication … I do believe in mind over matter." (Participant, p75). Some found it challenging to discuss these issues, but many found the information valuable: "There's a bit of me that thinks. . . 'I don't want to think about dying when I'm feeling well'. . . It's not easy to talk about these things at all, but … information is power." (Participant, p75). Concerns about the Future – Participants expressed concern about the process of deterioration and experiencing distressing symptoms, such as pain. Some also had fears about the dying process, and watching others die. Other concerns were for family, as patients feared that they may become a burden. Participants found advance care planning discussions helpful, as it helped to alleviate their concerns about the future: "It's very useful … I can see the point of having a talk like this. . . If I … were to fall ill now, I'd have absolutely no fear." (Participant, p76).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		<u>Timing and talking about the future with health professionals</u> – Some participants felt that doctors were reluctant to introduce such topics: “They always try to be positive … upbeat … So he’s not going … to say, “What happens if it goes wrong?” He doesn’t want to discuss it.” (Participant, p76). Insufficient time during clinic appointments to talk: “The doctors … are very busy … so I have not talked to them, because it is probably quite a lengthy subject.” (Participant, p76). Too soon for such conversations: “If … Dr [x] said to me, ‘look … it’s flaring up again’ … and if it was, then I think I’d say, ‘well, now let’s plan …’ “(Participant, p76). Some participants acknowledged that they might need prompting in order to address these issues: “There also needs to be a kind of a gentle nudging … You’re … prompted in a good way.” (Participant, p76). Over half of the participants wanted more information from their doctors about the future – the likely prognosis, process of deterioration, options for place of care, and future healthcare decisions: “Hopefully they can manage to give me answers … ‘That’s what you have and that’s what you can do about it’. . . . That would be more important than just letting me … carry on like this.” (Participant, p77). <u>Talking about the future with family and friends</u> – A small number of patients had talked openly with family members about the future, and some said they would talk more extensively if their condition deteriorated: “Timing is very important … I don’t think you want … people to … become distressed too, too early … So it would be something that would be done in stages.” (Participant, p77). <u>Preferences for place of care</u> – Participants appreciated	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		that options were available to enable them to be cared for in a place of their choice. Many wanted to be cared for at home for as long as possible to maintain quality of life: “If I had a choice, I would rather be at home … to have your things around you and be in a familiar place.” (Participant, p77). Some participants expressed concern about burdening those closest to them by being cared for at home, which may show a lack of knowledge about the support that could be available: “Being cared for at home in the beginning is a good thing, but you put lots of pressure on people if you do that.” (Participant, p77). Future healthcare decisions – Most patients would trust their health professionals to make future healthcare decisions in their best interest but would prefer those decisions be made in conjunction with family and friends: “If there was a decision to be made . . . and the doctors really didn’t know which was best . . . if they’re making a decision in your best interests, that interest may well be served by . . . having your family involved in the discussions.” (Participant, p77). They also wanted to talk to relatives about future healthcare decisions at some point. “I wouldn’t want to do it now … Because at the moment I’m trying to plan for success rather than failure … But if failure becomes a likely option then I’ll switch to a different mode.” (Participant, p77). Decisions about future treatments were limited by lack of knowledge about available treatments. “It’s a bit easier to write a birth plan than to write or plan on something when I’ve got no idea what the options are. . .or what the problems will be.” (Participant, p78). Participants felt that quality of life was more important than	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		length of life and would prefer not to be kept alive if quality of life were poor: “The purpose of medicine is to alleviate suffering. . . It’s not about extending your life at any costs. There’s got to be quality of life.” (Participant, p78). In summary, content analysis of discussion data showed that most patients had not spoken extensively to health professionals or close persons about the future. Their willingness to engage in advance care planning varied widely. There appeared to be tensions between wanting to get on with life as usual and considering end-of-life issues. Participants voiced specific concerns about a potential deterioration in health and a desire for more information, and felt it was doctors’ responsibility to initiate such discussions, but perceived that their doctors were reluctant to do so. However, some patients felt that the time was not yet right for these conversations. Many were not aware that they might exercise a choice of where to receive end-of-life care, while others simply left important decisions to their doctors, whom they assumed had their best interests at heart. There were also concerns related to experiencing distressing symptoms or worrying how family members would cope. These findings suggest that the timing of discussions should be tailored to individual need, with due respect to those patients who wish to postpone reflections on death and dying. Though participants wished for more accurate information, there is a need to recognise their broader values and goals, in particular interactions with family and others close to them. The authors noted that findings from this study do not fully support the current United Kingdom policy of introducing advance care planning early in life-threatening illness, as some patients were not yet ready, even late in their disease progression.	

7. Bond CJ and Lowton K (2011) Geriatricians' views of advance decisions and their use in clinical care in England: qualitative study. Age and Ageing 40: 450–456

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors aimed to '... to elicit geriatricians' views on advance decisions and their use in decision-making in England.' (p450). **Methodology:** Qualitative – semi-structured interviews. **Country:** United Kingdom – London. **Source of funding:** Not reported.	**Participants:** Professionals/practitioners – geriatricians (6 consultants and 4 trainees). **Sample characteristics:** • Age – consultants mean age = 54 years; trainees mean age = 33 years. • Gender – Not reported. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** N = 10.	Practitioners supported the use of Advance Decisions to Refuse Treatment in principle, but raised some concerns regarding practical issues. Geriatricians suggested that the documentation should be specific about what treatment may be declined and when; particularly when this involved refusal of 'life prolonging treatment'. Practitioners also reported that they should provide clarity regarding the use of invasive procedures: "I think as a doctor I would assume that it would make decision-making a lot easier if somebody had set out quite clearly what they wished before they became mentally incapacitated. Although I think there are obviously lots of difficulties from a doctor's point of view." (Participant, p452). "To deal with clinical idiots like me, it's best to be as clear as possible in envisaging the situations in, where the advanced statement should be enacted. Some of them are very vague … so the more detailed somebody can be the better – it helps decision-making. If it's vague it's open to interpretation and people might not get what they want." (Participant, p452) Context – Geriatricians reported that if a patient was likely to die regardless of any treatment, they were willing to withhold invasive techniques. In a situation where the outcome was less clear geriatricians stated that they would use the Advance Decision to Refuse Treatment to assist with decision-making. For some it was a key factor in decision-making, for others it was one of several factors determining what treatment to provide. "I think, well it's reasonable for that individual to want some degree of control over their life even if I disagreed with it, it's not, it's not forcing to do some, to give a treatment	**Overall assessment of internal validity**: + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		which I think is, is pointless and cruel it's simply asking me to err, fit in with their, with their wishes, so I don't treat pneumonia; well that's fine." (Participant, p452) If the person was likely to live as a result of treatment, interviewees said they would be hesitant to follow the advance decision. Others reported they would follow it if it were written clearly and without ambiguity. Personal values and professional practice: "It becomes harder for the health professionals, much harder because having an advance directive setting a ceiling of therapy is helpful and is err reassuring to the clinician if it's in line with what they're thinking, if in contrast that ceiling of therapy appears suboptimal it would be very difficult, very difficult." (Participant, p452). Professional Attitudes – The study found that the personal attitudes of the practitioner had considerable bearing on their views regarding advance decisions, and whether they used them often depended on their expertise and ability to predict patient survival. Advance Decisions to Refuse Treatment were thought to have an impact on the role of the practitioner as a decision- maker and it was thought that it would be difficult to write an Advance Decision to Refuse Treatment that reflected the likely complexity of any medical decisions to be made. Geriatricians acknowledged that while patients did not have the same knowledge and insight into their own conditions, the patient's wishes were central and advance decision should be used as the basis for treatment. Some felt that patients believed that an Advance Decision to Refuse Treatment order was a set of instructions for the geriatrician to be followed at a point in the future when capacity was lost; however, participants believed this was not the	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		case. The study found that advance decisions were used when they included detailed information about the case and supported the practitioner's decision-making: "... suppose in a way you're taking the responsibility from the, well the responsibility for decision-making isn't all yours any more it's um, you know the patient has taken that away from you." (Participant, p452). "How can the lay public understand all the intricacies of what we decide? They won't understand basic science, they don't understand interventions, they can't understand lots of issues." (Participant, p452)	

8. Boot M and Wilson C (2014) Clinical nurse specialists' perspectives on advance care planning conversations: a qualitative study. International Journal of Palliative Nursing 20: 9–14

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The aim of the study was to identify the challenges experienced by clinical nurse specialists when facilitating advance care planning conversations with terminally ill patients. This paper focuses on the factors that influence clinical nurse specialists when they are deciding whether to open an advance care planning discussion. **Methodology:** Qualita-	**Participants:** Professionals/practitioners – purposively selected palliative care clinical nurse specialists. **Sample characteristics:** • Age – Not reported. • Gender – Not reported. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** N = 8.	The data revealed that the clinical nurse specialists felt that opening advance care planning conversations entailed taking a risk and required courage. The risks identified were that the patient might be harmed and/or the nurse–patient relationship damaged, but also that the patient might miss the opportunity to be involved in advance care planning. <u>Raising the issue vs. missing the opportunity</u> – Clinical nurse specialists felt the need to ensure that patients have the opportunity to engage with advance care planning but were sensitive to patients' individual wishes, recognising that some patients did not want to undertake the advance care planning process: "[I] feel there is a moral obligation to do the best you can to be in touch with what people would like so we can plan sensitively for their future. It is that kind of moral dissonance about getting the timing	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
tive – semi-structured interviews. **Country:** United Kingdom. **Source of funding:** No external source of funding.		right. Not robbing of the opportunity, but not stepping in insensitively.” (p11). To introduce advance care planning with individual patients clinical nurse specialists looked for cues from the patients to see if they wished to discuss end-of-life issues: “... if somebody doesn’t want to go back into hospital then I would think that I make sure that they realise that they will be getting good symptom control and good quality of life at home.” (p11). Clinical nurse specialists described adopting a ‘watching and waiting’ approach to the timing of advance care planning: “[I] do tend to pick up on people’s cues ... and get the feel if they want to start to talk about end-of-life planning ... and if I do get any cues like that then I will grab the opportunity because they don’t really come around very often.” (p12). Clinical nurse specialists reported times when they had started conversations and found that the patient did not want engage with them: “To actually start talking about when their life is coming to an end is something that people push away and we don’t want to face until the end [...] some people never get to that point.” (p12). <u>The nurse–patient relationship</u> – Clinical nurse specialists identified that establishing a relationship was an important prerequisite to facilitating the process: “She said, ‘Look I just don’t want to know, I want to go on a day-to-day basis and that is how I cope’ ... but if I am present there is more chance that when she is ready she will share it with me. But I also have to accept that some people are never ready. It is to establish that relationship.” The risk of opening the conversation was weighed against the risk of harming the relationship: “... if people aren’t ready to start talking about end of life I think it can really	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		distance your relationship with them and I have heard of cases where that has happened with healthcare professionals" (p12). One clinical nurse specialist reported that she was able to press ahead with advance care planning without forming the relationship when she felt that circumstances demanded this: "I had to make it a priority, I had to do it the day I met the patient. So sometimes I think you have got [to get] a handle around how quickly you have got to do it." (p12). The clinical nurse specialists reported occasions when they 'got it wrong' when trying to introduce an advance care planning discussion. Family – Families were identified as an important factor in advance care planning and should be involved: "... supporting the family is a very strong theme in end-of-life planning ... you need to do it sensitively and pick the right moment otherwise you can distance yourself from the family." (p13). The clinical nurse specialists reported ethical challenges when families expressed strong views that they felt were either not in-keeping with the patients' or not in the patients' best interests: "You have occasions when the family views outweighs the patient and so a member of the family's views are important, [but] it is obviously about the patient..." (p13).	

9. Brazil K, Carter G, Galway K et al. (2015) General practitioners perceptions on advance care planning for patients living with dementia. BMC Palliative Care 14: 14

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To describe the attitudes and practice	**Participants:** Professionals/practitioners – general practitioners.	The survey included a section asking general practitioners to give their perspectives on discussing with patients and	**Overall assessment of internal validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
preferences of general practitioners working within the National Health System regarding communication and decision-making for patients with dementia and their families. **Methodology:** Survey – cross-sectional survey using a purposive cluster sample. **Country:** United Kingdom – Northern Ireland. **Source of funding:** Voluntary/Charity – Care to Know Centre.	**Sample characteristics:** • Age – Mean average 49.3 years (SD 8.3). • Gender – Female 42.6%; male 57.4%. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Years in practice (mean) 24.7 (SD 8.0). **Sample size:** 340 general practitioners (174 practices) – 138 responses received, 133 completed surveys (response rate 40.6%) represented 60.9% (106/174) of the surveyed practices.	their families: "… what severe dementia looks like …" (p3) around the time of the diagnosis. These results have not been extracted by the NCCSC review team because they are not relevant to the review question on advance planning. Physicians were asked to indicate to what extent they agreed with a number of statements about advance care planning and future care at the end of life: <u>Advance care planning on end-of-life care should be initiated at the time of diagnosis of dementia (respondents n = 133)</u> – strongly disagree 20 (15.0%); moderately disagree 41 (30.8%); neither agree nor disagree 19 (14.3%); moderately agree 41 (30.8) strongly agree 12 (9.0%); don't know 0. <u>The process of advance care planning should involve revisiting plans with the patient and the family on a highly frequent basis (n = 133)</u> – strongly disagree 11 (8.3%); moderately disagree 47 (35.3%); neither agree nor disagree 11 (8.3%); moderately agree 44 (33.1%); strongly agree 20 (15.0%); don't know 0. <u>When a patient cannot participate in treatment decisions an advance directive is essential (n = 132)</u> – strongly disagree 9 (6.8%); moderately disagree 21 (15.8%); neither agree nor disagree 34 (25.6); moderately agree 51 (38.3%); strongly agree 17 (12.8%); don't know 1 (0.8%). <u>The physician should take the initiative to introduce and encourage advance care planning (n = 133)</u> – strongly disagree 1 (0.8%); moderately disagree 4 (3.0%); neither agree nor disagree 18 (13.5%); moderately agree 65 (48.9%); strongly agree 45 (33.8%); don't know 0. <u>The advance care planning process requires my making family members agree with the physician on goals of care</u>	**Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		(n = 133) – strongly disagree 25 (18.8%); moderately disagree 45 (33.8%); neither agree nor disagree 26 (19.5%); moderately agree 30 (22.6%); strongly agree 7 (5.3%); don't know 0. When family members have difficulty understanding the limitations and complications of life-sustaining therapies, the physician cannot successfully guide the advance care planning process (n = 132) – strongly disagree 4 (3.0%); moderately disagree 47 (35.3%); neither agree nor disagree 26 (19.5%); moderately agree 46 (34.6%); strongly agree 9 (6.8%); don't know 1 (0.8%). When the physician cannot make family members accept their loved one's prognosis, the advance care planning process fails n = 130 – strongly disagree 7 (5.3%); moderately disagree 47 (35.3%); neither agree nor disagree 35 (26.3%); moderately agree 35 (26.3%); strongly agree 6 (4.5%); don't know 3 (2.3%). There should be an agreed format for advance care plans (n = 132) – strongly disagree 1 (0.8%); moderately disagree 2 (1.5%); neither agree nor disagree 9 (6.8%); moderately agree 67 (50.4%); strongly agree 53 (39.8%); don't know 1 (0.8%). Physicians need improved knowledge to successfully involve families in caring for dementia patients at the end of life (n = 133) – strongly disagree 1 (0.8%); moderately disagree 6 (4.5%); neither agree nor disagree 20 (15.0%); moderately agree 65 (48.9%); strongly agree 41 (30.8%); don't know 0. The pace of advance care planning is primarily determined by patient's and family's willingness to face the end of life (n = 132) – strongly disagree 1 (0.8%); moderately disagree 11 (8.3%); neither agree nor disagree 19 (14.3%);	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		moderately agree 64 (48.1%); strongly agree 37 (27.8%); don't know 1 (0.8%). Families and patients who are involved in advance care planning should become informed about commonly occurring health problems associated with severe dementia, such as pneumonia and intake problems (n = 133) – strongly disagree 0; moderately disagree 2 (1.5%); neither agree nor disagree 2 (1.5%); moderately agree 62 (46.6%); strongly agree 67 (50.4%); don't know 0. In the case of increasing severity of dementia, the patient's best interest may be increasingly served with a primary goal of maximising comfort (n = 133) – strongly disagree 1 (0.8%); moderately disagree 0 neither agree nor disagree 1 (0.8%); moderately agree 24 (18.0%); strongly agree 107 (80.5%); don't know 0. In their discussion section the authors' report that most respondents thought that discussions in the early stages following a diagnosis would enable decision-making during the advanced stages, but a sizeable number felt that these discussions should not happen at the time of diagnoses. Most felt that timing of advance care planning discussions should accord with the patient and their family's willingness to consider end-of-life issues. This emphasises the importance of the relationship between general practitioners and the patient and their family – so that the optimum time to discuss these can be identified. Most respondents viewed shared decision-making as a goal of advance care planning but reported that a major barrier to achieving this was families' reluctance to accept the patient's prognosis. Families and patients also struggled to understand the 'limitations of complications of life sustaining therapies' (p5). This stresses the importance of	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		education for families (and patients) to help them understand the disease trajectory of dementia and common associated health problems. (Although training sessions alone have been found not to be as effective as when combined with other interventions such as discussion sessions with a trained facilitator.)	

10. Farrelly S, Lester H, Rose D et al. (2014) What service users with psychotic disorders want in a mental health crisis or relapse: thematic analysis of joint crisis plans. Social Psychiatry and Psychiatric Epidemiology 49: 1609–1617

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To '… examine mental health service users' preferences and priorities in the event of a future mental health crisis or relapse.' (p1608). **Methodology:** Qualitative – the authors report that the '… paper describes a sub-study of the CRIMSON trial. The CRIMSON trial was a multi-site randomised controlled trial of JCPs compared with treatment as usual for individuals with psychotic disorders. This sub-study analyses the content of JCPs to explore what types of requests service users make for crisis care." (p1610).	**Participants:** Service users and their families, partners and carers – service users with psychotic disorders. **Sample characteristics:** • Age – Mean age of sample 40.4 years. • Gender – Male = 51%. • Ethnicity – White = 63.5% Black = 23.5% other (mostly British Asian) = 13%. • Religion/belief – Not reported. • Long-term health condition – Schizophrenia spectrum = 74% Affective psychosis = 26%. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** N = 221.	The thematic analysis identified 2 major categories of content in joint crisis plans: delivery of care and the type of treatments/interventions that service users would/would not like in a crisis situation. Delivery of care – Treat me with respect – The wish to be respected was a central theme in all the joint crisis plans and frequently respect was seen to be absent in the manner in which clinicians communicated. Respect could also be shown by looking more broadly than just symptom management and illness. For example, "[Other information I would like to be known or taken into account) If I am in hospital for a long period I would like nurses to arrange for me to have a haircut …" (Participant, p1612). Similarly, flexibility in aspects of delivery of care, such as consulting with service users about conveniently timed home visits was another way in which respect could be demonstrated: "[Treatments or other things that have not been helpful in the past) The last time I was unwell, I felt Home Treatment Team messed me about. They came to my flat whenever it suited them. They wanted me to stay in all day. They wanted to visit me twice a day to give me my medication I couldn't do that because I was in the middle of a divorce, I	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Country: United Kingdom – England. **Source of funding:** Other – Medical Research Council.		had appointments to see my solicitor, children and other commitments.” (Participant, p1612). Understanding what is ‘illness’ and what is not – service users described situations in the past where clinicians/ police have misunderstood their behaviour. Other service users stressed the importance of clinicians knowing them as individuals and understanding when it is that they require help: “[Preferred treatment or social care during a crisis or relapse] I have been in and out of hospital because the assessment was done by people who do not know me and didn’t pick up that I was becoming unwell so kept discharging me. I would like the Triage ward not to discharge me before speaking to my Consultant.” (Participant, p1612). Continuity, consistency and clarity – Most service users said that the first contact with services when they started to feel unwell was their usual mental health team. Staff change created stress and usually led to a lack of continuity in treatment. When unwell, having clear treatment plans helped to reduce the stress of relapse: “[What I would like to be done when I first start to become unwell] Clarity with my medication—a proper plan of who is giving me my medication and when.” (Participant, p1613). Having control/involvement in decisions – The majority of service users wanted to involved in decisions about their care and the need to retain a certain degree of control led to other treatment decisions such as a desire to be treated at home or admitted to hospital on a voluntary basis: “[Preferred treatment or social care during a crisis or relapse] I would prefer to be in hospital on an informal basis so I can be involved in decision making around my care.” (Participant, p1613). <u>Particular treatments/interventions that service users</u>	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		would/would not like in a crisis situation – Significantly, the most prevalent first choice for treatment in a crisis was for home treatment team support (35% of the sample), followed by hospitalisation (19%), and medication changes (14%). Self-management – For many service users, the first step in managing a potential relapse was to take care of their general health/wellbeing, e.g. the need to reduce alcohol, to focus on healthy eating and getting enough sleep. Talking and support – The majority of service users talked about the need for support and to talk to someone to reduce the stress of the relapse, including the importance of clinicians' understanding that they were experiencing difficult emotions. "[Treatments or other things that have not been helpful in the past] Staff who have no respect or empathy for the fact that I am an adult who is suffering." (Participant, p1613). Staying at home – For many service users, being able to stay at home for as long as possible was important. While 35% of the sample described it as their preferred first line treatment the involvement of home treatment teams was amongst the preferences of 67% of the sample. Some service users preferred to keep contact with their regular team or care co-ordinator via home visits and to have additional support from the home treatment team if necessary. But overwhelmingly, the most common response to 'preferred treatment or social care during a crisis or relapse' was simply 'the home treatment team'. (Authors, p1614). Medication – 56% of those who made a refusal, made a refusal about medication; 80% of which related to a specific medication and often an alternative was presented.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		The remaining medication-related refusals referred to injections, high doses and medication changes. A far more common scenario was medication review/increase as a first strategy to deal with relapse; one for many service users that was preferable to hospitalisation. Hospital admissions – For the majority of service users, hospital admission was challenging and created further stress to their relapse and could potentially worsen the episode: "[Circumstances in which I would wish to be admitted to hospital for treatment] In no circumstances would I agree with coming into hospital—it makes me more paranoid. There's nothing they have in hospital that I need except for meds and I can take those at home. The only reason you get better in hospital is because you're back on the meds and not because you're in hospital." (Participant, p1614). Eight per cent of the overall sample made a refusal in relation to hospitalisation, half of whom refused hospitalisation. The remaining refusals were associated with particular wards or being treated compulsorily. Most service users were conscious that in some circumstances a hospital admission would be necessary and 77% made a specific statement about when they would like to be admitted, most preferring to go voluntarily to allow them to maintain a certain degree of control.	

11. Farrelly S, Lester H, Rose D et al. (2016) Barriers to shared decision making in mental health care: qualitative study of the Joint Crisis Plan for psychosis. Health Expectations 19: 448–458

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To explore clinicians and service users' views of a joint crisis plan delivered as part of	**Participants:** • Service users and their families, partners and carers – Service users with a psychotic disorder.	Clinicians identified four main barriers to the implementation of shared decision-making in the form of the joint crisis plan, which are contrasted with overall responses from service users.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
an earlier pilot study. Although a pilot study had found the intervention to be effective in reducing the use of compulsory admissions made under the Mental Health Act, the 'definitive' trial (CRIMSON) conducted across 4 English mental health trusts, contradicted these results. The authors, therefore, focused specifically in this study on the barriers to shared decision-making. **Methodology:** Qualitative – focus groups and semi-structured interviews. **Country:** United Kingdom – England. **Source of funding:** Other – Medical Research Council.	• Professionals/practitioners – Care co-ordinators and psychiatrists from various professional groups (care coordinators included nurses and social workers) were purposively sampled if they had participated in at least 1 joint crisis plan meeting. Seventy-five per cent of care co-ordinators were nurses. Psychiatrists had been working at consultant level for an average of 6.5 years (range 3–11 years). **Sample characteristics:** • Age – Service users – average age of 39 years; 45 clinicians broken down as: 29 care coordinators – average age of 44 years. No detail on ages of male care co-ordinators or male or female psychiatrists. • Gender – Service users 52% female; care co-ordinators (n = 29) 58% female; psychiatrists (n = 16) 20% female. • Ethnicity – Service users - 64% were white, 32% were black and 4% Asian. Details on ethnicity not reported for professionals. • Disability – Not reported. • Long-term health condition – Service users – psychotic disorders. No details reported for professionals. • Sexual orientation – Not reported. • Socioeconomic position – Not reported.	Ambivalence regarding care planning – The majority of care co-ordinators were frustrated that service users did not value or comply with standard care plans. There was scepticism, therefore, with introducing a joint crisis plan: "One of the reasons I'm so sceptical is that I actually do sit down and do care plans with people, but I go back the next week and say oh can we look at that copy of the care plan again, and they can't find it. And you think...you know... am I really kidding myself that doing it jointly actually does make a difference?" (Participant, p452). Others spoke about service users knowing what to do during a crisis anyway and the joint crisis plan, therefore, presenting an additional care plan of 'questionable value': "Most of them are aware . . . a lot of them are fairly basic anyway it's just err, contact your care coordinator who may arrange an emergency appointment, and you know to try and see the consultant or the doctor as soon as possible. And then consider home treatment, go to [Accident and Emergency Centre) if it's outside hours. You know it's very standard and the clients just . . . they know most of it anyway." (Participant, p 452). Shared decision-making already taking place – The authors note that there seemed to be a lack of awareness by clinicians of the power imbalance between them and the service user. Two key problematic areas were: firstly, interaction styles and use of language. "When I meet the patients, I explain to them what a consultant is. 'I am your consultant and am the person who you consult for expert advice. You are in charge.' It is more or less what I tell them...You come to see me and I am your expert...I will implore you, at times, to follow my advice." (Participant, p453).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Sample size: Service users n = 50; practitioners n = 45 (drawn from CRIMSON trial sample); total N = 95.	Secondly, clinicians may inadvertently be in control of discussions by withholding information and restricting the options on offer, despite their commitment to shared decision-making: “And if there is anything that I feel needs to go in, I suggest it, I say ‘what do you think?’ And then I say, ‘the other thing that needs to go in is this’ and we go through it. That’s it. I ask them to agree and that’s it.” (Participant, p453). <u>Appropriateness of service users’ choices</u> – Many clinicians expressed concerns that service users would make choices that they would not consider to be in the service users’ best interest: "And also, there are things that the service user will want and request and you know it’s not really what they need. You have to find a way, to actually communicate that, get them to understand without actually hurting them or without actually sending a message that you don’t want them to get that, or you don’t want to do it.” (Participant, p453). <u>Availability of service users’ choices</u> – Concern was expressed about the potential of service users requesting treatments or services that clinicians could not cater for and that the joint crisis plan process was in fact giving false hope. Furthermore, clinicians expressed anxiety that choices made by the service user in their joint crisis plan would not be met as crisis situations would normally be dealt with by a different clinician and not themselves. The experience of service users: Many service users talked about feeling disempowered with respect to decision-making, not trusting their clinicians, and doubting that they were able to engage in a dialogue with clinicians. For some service users, this was ex-	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		acerbated by delusional experiences in the past or questioning from clinicians: "I have to ask myself while [talking to clinicians about treatment decisions] are any of these ideas delusional, are they psychotic? Actually to be honest, once people start talking to you about delusions and psychosis and a lack of insight, you don't half begin to doubt yourself. So yeah, I think I'm probably okay, but I'm having to ...regain my trust I suppose in my own thinking." (Participant, p454). The joint crisis plan was, therefore, valued by many service users because of the perception that having an external person in attendance during the joint crisis plan sessions increased their sense of empowerment and ensured that the clinicians were fair: "Well it was just like, they didn't say 'no we can't do that', they said 'we'd try and do x. . .' They were very helpful, they were saying that as the very last resort you will go into hospital . . . Whereas before my doctor would say to me, well if you sister thinks you're going to go to hospital, we'll put you in." (Participant, p454). Where clinicians did not engage with the joint crisis plan process through, for example, not being at meetings or not taking part in discussions, this had a negative impact on the experience and trust in the joint crisis plan process for many service users: "I wanted a joint crisis plan cos I thought it might make a difference [. . .] with regards to how the psychiatrist would approach things if I got sick. Cos I've been sectioned so many times. But I remember, on the day that [the facilitator] came [the psychiatrist] was on the [computer], he was so rude [. . .] and he was on his [computer] most of the time when [the facilitator] was talking. He had his back turned." (Participant, p455).	

12. Henderson C, Flood C, Leese M et al. (2009) Views of service users and providers on joint crisis plans. Social Psychiatry and Psychiatric Epidemiology 44: 369–376

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To report participants' and case managers' use of joint crisis plans and their views regarding the plans. **Methodology:** Survey–questionnaires (postal and interview). **Country:** United Kingdom – London. **Source of funding:** • Government – The Maudsley Trust health services research committee grant. • Other – Medical Research Council and the Maudsley Trust health services research committee grant.	**Participants:** • Service users and their families, partners and carers – People who had been admitted to a psychiatric inpatient service at least once in the previous 2 years; had a diagnosis of psychotic illness or bipolar affective disorder without psychotic symptoms. Participants were patients with mental illness who were randomly selected into the intervention group in the context of a randomised controlled trial (the trial was conducted to assess the use and views on the values of the joint crisis plan between the intervention acceptance and involvement with the making the joint crisis plan) and control group (standard service, no joint crisis plan). However, this study did not compare the views between the intervention group and the control group. This study compared the views of the intervention group (joint crisis plan holders) and their case managers immediately after the intervention and at 15 months follow-up (this did *not* include a before-and-after design either). This study was therefore not appraised as a randomised controlled trial but as a survey of views at 2 points, immediately after the intervention and 15 months later. • Professionals/practitioners – Case managers of participants with a joint	<u>Reported use of the joint crisis plan by holders, case managers and nominees</u> – n = 42 (96%) said that the joint crisis plan reflected the holders' wishes. However, preference statements were not followed, either because staff felt it was not in the patient's interest to follow the plan or because they were unaware of it. At 15 months follow-up, 36/45 (80%) of the participants still had their joint crisis plan; of these, the majority kept them at home; 88% of case managers had access to the joint crisis plan. All participants stated that they had looked at it on receipt; 63% of holders and 66% of case managers had made no further use of it. Both groups' primary use of the card was to refer to it themselves rather than to show it to others. <u>Views on the joint crisis plan</u> – At immediate follow-up, 46–96% of joint crisis plan holders (n = 44) responded positively in terms of (Table 3) a. Change in relationship with mental health team – joint crisis plan holders: 20/44 (46%) at immediate follow-up vs 12/50 (24%) at 15-month follow-up; case manager 11/28 (39%) at 15 months. <u>Change in feelings about holder's situation</u> – joint crisis plan holders 30/44 (67%) at immediate follow-up vs 24/50 (48%) at 15 months; case manager 15/28 (53%) at 15 months. <u>Would recommend the joint crisis plan to other service users</u> – joint crisis plan holders 90% at immediate follow-up vs 82% at 15 months; case manager 85% at 15 months. <u>Change in whether to continue with care</u> – joint crisis plan holders 59% at immediate follow-up vs 28% at 15 months;	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	crisis plan. **Sample characteristics:** - Age – Not reported. - Gender – Not reported. - Ethnicity – Not reported. - Religion/belief – Not reported. - Disability – Mental illness. - Long-term health condition – Not reported. - Sexual orientation – Not reported. - Socioeconomic position – Not reported. **Sample size:** The participants received joint crisis plan as an intervention in a randomised controlled trial; their views on joint crisis plan were reported in the present study 86 offered joint crisis plan, 65 accepted joint crisis plan. 45/65 (69%) completed initial follow-up questionnaires. At 15-month follow-up, 80% (52) were interviewed. 62/65 people who received a joint crisis plan (95%) were interviewed at least once. Case manager (N = 65) questionnaires were partially or fully completed regarding 60% (39/65) of joint crisis plan holders.	case manager NA; e. Change in level of control over mental health problem (joint crisis plan holders 71% at immediate follow-up vs 56% at 15 months; case manager NA) f. Change in involvement in care – joint crisis plan holders 76% at immediate follow-up vs 50% at 15 months; case manager NA. Change in care – joint crisis plan holders NA at immediate follow-up, 14% at 15 months; case manager 53% at 15 months. At 15 months, positive response had widened to 14–82% (N = 50). 39–85% of case managers (N = 28) responded positively at 15 months. Changes in holders' views between immediate vs. 15 month follow-up – Summed responses of participants who had completed both the initial and follow-up questionnaires (n = 35) showed a shift in ratings, from positive to no change, from the immediate follow-up to 15 months (means 6.1 vs. 8.3, difference 2.2, 95% CI 0.8 to 3.7, McNemar's P = 0.003; a higher score indicates less positive views). One individual change – the likelihood of continuation with treatment as a result of developing the joint crisis plan was statistically significant (36% of comparisons showed a positive to no change/negative shift compared to 3% in the opposite direction; McNemar's P = 0.002). The least shift occurred in the response to whether joint crisis plan holders would recommend a joint crisis plan to others receiving mental health services. Ninety per cent gave an affirmative answer at the immediate follow-up, and this percentage had changed little (82%) at 15 months. Summed responses of participants and their case managers at 15 months (data available for 30). Case managers were more positive than participants (means 5 vs. 7.8, difference -2.8, 95% CI −4.5 to −1.2, McNemar's *p* = 0.002).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		In summary, the joint crisis plan was liked by most holders and case managers, providing evidence for the feasibility of shared decision-making in psychiatry. It also suggests that both producing and holding the joint crisis plan promotes self-determination and empowerment among service users. The impact of the joint crisis plan shifted in the direction from positive to no change over the 15 months follow-up period, in terms of overall ratings and for the question on its impact on the likelihood of the holder's continuing with care. The two highest endorsements which showed least shift over time were: whether the participant would recommend the joint crisis plan to others (90% initial vs. 82% at 15 months) and whether they felt more in control of their mental health problem as a result (71% at initial vs. 56% at 15 months).	

13. Horn R (2014) 'I don't need my patients' opinion to withdraw treatment': patient preferences at the end-of-life and physician attitudes towards advance directives in England and France. Medicine, Health Care, and Philosophy 17: 425–435

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The author presents '… the results of a qualitative interview study exploring English and French physicians' moral perspectives and attitudes towards end-of-life decisions when patients lack capacity to make decisions for themselves. The paper aims to examine the importance physicians from different contexts accord to patient preferences	**Participants:** Professionals/practitioners – 28 hospital-based physicians, 14 in England and 14 in France. They came from a variety of specialisms whose practice included providing or arranging end-of-life care and treatment. 'Out of the 14 English physicians, 3 were oncologists, 3 neurologists, 3 palliative care specialists, 3 nephrologists, and 2 were geriatrics. In France, out of 14 physicians, 3 were oncologists, 3 neurologists, 3 palliative care specialists, 2 nephrologists, 2 were geriatrics, and 1 doctor worked in intensive care.' (p427). **Sample characteristics:**	The philosophical and historical differences between England and France have led to advance directives holding different positions in the legal systems of the 2 countries. In English law, patient autonomy is central, so that a competent patient's refusal of treatment has to be treated with respect. The patient's wishes as expressed in the advance directive (provided it is voluntary and sufficiently informed) are binding in common law, even where the patient has since lost competence. Where it would involve withdrawing life-sustaining treatment, the advance directive must be in writing, and signed and witnessed. The patient can appoint someone to make the decision for them. Where there is no advance directive the decision is taken on the basis of what is in the patient's best interests. In France, although patients have had the power to make	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
and to explore the (potential) role of advance directives (ADs) in each context [...] Identifying cultural differences that complicate efforts to develop the practical implementation of ADs can help to inform national policies governing ADs and to better adapt them to practice ...' (p425–6). **Methodology:** Qualitative – semi-structured face-to-face interviews. **Country:** Range of countries – United Kingdom and France. **Source of funding:** Other – Range of research grants provided to the author.	• Age – Not reported. • Gender – 7/14 English interviewees were female, as were 5/14 French interviewees. • Ethnicity – The study refers to '14 English and 14 French physicians' (p427), but it appears to be referring to physicians who work in English and French hospitals, rather than their actual nationality, e.g. the description of the recruitment process refers only to recruiting from university hospitals located in cities in each country, and makes no reference to nationality being a criterion. Given the international nature of NHS staff, choosing only English staff would make that part of the sample highly unrepresentative. However, nothing in the report indicates that it is nationality which is being referred to, so we must assume that it is French and English workplaces that are being referred to, rather than French and English doctors. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – All interviewees were specialist hospital doctors. 'Out of the 14 English physicians, 3 were oncologists, 3 neurologists, 3 palliative care specialists, 3 nephrologists, and 2 were geriatrics. In France, out of 14 physicians, 3 were oncologists, 3 neurologists, 3	advance directives since 2005, doctors can take them into account but do not have to – the patients' are indicative, not determinative, with the doctor making the final decision. English doctors all stated how important it was to have discussions about withdrawing or withholding treatment with the patient. Issues that arose in interviews with English doctors included: concern about making such decisions on behalf of another person who was unable to communicate; picking the 'right time' for holding these discussions, preferably once they had got to know the patient; holding these discussion with patients with neurodegenerative disease; and the acknowledgement that it would be implicit in the discussion that life was now limited for the patient, said by one interviewee to be connected to doctors' difficulties with facing their own mortality. The study considers that English '... physicians seem to be torn between their wish to respect patient preferences, which is emphasised in law and professional guidelines (*Mental Capacity Act 2005*; General Medical Council 2008, 2010; Liverpool Care Pathway 2012) and their unease about communicating a bad prognosis. Hence, deciding to discontinue life-sustaining treatment where the patient's wish is not clearly known is a dilemma for English physicians ...' (p428). Although French law in 2005 ostensibly strengthened patients' rights, the study considers that 'by clarifying the conditions under which a physician can withdraw/-hold life-sustaining treatment in accordance with their professional opinion, the law principally focuses on reassuring physicians of the legitimacy of their acts' (p428). One French interviewee stated "I don't need my patients' opinion to withdraw treatment […] If I think that the patient shouldn't be resuscitated, that she has no chance, I don't need her opinion for this." (Participant, p428). However, another interviewee stated that she would never	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	palliative care specialists, 2 nephrologists, 2 were geriatrics, and 1 doctor worked in intensive care.' (p427). **Sample size:** Total N = 28 (n = 14 French; n = 14 English).	stop treatment, and said that to do so would feel like betraying her patients – she finds it very hard to respect a treatment refusal. The study considers that these 2 different responses are actually similar in their attitude towards patient wishes: “Where the doctors have a strong opinion about the medical decision they do not consider the patient’s will. The latter is evoked only in cases where it supports the physician’s decision …” (Participant, p429). One interviewee stated that “… most physicians still maintain a curative perspective and always want to go further in order to avoid death …” (Participant, p429). One doctor interviewed even called this attitude the “… barbarism of French doctors …” (Participant, p429). Although the French interviewees did recognise some limits to this, e.g. if a patient was in a persistent vegetative state for 3 months, none of them gave patient preference as being 1 of the criteria on which basis they would maker end-of-life treatment decisions. English doctors stressed the importance of making sure patients were making an informed choice at a time when they were competent. If they were not competent and did not have a valid advance decision, doctors would still try to take into account their known views and information from family, friends and the general practitioner. However, since families can find it hard to make a decision which could involve feeling as though they were the agent of death for a loved one, one doctor described how she makes it clear to families that responsibility for the decision is hers alone. The French doctors also considered it important to give patients information before asking for their opinion, but were doing so for different reasons. They believed that they should let the patient know their clinical views because '”… the final decision remains medical …” (Participant, p430). They want to reassure the patients that they will be treated in accordance with social values of humanity, dignity and solidarity. English doctors expressed some doubts about	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		whether advance decisions genuinely expressed a patient's wishes – they were a snapshot of what they thought at one moment, and they could feel differently when actually facing the situation. There was also a recognition that it is a difficult discussion for doctors, discussing treatment and possible demise at the same time. However, French doctors were more likely to question the existence of advance directives, as they felt it was a problem that could not be resolved by 'signing a paper' (p432). English doctors did make some suggestions for improving advance decisions: having it on a smart card or microchip everybody carried; including the general practitioner; standard advance decisions on medical files; and more discussion with patients so it is less of a bureaucratic exercise. French doctors also thought advance decisions could be improved, but did not make concrete suggestions for doing so.	

14. Kazmierski M and King N (2015) Role of the community matron in advance care planning and 'do not attempt CPR' decision-making: a qualitative study. British Journal of Community Nursing 20: 19–24

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The overall aim of the study was to explore community matrons' experience of end-of-life decision-making for individuals with a life-limiting long-term condition, focusing in particular on advance care planning and Do Not Attempt Cardio Pulmonary Resuscitation decision-making.	**Participants:** Professionals/practitioners – Community matrons. **Sample characteristics:** - Age – Not reported. - Gender – Not reported. - Ethnicity – Not reported. - Religion/belief – Not reported. - Disability – Not reported. - Long-term health condition – Not reported. - Sexual orientation – Not reported.	<u>Experiences of training in Advance Care Planning and use of Do Not Attempt Cardiopulmonary Resuscitation documents</u> – 5 of the participants had been in post for at least 3 years, yet none of them had received any training in Do Not Attempt Cardio Pulmonary Resuscitation decision-making: "Being new to the role, it's not something that gets talked about, but you don't get any training in how to approach it, really." (Participant, p21). Another participant reported that she had attended an advanced communication course but felt that it did not relate to caring for patients with a long-term condition, especially	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Methodology: Qualitative – broad interpretive phenomenological perspective. **Country:** United Kingdom. The research was conducted within the NHS Yorkshire and the Humber region. **Source of funding:** Not reported.	• Socioeconomic position – Not reported. **Sample size:** N = 6.	the difficulty clinicians have when deciding the appropriate time to put in a Do Not Attempt Cardio Pulmonary Resuscitation request. When the authors investigated why the Community Matron had not been included in this training, it was reported that: "…Thinking about where I work at the present which is [location of work and area], is that the community matron's role in palliative care hasn't particularly been seen to be, erm, that important. It's been mainly district nurses have very much taken the lead on palliative care, erm, and…advance care planning." (Participant, p21). <u>Personal experiences with Advance Care Planning and use of Do Not Attempt Cardiopulmonary Resuscitation documents</u> – All participants expressed confidence with the concept of advance care planning and Do Not Attempt Cardio Pulmonary Resuscitation decisions, particularly when they knew the patient/family were in agreement with the decision-making process and/or they knew them well. However, when it came to actually signing the Do Not Attempt Cardio Pulmonary Resuscitation form, many participants were not confident completing the form and expressed insecurity. "I've not actually spoken to a lot of patients and ...their families about do not resuscitate ...To be quite honest I've stayed clear of it really." (Participant, p21). Four of the participants expressed: "To be honest, on reflection of that, I think most of my patients should really have some sort of advance care plan from now." <u>Role in palliative care</u> – All the participants felt that the Community Matron role was a palliative role. "I think it's just like being a palliative care nurse, really; that's what I truly feel." (Participant, p22). Another participant felt that the Community Matron was in the best position to lead on palliative care with patients with a long-term condition, as their advanced clinical skills,	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		knowledge of long-term conditions and case management were unique among professionals in the community. Working collaboratively with other professionals around long-term conditions, symptom management and ensuring that they know the patient's journey was seen as: "… enhancing the end-of-life care pathway for the patient …" (Participant, p22). <u>Long-term conditions versus cancer</u> – Participants in the study continued to struggle to get patients on the Gold Standards Framework register in their practice because they were not deemed to be palliative: "We only think of palliative as cancer. Every one of my COPD patients should be on that Gold Standards Framework, but I can't get them on there—you know I can't—it's, there's still that thing of trying to get through to the GPs and I think until that's done the only people that are there is the community matrons …" (Participant, p22). "I still think GPs struggle to [know]... when to put [the DNACPR form] in, especially if they're long-term conditions. Cancer patients, they're quite happy, but for long-term conditions there's still that ... they don't know whether we are gonna actually make them better this time." (Participant, p22). <u>Relationships: knowing patients well</u> – Participants felt that because they knew their patients well, they were able to recognise clinical deterioration against the patient's norm rather than standard or expected levels: "Well, because, I mean, she runs on saturations around 82 most of the time, but if you go in and they're 70 you know something's pretty wrong …" (Participant, p22). "[The] community matron... are often in that unique role, but I also see us being in a position where we are able to	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		care coordinate and be a very valuable ... professional in the end-of-life care in helping other people understand the journey that they've come on and where they are ... from a disease progression and symptom management and work alongside district nurses, Macmillan nurses, specialist nurses and the wishes of the patient in wherever they wish to end their life …" (Participant, p22). <u>Communication: transfer of care and lack of discussion</u> – All participants described scenarios, often traumatic, whereby patients had been transferred back into the community with a Do Not Attempt Cardio Pulmonary Resuscitation order in place but with no proper discussion with the patient or their family. One participant described a case where the patient had been very ill and placed on the Liverpool Care Pathway in hospital. He then made a recovery and was discharged home with no review of the Do Not Attempt Cardio Pulmonary Resuscitation status: "He was given a DNR form and, when he came home, the form was sent with him, which his son-in-law promptly waved in my face and said 'what do you think of this?'" (Participant, p23). There appeared to be specific barriers when discussing advance care planning and Do Not Attempt Cardio Pulmonary Resuscitation orders; in particular, it was seen as negative by the patient and their carers. One participant felt that the recent negative press had had an impact in the sense that more people were aware of Do Not Attempt Cardio Pulmonary Resuscitation decision-making, but in a negative way. She felt that if she broached it with patients they would think she was trying to 'euthanise them'. When one participant was asked why they had not initiated Do Not Attempt Cardio Pulmonary Resuscitation orders,	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		they replied that it was because they went in with "… a positive outlook in goal setting …" (Participant, p23) implying that discussing advance care planning would be seen as negative by the patient.	

15. MacPherson A, Walshe C, O'Donnell V et al. (2013) The views of patients with severe chronic obstructive pulmonary disease on advance care planning: a qualitative study. Palliative Medicine 27: 265–272

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The study was designed to '… explore the views of people with severe COPD about advance care planning.' (p265). **Methodology:** Qualitative – semi-structured interviews. **Country:** United Kingdom. **Source of funding:** No external source of funding.	**Participants:** Service users and their families, partners and carers – Patients with advanced chronic obstructive pulmonary disease. **Sample characteristics:** • Age – Range 58–86 years. • Gender – 9 male, 1 female. Ethnicity – All white British. • Religion/belief – Not reported. • Disability – Not reported • Long-term health condition – All had advanced chronic obstructive pulmonary disease. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** N = 10.	The primary issues to emerge from the data from the interviews were: provision of information; decision-making; experiences of discussions about the future; and the views expressed by participants about planning for their future, in particular, where they would be cared for in the future. Participants reported not having had much discussion with health professionals about the nature of chronic obstructive pulmonary disease, making some angry about this lack of communication. One participant said: "Nobody's ever talked to me about anything really, seriously. I did...I said to you I didn't even know I had COPD. That's how much the doctors have talked to me." (Participant, p268). All participants were aware of chronic obstructive pulmonary disease being a disease which was progressive and would in the end be fatal, but this was from seeing what happened to other people with chronic obstructive pulmonary disease or observing how it had progressed in themselves. Many had a fatalistic attitude, and felt there was not much anybody could do. Most of the participants had not had discussions with healthcare professionals about the future – only 2 had. "The first had consisted of a district nurse mentioning that he [the participant] was very unwell, and had he thought about the future, which he took to mean had he planned	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		his funeral. He had become very upset by this, and had complained about that nurse.” (Participant, p268). The other was initially upset when he was asked to think about what healthcare he might want in the future, but said it no longer bothered him. He had had time to think and prepare for completing a 'preferred priorities of care' document with his community matron. “He knew that he would prefer to be at home; however, he was uncomfortable documenting this, and felt that this decision could change depending on the circumstances: "They kept asking me in the hospital, well what do you want to do? Do you want to be at home, do you want to be in here? Well you don’t know until it happens." (Participant, p268). The experience of other participants was of discussions with health professionals that focused on the present and on their current problem, with future preferences for treatment never discussed. Most of them did want more information about how their illness would progress, but felt awkward about bringing it up themselves. However, some were not interested in discussing the future, as they felt the discussions would not change anything. However, participants did want to be involved in discussions about treatment options and in decisions about their treatment, and trust in their healthcare provider could be damaged if decisions were taken without their involvement, e.g. a change in medication. A few did prefer their doctors to generally make the decisions and felt that they would be happy to go along with that. They would have a responsibility as patients to raise it if they felt there were any concerns. However, these participants did still welcome being included in the discussion, which they felt showed respect for their opinions. Although	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		they liked to be involved in discussions about current treatment options, participants were more circumspect about making advance decisions concerning future treatment, and found it hard to see why this would be helpful. Due to the way their symptoms could vary considerably, they were all used to making routine decisions themselves day by day as needed. Although they usually had a fair idea of what they wanted, they did not feel this firmly enough to make a binding decision for the future: '"I mean, because I don't know how I would feel until I get there, you know, so... I don't make advance decisions, you know." (Participant, p269). "People had often discussed these general preferences for care with family members, and would expect their family to have input into decisions if unable to decide for themselves. Participants had not discussed these preferences with healthcare professionals, but, as above, all participants stated they would be comfortable with these discussions if asked …" (Participant, p269). Place of care was the most important future consideration identified by participants. They had often thought about this more than they had thought about particular treatments. There were 2 main considerations in participants stating where they would prefer to be cared for. Previous experience of a particular environment was a strong factor. Due to previous negative experiences of hospital, some would only go there as a last option, and being cared for at home was a way of avoiding repeating such negative experiences: '"Last thing at night, nurses had some rubbish and they'd go up with the lid then, let go of the lid and crash! And this is all I remember. That was my main complaint. They were coming round with drugs at two, three o'clock in the morning. You're up again at five. Oh, I just couldn't get no sleep. And nobody could tell me	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		what was wrong with me. Nobody could tell me what was wrong with me. And I swore I would never go back there again." (Participant, p269). The issues participants expressed with hospital care were lack of care by hospital's healthcare staff, lack of communication to them about managing their condition, and the treatment being no different to what they could have at home. The other consideration was the amount of social support participants would have at home, with higher levels of support needed if they became unwell, a particular concern for those living alone. “People identified their family as the main source of support at home; they felt that if their family could not support them at home, they would go to hospital …” (Participant, p270).	

16. Musa I, Seymour J, Narayanasamy MJ et al. (2015) A survey of older peoples’ attitudes towards advance care planning. Age and Ageing 44: 371–376

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The aim of the study was ‘… to assess the attitudes of older people in East Midlands [towards advance care planning] through the development and administration of a survey.’ (p371) **Methodology:** Survey – postal survey. **Country:** United Kingdom – East Midlands. **Source of funding:**	**Participants:** Service users and their families, partners and carers – The study population was not restricted to service users. They were people over 65 who were contacted via their general practitioner’s surgery. There was no requirement to have, or be considering, or be in a position where they might want to consider an advance care plan. **Sample characteristics:** • Age – Respondents to the survey were all aged 65 or over. The median age was 73. For multivariate analysis they were grouped into age bands 65-74, 75–84 and 85+, but data on how	Only 84 of 1,823 respondents (4.6%, 95% CI 4.0 to 5.7%) stated that they had been offered an opportunity to talk about advance care planning. This was consistent across the various practices (range 0–8%). Of the 84 respondents who had discussed advance care planning, 58 (70%) had prepared an advance care planning document (which included an Advance Decision to Refuse Treatment order or an advance statement of wishes and preferences). Multivariate predictors of completing an advance care planning document included: ‘being offered the opportunity to discuss advance care planning (OR = 16.5, 95% CI 13.2 to 35.9), older age group (OR = 1.5, 95% CI 1.1 to 2.0), better physical function using the Katz scores (OR 0.6,	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Voluntary/Charity – British Geriatrics Society and the Sasakawa Foundation.	many respondents were in each age band was not provided. - Gender – 59% of respondents were female. - Ethnicity – 5% of respondents were non-white. - Religion/belief – 15% of respondents were non-Christian. - Disability – Not reported. - Long-term health condition – Not reported. - Sexual orientation – Not reported. - Socioeconomic position – 'There was an equal spread across the social class groups; however, a relatively smaller proportion (3%) was from the professional group' (p374). 'The deprivation score ranged from 6% to 52%' (p373) which was scored using the Index of Multiple Deprivation. **Sample size:** 5,375 questionnaires were sent out, and 1,823 valid (i.e. not blank) questionnaires were returned.	95% CI 0.4 to 0.9) or male gender (OR 0.5, 95% CI 0.3 to 0.8)' (p374). Of 1,823 respondents (4%, 95% CI 1.5 to 7.9%), 77 had prepared an advance decision to refuse treatment. Again there was no significant association with the size or location of the general practitioner's surgery. Multivariate predictors of completion of an Advance Decision to Refuse Treatment order included: being offered the opportunity to discuss advance care planning (OR 10, 95% CI 4.5 to 19.7), older age (OR 1.5, 95% CI 1.0 to 2.2) and male gender (OR 0.5, 95% CI 0.2 to 1.0). 219/1823 respondents (12%) had approached somebody with a view to discussing advance care planning. One hundred and fifty-nine of these (73%) had spoken with family or friends, 38 (18%) with their general practitioner, and 15 (5%) with another health or social care professional. 63 had also discussed advance care planning with 'others', mainly family and friends. 1350/1823 (74%) 'felt it would give them comfort knowing they have left some guidance for their family through engaging with advance care planning, while 57 (3%) respondents disagreed. A total of 1,101 (60%) respondents would only talk about advance care planning if the topic was raised with them.' (p374). 796/1823 respondents (44%) replied that if they were unable to express themselves, they would leave decisions about their health to others. Of these, 603 (76%) agreed with the statement that they would trust their doctor/health professionals to make these decisions and 749 people (94%) would trust their families to make the right decisions for them.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		'Overall, despite whether the respondents would leave decisions to others or not, 1,557 of 1,823 respondents (85%) would trust their families to make the right decision for them and 1,078 of 1,767 (61%) respondents would trust their doctor. Finally, 1,557 of 1,823 respondents (85%) would rather discuss decisions informally than write them down.' (p374). Six hundred and eleven (34%) of respondents thought there was no point in planning, as it would not change what would happen, but 856 (47%) disagreed. Respondents of an Asian background and those with strong religious beliefs were the most likely to think there was no point in planning; 1228 (67%) thought there was no point in planning unless there was help to meet the wishes; 1,076 (59%) felt that it was difficult to know whether their wishes would be respected if a care plan was prepared. Of the 1,823 respondents, 636 (35%) were worried that doctors would stop treatment too soon if they had an advance care plan (p 374). 'About one-third of respondents, 597/1,823 (33%), were interested in attending sessions on advance care planning if available: 696/1,823 (38%) people would not be interested and 507/1,823 (28%) people were not sure. In the multivariate analysis, independent predictors of willingness to engage in advance care planning training session included: male gender (OR 0.6, 95% CI 0.5 to 0.8) and older age (OR 0.6, 95% CI 0.5 to 0.8). More than one-third of respondents 648 (36%) would be interested in talking with their doctor about advance care planning at an annual check-up, with 422 (23%) respondents not being interested and 293 (16%) people being unsure.' (p374). Around 1 in 6 (17%) of respondents had actually prepared some sort of advance statement, with 1 in 25 (4%) completing an Advance Decision to Refuse Treatment order.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		People were most likely to make an advance statement if they had been offered the chance to do so. There was a preference for expressing these views informally, and for having these discussions with their families rather than professionals. The survey did not show why people preferred to talk to family, but preliminary focus group discussions showed that 'participants perceived issues relating to advance care planning to be of a sensitive nature and that they felt more comfortable discussing these with loved ones in an informal environment. Thirty-five per cent (35%) of the survey respondents were worried that doctors would stop treatment too soon if they had an advance care plan and 59% were concerned that even with an advance care plan in place their wishes might not be respected.' (p375). 'Predictors of completing any ACP document included: being offered the opportunity to discuss ACP, older age, better physical function represented by Katz scores and male gender.' (p375).	

17. Preston H, Cohen Fineberg I, Callagher P et al. (2011) The Preferred Priorities for Care document in Motor Neurone Disease: Views of bereaved relatives and carers. Palliative Medicine 26: 132–138

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors aimed to explore the experiences of bereaved relatives of people with a motor neurone disease regarding their views on Preferred Priorities for Care documents and the impact of these on end-of-life care.	**Participants:** Service users and their families, partners and carers – Bereaved relatives of people with a motor neurone disease. The inclusion/exclusion criteria were: '… the patients must have died at least 3 months prior to the study and had completed a PPC document during life. All patients were over 18 years of age. Non-English speaking relatives or carers and those lacking the capacity to consent	The authors report that 4 main themes arose from interviews regarding Preferred Priorities for Care documents. Completion – The authors note that this theme was comprised of 3 further subthemes. Persons involved in completion – The majority of participants reported that their relative had completed their Preferred Priorities for Care document with both a relative or carer and a healthcare professional. This professional was	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Methodology: Qualitative – Semi-structured face-to-face interviews. **Country:** United Kingdom – England – Preston. **Source of funding:** No external funding provided.	or experiencing significant health problems were excluded.' (p133). **Sample characteristics:** • Age – The authors report that the majority were over 65 years of age. • Gender – The authors report that the majority were male. • Ethnicity – The authors report that most participants were white British. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** N = 11.	usually a specialist motor neurone disease nurse or a district nurse. All interviewees were reported to have believed that these were the most appropriate practitioners to be involved given the fact that they had an established relationship with the patient and that the patient felt comfortable with them. Timing – The authors report that the Preferred Priorities for Care documents had been completed between 2 and 17 months prior to the death of the patient. However, they note that almost all of the participants recalled that their relatives had begun to discuss their preferences before use of the Preferred Priorities for Care document. Relatives reportedly emphasised that it was important that these documents had been completed during a period in which their relative was still able to communicate verbally or sign the document. In cases where a patient had lost the ability to talk; some relatives felt that the document should have been completed before this point. In contrast, the authors note that for those interviewees with a "… strong sense …" (p133) of their relatives' wishes, timing was less significant. They go on to note that none of the participants had reviewed the Preferred Priorities for Care document after it had been completed. "Nudging a big button, a very slow word processor, is not the same as talking and I think . . . if we had done it January February time . . . [patient] would have been able to express probably more forcefully her feelings." (Participant, p133). Experience of completion – The authors' state that the majority of participants viewed the completion of the document as a positive experience which was especially valuable for their relative through provision of peace of mind/relief. Participants also reported that they had found the experience to be emotionally difficult. While the majority	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		agreed with the wishes of their relatives, the authors note that 1 participant did not. Document availability to others – The authors note that the people to whom the Preferred Priorities for Care documents were shown tended to be either family and friends or healthcare practitioners. Family and friends – The majority of participants reported that patients had shown the document to other members of their family or friends, and that this often took place soon after the document had been completed. However, 2 participants reported that the document had been regarded as private and not shared with others. "Everybody, all the family and husbands and wives all read it and all said 'Yeah, Ok we understand it' so if I wasn't here and anything happened they knew and they knew where the document was." (Participant, p134). Healthcare professionals – The authors report that the documents were less likely to be shared with practitioners; with only 2 participants reporting that the document had been shown to all healthcare practitioners involved in the care of their relative, and less than half of the interviewees reporting that it had been shared with a General Practitioner or District Nurse. The authors go on to report that several participants reported that they had shared the document with a paramedic in an attempt to prevent hospitalisation of their relative; however, they note that once their relative had been taken into hospital, only half of the participants stated that they had shared it with hospital staff. Similarly, the authors found that interviewees were more likely to tell practitioners about the existence of the document than show it to them. The authors also report that participants who had a 'strong' understanding of their relative's wishes were less likely to believe that showing the document to professionals was important.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		"Yeah well there's no point in the document if people don't know it exists especially if it's to do with someone's care errmm, so everybody who came into contact I showed 'em the document and give 'em time to read it." (Participant, p133). "I actually told him 'She's got a document' I told 'em all but no one actually asked to see it." (Participant, p133). Importance and influence on the end-of-life experience – Importance – The authors state that Preferred Priorities of Care documents were, on the whole, seen as a valuable tool, particularly as they can provide peace of mind for patients and increase the awareness of professionals with regard to patient wishes. "It was formalised, everyone knew what [patient) wanted and everybody worked to give her that and we had confidence then that if she did go into hospital and we weren't with her at least the document was there and everybody knew what was required." (Participant, p134). The researchers note that those participants who had a "… strong agreement with patient wishes …" (Authors, p134) did not see the document as particularly useful; however, they reportedly acknowledged that it might be found useful by others and that it had on some occasions prompted a discussion regarding an issue that had not previously been discussed such as resuscitation. "I think we knew from the very beginning of what we wanted . . . they all knew exactly what we wanted, see, so I wouldn't say you could forget the document but in our case I'm not entirely certain the document actually worked." (Participant, p133). Influence on the end-of-life experience – The authors note that while participants viewed the document as important,	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		a number of them felt that its impact on end-of-life care was minimal, and that their own awareness of the patient's wishes had been more influential. "I tend to suspect that it was more us made it happen rather than that piece of paper . . . If I was to be honest I can't say that document made [patient's] end of life as she wanted it, I think that was us that did it." (Participant, p134). The authors also note that 2 participants felt that the document had had a negative impact, however, they do not provide further details in relation to this finding. Despite a small number of negative views regarding the document, the authors report that the majority of participants stated that they would use one themselves or recommend them to others. However, there were also concerns from many regarding the extent to which healthcare professionals take these into consideration. "If they're wishes are implemented, yes, but if hospital staff are going to completely ignore any of their wishes why bother?" (Participant, p135). <u>Limitations of Preferred Priorities of Care documents</u> – participants reportedly identified a lack of awareness among practitioners as a major barrier to the effective use of a Preferred Priorities of Care document, particularly during admission to hospital. The authors state that issues tended to arise when staff did not understand the purpose of the document or appeared to ignore the stated wishes of the patient. The authors report that participants therefore felt that awareness of the documents needed to be improved. "I think it were the, the not knowing outside the people that knew about the, the disease . . . that's the only point that we felt the document was useless was the fact that not	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		enough people knew about the document." (Participant, p135).	

18. Seamark D, Blake S, Seamark C et al. (2012) Is hospitalisation for COPD an opportunity for advance care planning? A qualitative study. Primary Care Respiratory Journal 21: 261–266

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The aim of this study was '… to examine whether an admission to hospital for an exacerbation of COPD is an opportunity for ACP and to understand, from the patient perspective, the optimum circumstances for ACP.' (p261). **Methodology:** Qualitative – interviews. **Country:** United Kingdom. **Source of funding:** Other – Royal Devon and Exeter NHS Foundation Trust Research and Development Directorate.	**Participants:** Service users and their families, partners and carers – People with chronic obstructive pulmonary disease and their carers. **Sample characteristics:** • Age – Patients were aged from aged 5890. • Gender – 4 females; 12 males (patients). • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – 3 patients had mild disease, 6 had moderate disease, 6 had severe disease and 1 had very severe disease. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** N = 16.	Was advance care planning discussed in hospital? No patients remembered discussion in hospital about issues of resuscitation, the possibility of being ventilated, and planning for future exacerbations. One patient had a directive kept at home asking not to be resuscitated; however, the form was left at home when the patient attended hospital. Possible reasons for lack of discussion about advance care planning appeared in the following theme. Hospital admission and discharge – chaotic and too ill to engage – Most patients (14 of 16) were admitted as rushed emergencies with little discussion with the ambulance crew or attending medical professional. "I was seen by a doctor as far as I can remember and pushed into hospital." [Patient 8] (p263). No chance to think, I was whipped in and that was it – 'you're going'." (Participant, p263). Most patients thought admission was chaotic, confusing and lacking in continuity. Extreme illness made decision-making and recall of events extremely difficult. For instance, none of the patients remembered end-of-life care discussions with hospital staff during their admission. Attitudes to advance care planning – All patients in the sample agreed to talk about advance care planning and related matters, but many found it emotionally difficult and preferred not to make decisions, while for others advance care planning provided an opportunity to focus on the problem. Advance care planning was also considered an area where it could be hard to make firm decisions. With	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		resuscitation, for example, the commonly held view was that patients would only consider this as an option if a successful outcome could be guaranteed, therefore it seemed more rational that this was a medical decision to be made by clinicians. Who to talk to – someone you know or someone who knows? In response to the question who should discuss advance care planning, there was a desire for a familiar person as well as a person who had expertise in their condition. Most patients favoured their own doctor as the person best placed to talk to them about end-of-life issues with the preferred setting being the home or general practitioners surgery in the period after admission. Some patients felt that family involvement in such discussions would be beneficial.	

19. Stewart F, Goddard C, Schiff R et al. (2011) Advanced care planning in homes for older people. Age and Ageing 40: 330–335

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The purpose of the study was to explore the views of care home staff and the families of older residents on advance care planning. **Methodology:** Qualitative – individual semi-structured interviews. **Country:** United Kingdom – London. **Source of funding:** Voluntary/Charity – Guy's	**Participants:** Service users and their families, partners and carers – Care home staff and the families and friends of care home residents. **Sample characteristics:** • Age – Not reported. • Gender – Not reported. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported.	Benefits of advance care planning – Staff and families spoke positively about advance care planning. However, family and friends failed to qualify why they perceived advance care planning as a good idea. "I think, so much of this stuff can be just tokenism ... my father, when I filled in something for him about his life but then I didn't hear anything about it after that …" Participant, p332). Staff felt advance care planning promoted respect for residents' wishes and aided their treatment decisions. Barriers to advance care planning – Staff and families identified residents who lacked cognitive capacity as a common barrier to advance care planning.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
and St Thomas' Charity.	**Sample size:** Care home managers – 33; Care assistant – 29; Nurses – 18; Community nurses – 10; Resident's family and friends – 15.	"Yeah if you ask mum where she'd want to be she'd say with me she doesn't know she's in a residential home, she thinks she's in a waiting room from the hospital, waiting to go home." (Participant, p332). Nurses and managers (the majority of whom were qualified nurses) identified unforeseen medical scenarios as barriers to fulfilling certain advance recommendations: "Somebody may tell you, yes I'd be happy to die here but if, during an end of life phase they have some terrific bleed there's no choice other than sending to hospital." (Participant, p332). Staff and family alike felt that the reluctance of some residents to discuss end-of-life issues were related to fear of thinking about death, and not feeling comfortable discussing these issues with care home staff and care assistants. They felt it should be the role of the resident's family to engage in advance care planning discussions and not the role of the staff. Some care home staff had difficulty with advance care planning because of their cultural beliefs: "I know there's other people [staff], some of them they have trouble discussing it …" (Participant, p332). Care assistants who reported reluctance were from a similar range of ethnic backgrounds to the nurses and managers, who themselves indicated no reluctance to engage in advance care planning discussions. Staff also perceived that at times family members are reluctant to discuss their relatives' preferences. This was attributed by staff to their reluctance to accept that their relative was towards the end of life. Conflict between family and staff over advance care planning was identified by care managers and nurses but not	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		by care assistants or family members. A common conflict concerned the nurses' and managers' awareness of the resident's wish to die in the care home, but family insisting on a transfer to hospital. Staff felt that families believed that their relative would receive better care in hospital. In contrast, staff believed the care home could provide a more comfortable setting for end-of-life care. "Relatives they've discussed with you and they've understood what the relative [wants] but at the last minute they've changed their minds, and they think that the hospital will be the best place for their relative." (Participant, p332). <u>Facilitators</u> – Perceived facilitators of advance care planning were: to involve family members to help establish the resident's preferences, staff who approach discussions with residents should have a prior familiarity with them and should start discussions early and in gradual stages before the onset of serious health problems. Advance care planning was also seen to be facilitated by providing guidance to staff on how to approach such discussions; some considering a direct approach and some felt an indirect approach. Family members and care assistants stated it was important to approach the subject sensitively.	

20. Stone L, Kinley J, Hockley J (2013) Advance care planning in care homes: the experience of staff, residents, and family members. International Journal of Palliative Nursing 19: 550–557

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: This study aimed to explore the experience of staff, residents, and families having advance care planning discussions within the context of care	**Participants:** Service users and their families, partners and carers – Care home residents and their families. Professionals/practitioners – Care home staff (5 registered general nurses and 1 healthcare assistant).	<u>Understanding advance care planning</u> – When asked to define the term advance care planning, there was no clear idea of what it was. Some staff understood the significance of recording residents' views and thoughts on end-of-life care and other staff thought advance care planning applied to everyday care. Similarly, residents' and families' understanding of advance care planning also varied, 1 resident	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
homes with nursing. **Methodology:** Qualitative – semi-structured interviews. **Country:** United Kingdom – England. **Source of funding:** Voluntary/Charity – St Christopher's Hospice.	**Sample characteristics:** - Age – Not reported. - Gender – Not reported. - Ethnicity – Not reported. - Religion/belief – Not reported. - Disability – Not reported. - Long-term health condition – Residents health conditions included cancer of the oesophagus and breast, muscular dystrophy, heart failure and rheumatoid arthritis. - Sexual orientation – Not reported. - Socioeconomic position – Not reported. **Sample size:** Eleven residents, 6 family members 6 staff (5 registered general nurses and 1 healthcare assistant).	relating it to end-of-life care and thinking that if someone was having such a conversation it suggested that they were going to die soon. Other residents thought advance care planning was about general everyday care: "Well, I'm not quite sure ... Continues all the time, yes, in my care, sort of thing ... And I can ask questions, you know, where I like and I get sensible answers for them." (Participant, p552). Undertaking advance care planning discussions – The decision to have an advance care planning conversation was frequently introduced through the monthly GSFCH meetings, where deterioration of a resident acted as the prompt. "She was identified as a lady who … might not survive more than a few weeks. She ... she's our most ill person." (Participant, p553). Decisions about when to undertake an advance care planning discussion varied between different individuals and families. For some, an advance care planning conversation was appropriate soon after admission, but for others it was too overwhelming to handle such discussions at this point. "You don't really want to load too much of the protocol when you're trying to just get to know the staff, get to know your surroundings ... she sort of left it with me as to when we would fill it out." (Participant, p553). Many staff simply found it challenging to make time to conduct an advance care planning discussion and some felt that it was not valued by colleagues and management. And some felt that it was not valued by colleagues and management. "Where you spend time talking to relatives, then you're not spending time nursing." (Participant, p553). Staff, particularly those with limited experience in palliative care, could be intimidated by approaching the subject of advance care planning. On the other hand, they had more confidence where relationships with the resident or family	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		member was good. The advance care plan document was usually used to guide advance care planning conversations or given to family members to look at. But this could be constraining as different ways of approaching the discussion were not considered. One resident found the approach of the staff member unsettling and felt that advance care planning was just another job that had to be done. “She, she came breezing in and she said she’d got something to fill in and ... ‘How, where do you want to die?’ ... There was, whatever question was at the top, she just read the question out and wanted a tick or a cross ... Well, I felt it was a bit premature: I wasn’t ready for that ...It wasn’t introduced, it was badly, you know, banged into.” (Participant, p553). <u>Impact of and reactions to advance care planning discussions</u> – Before the formal implementation of advance care planning, conversations had often been had with residents and/or families about the end of life, but these were usually casual and held during a crisis when a resident's health was declining. In contrast to staff apprehension about advance care planning conversations, the researcher felt that most residents were comfortable talking about end-of-life care. “Well it didn’t worry me ‘cos I wa-, I, I thought to myself ‘Oh well, they wanna know things.’ You know ... But er, they asked questions and I er, I just answered them.” (Participant, p554). Not all of the issues mentioned (e.g. worries about death) within the residents’ interviews had actually been written up on their advance care planning forms. An advance care planning conversation gave relatives an opportunity to talk about future care and to hear what their loved ones desired. It also provided a chance for them to plan for the future. "I thought well at least they know now what we want and all that ... The fact that we’d discussed it and they knew what we wanted.” (Participant, p554).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		The place of death seemed to be a priority of the advance care planning conversation. "It's her home, this is her home and this is where she wants to be, and this is where she wants to pass away." (Participant, p555). However, not all residents had indicated a preference and thought that staff and family were better placed to consider the best option. One occasion was discussed where the Gold Standards Framework in Care Homes facilitator had role-modelled an advance care planning discussion. This process helped a member of staff to learn about the advance care planning and supported change in practice.	

21. Whitehead B, O'Brien MR, Jack BA (2011) Experiences of dying, death and bereavement in motor neurone disease: A qualitative study. Palliative Medicine 26: 368–378

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To '… explore the experiences of people with Motor Neurone Disease (MND), current and bereaved carers in the final stages of the disease and bereavement period.' (p369). This included discussion of advance care planning. **Methodology:** Qualitative – narrative interviews (face to face and email). **Country:** United Kingdom – England – North West England.	**Participants:** Service users and their families, partners and carers – People with Motor Neurone Disease and carers of people with motor neurone disease (including recently bereaved). **Sample characteristics:** • Age – Patients – age range 25–84 years (at diagnosis); carers – age not reported. • Gender – Patients – female n = 16; male n = 9. Carers – female n = 14; male n = 14. • Ethnicity – Not reported for patients or carers. • Religion/belief – Not reported for patients or carers.	NB. Only those findings relating to planning in advance have been extracted. Anxiety – In addition to general anxiety regarding progress of their diseases and its final stages, the authors report that patients also worried that the deterioration in physical abilities and loss of communication ability would affect their ability to participate in decision-making. Advance care planning and end-of-life decision-making – The authors report that some participants felt that they needed more information in order to make end-of-life care decisions and that in some cases relevant information was being withheld. "… I would like to know how it will be managed and what my choices are …" (Participant, p372).	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Source of funding: Other – National Institute for Health – Research for Patient Benefit Programme.	• Disability – Patients had a motor neurone disease such as Amyotrophic Lateral Sclerosis, Progressive Bulbar Palsy, and Primary Lateral Sclerosis. No other details are reported. • Long-term health condition – Not reported for patients or carers. • Sexual orientation – Not reported for patients or carers. • Socioeconomic position – Not reported for patients or carers. **Sample size:** N = 53. NB The authors report in their narrative that there were 52 participants in total; however, data from the table suggest that the total number of participants was 53.	The authors go on to state that ensuring that individuals had the opportunity to outline their thoughts regarding future care was itself an important means of "… giving voice to people's wishes …" (Authors, p371) and that this could be achieved through both the use of tools such as a Preferred Priorities for Care document, or through discussion with practitioners. Despite the apparent utility of advance care planning tools, the authors report that there were concerns from some participants that patient preferences were not always honoured, and they note that 1 participant felt that such tools were unlikely to be of any use. In some cases, these were reported to have been ignored by practitioners, citing a bereaved carer who reported that her husband's Preferred Priorities for Care document had been disregarded: "… so when I see the A and E doctor . . .I said, 'look , can I show you?' he said 'Well, what is this, what are you talking about?', 'Well this is what my husband wants to happen' and I showed him the part where it says in the event of serious collapse, the patient does not want to resuscitated, but the A and E doctor said 'well it's not worth the paper its written on, what are you talking about?' " (Participant, p372).	

Research question 2. Supporting decision-making on the presumption of mental capacity:

- 2.1 – What interventions, tools, aids and approaches are effective and cost-effective in supporting people, on the presumption of capacity, to make decisions?
- 2.2 What are the views and experiences of people who may lack capacity, their families and carers, practitioners and others interested in their welfare on the acceptability of interventions, tools, aids and approaches to support people, on the presumption of capacity, to make decisions?

Effectiveness data

1. Dukes E and McGuire BE (2009) Enhancing capacity to make sexuality-related decisions in people with an intellectual disability. Journal of Intellectual Disability Research 53: 727–734

Research aims.	**PICO (population, intervention, comparison, outcomes)**	**Findings.**	**Validity ratings.**
Study aim: To apply an intervention to the area of sexual knowledge in order to determine if capacity to make sexuality-related decisions could be improved. **Methodology:** Quantitative – before and after study. **Country:** Ireland. **Source of funding:** Not reported.	**Participants:** Service users and their families, partners and carers – adults with moderate intellectual disability. **Sample characteristics:** • Age – 22–23 years. • Gender – 2 male, 2 female. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Stanford-Binet full scale IQ 45, 40, 40, 45. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – All were resident in community group homes. **Sample size:** N = 4. **Intervention category:** Support for decision-making – sex education. • Description – The sex education intervention was drawn from Living Your Life – The Sex Education and Personal Development Resource for Special Education Needs – Revised Edition (Bustard 2003). 'Living Your Life is specifically designed as a teaching resource for teachers and others working in both mainstream and special schools with young people who have learning difficulties. The researchers adapted the programme material to suit the one-to-one format of delivery and individual abilities." (p729) Worksheets, line drawings	Statistical data: Not reported and data not available to calculate. The results indicated that '… all four participants improved their knowledge in all targeted areas as measured by an increase in the number of SCEA items correctly answered after the intervention.' (p727) Higher SCEA scores are correlated with greater capacity to make sexuality related decisions – so the results show that capacity was improved through sexuality education. At six-month follow-up, three participants maintained their scores (from post intervention) on the S Scale (knowledge of safety practices) and some scores dropped at follow-up (from post intervention) on the K-scale (e.g. education on choices and consequences). For all three participants with follow-up scores, the follow-up scores were an improvement on baseline scores. There was no increase from pre to post or at follow-up on the inappropriate sexual behaviour scale. <u>Change in knowledge of safety practices (SCEA S-Scale, 10 items)</u> – Baseline: Marc, 7; Tina, 6; Josh, 5; Debbie, 5. Intervention: Marc, 8, 9, 10; Tina, 7, 8, 9; Josh, 6, 7, 9; Debbie, 6, 7, 9. Post-intervention: Marc, 10 (for 4 weeks); Tina, 9 (for 4 weeks); Josh, 7 (for 4 weeks); Debbie, 8 (for 4 weeks). Follow-up: Marc (no score reported); Tina, 9; Josh, 9; Debbie, 8. <u>Change in knowledge of the physical self (SCEA K-Scale, 4 items)</u> - Baseline: Marc, 2 (for 7 weeks); Tina, 2 (for 8 weeks); Josh, 2 (for 9 weeks); Debbie 2 (for 10 weeks). Intervention: Marc, 3, 4; Tina, 3, 4; Josh, 3, 4; Debbie, 3, 4.	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** −

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	and 2 anatomically detailed dolls (1 male and 1 female) were also introduced as additional elements of the programme. • Delivered by – Although not explicitly stated, it is likely that the researchers delivered the intervention. • Delivered to – Four adults with a moderate learning disability. • Duration, frequency, intensity, etc. – Twice weekly one-to-one sessions, each of 45-minute duration. • Key components and objectives of intervention – Four target areas – knowledge of sexual safety practices, knowledge of the physical self, knowledge of sexual functioning, and knowledge of choices and consequences in sexual matters. • Content/session titles – See key components. • Location/place of delivery – A 'private room' was used for the interviews but it is not clear where the education programme was delivered. **Comparison intervention:** No comparison intervention – the comparison was between baseline and end point scores. **Outcomes measured** – service user related outcomes - • Change in knowledge of safety practices, the SCEA S-Scale, items 1 to 10 were administered weekly at baseline, intervention and post intervention stages.	Post-intervention: Marc, 4 (for 4 weeks); Tina, 4 (for 4 weeks); Josh, 4 (for 4 weeks); Debbie, 4 (for 4 weeks). Follow-up: Marc (no score reported); Tina, 4; Josh, 4; Debbie, 4. <u>Change in knowledge of sexual functioning (SCEA K-Scale, 3 items)</u> - Baseline: Marc, 0 (for 9 weeks); Tina, 0 (for 10 weeks), Josh, 0 (for 11 weeks); Debbie, 0 (for 12 weeks) Intervention: Marc, 1, 3; Tina, 1, 2; Josh, 1, 2; Debbie, 1, 2. Post intervention: Marc, 2 (for 4 weeks); Tina, 2 (for 4 weeks); Josh, 2 (for 4 weeks); Debbie, 2 (for 4 weeks). Follow-up: Marc (no score reported); Tina, 2; Josh, 2; Debbie, 2. <u>Change in knowledge of choices and consequences in sexual matters (SCEA K-Scale, 5 items)</u> - Baseline: Marc, 1 (for 11 weeks); Tina, 1 (for 12 weeks); Josh, 0 (for 13 weeks); Debbie, 0 (for 14 weeks). Intervention: Marc, 2, 3, 5; Tina, 2, 3, 5; Josh, 1, 2, 3; Debbie, 2, 3, 5. Post-intervention: Marc, 4 (for 4 weeks); Tina, 5, 4 (for 4 weeks); Josh, 2 (for 4 weeks), Debbie, 5 (for 4 weeks). Follow-up: Marc (no score reported), Tina, 3; Josh, 2; Debbie, 3.	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	• Change in knowledge of the physical self, the SCEA K-Scale, items 1 to 4, were administered weekly at baseline, intervention and post intervention stage. • Change in knowledge of sexual functioning, the SCEA K-Scale, items 5 to 7, were administered weekly at baseline, intervention and post intervention stages. • Change in knowledge of choices and consequences in sexual matters, the SCEA K-Scale, items 8 to 12, were administered weekly at baseline, intervention and post-intervention stages. **Follow-up:** Six months. **Costs?** No. Costs and resource information not reported.		

2. Ferguson L and Murphy GH (2013) The effects of training on the ability of adults with an intellectual disability to give informed consent to medication. Journal of Intellectual Disability Research 58: 864–873

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
Study aim: To '… investigate the capacity of individuals with intellectual disabilities (ID) to make decisions about their medications, and to evaluate whether the provision of training (information) sessions on medications would increase their capacity.' (p864).	**Participants:** Service users and their families, partners and carers – adults over the age of 18 with a '… mild to moderate ID …' (p866) who were currently taking a specified medication for diabetes (Metformin), epilepsy/convulsions (Epilim), or a psychotropic medication (Haloperidol). Individuals were excluded if they were unable to consent to their participation in	The authors used a significance level of .01 to account for type 1 errors. Association between receptive language comprehension ability and capacity to give informed consent: Very strong positive correlations between scores on a measure of receptive language comprehension ability (British Picture Vocabulary Scale-II) and scores on a measure of capacity to give informed consent (Adapted – Assessment of Capacity Questionnaire) at baseline assessment (r = 0.903, p < 0.01); at first re-assessment (r = 0.873, p <	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
Methodology: Quantitative – before and after study. **Country:** United Kingdom – England. No further details reported. **Source of funding:** Not reported.	the study, if they were not taking medication, or if they were taking multiple medications. It is not clear how the researchers determined the 'level' of an individual's disability and how this impacted on selection procedure, although it is reported that after the initial identification of potential participants by practitioners, a number of individuals were excluded due to the severity of their intellectual disability or communication difficulties. **Sample characteristics:** • Age – Range 20 – 56 years; mean = 38.71 years; SD = 10.41 years. • Gender – Males n = 18; females n = 10. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – All participants are reported to have mild to moderate intellectual disabilities; however, it is not clear how this was determined and what role this played in the selection of the sample, for example, was a standardised tool used? Vocabulary age score was measured at baseline using the British Picture Vocabulary Scale-II (reported by authors to correlate closely with IQ scores): Mean raw score at baseline = 70.46 (SD = 5.51, range = 63 – 81). The authors report that this was equivalent to a mean vocabulary age score of 6 years and 8 months (range 6 years 2 months – 7 years 11 months).	0.01); and at second re-assessment ($r = 0.915$, $p < 0.01$). These results were significant. The authors report that the correlation between scores on a measure of receptive language comprehension ability (British Picture Vocabulary Scale-II) and the change in scores on a measure of capacity to give informed consent (Adapted – Assessment of Capacity Questionnaire, change in scores between first and second re-assessment, i.e. after the provision of training) was not significant ($p = 0.033$, no further details reported). NB. As these data do not demonstrate the effect of an intervention, they have not been included in the corresponding narrative summary or evidence statements. Association between baseline scores of capacity to give informed consent and first and second re-assessment scores of capacity to give informed consent: There was a very strong positive correlation between baseline scores and scores at first re-assessment ($r = 0.984$, $p < 0.01$), and baseline scores and scores at second re assessment ($r = 0.933$, $p < 0.01$) on a measure of capacity to give informed consent (Adapted – Assessment of Capacity Questionnaire). These results were significant. There was also a very strong positive correlation between first re-assessment scores and scores at second re-assessment on this measure which was also significant (i.e. post-intervention, $r = 0.933$, $p < 0.01$). Impact of training on capacity to give informed consent (measured by Adapted – Assessment of Capacity Questionnaire) – The authors report that in the statistical analysis, "… Mauchly's test indicated that the assumption of sphericity had been violated (chi-square = 12.53, $p < 0.01$). Degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity (epsilon = 0.71)." (p 869).	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	- Long-term health condition – Participants were included on the basis of the medications that they were taking; however, no information regarding specific diagnoses is reported. Participants were taking: - Epilim (n = 16, 57.1%); Haloperidol (n = 5, 17.9%); and Metformin (n = 7, 25%). The length of time for which participants had been taking these medications was on average 8.46 years (range 1 – 30 years). Epilim – average = 12.63 years (range = 1 – 30 years); Haloperidol – average = 2.4 years (range = 1-4 years); Metformin – average = 3.29 years (range = 1-5 years). The authors report that none of the participants were under the care of a psychiatrist. - Sexual orientation – Not reported. - Socioeconomic position – Details on sociodemographic background are not included; however, the authors report that 13 participants lived in supported living environments, 6 lived with their family, 1 lived alone and 1 lived in a family placement. **Sample size:** N = 28. **Intervention category:** Support for decision-making – information sessions/training to improve capacity to consent to treatment. - Description – Participants were provided with medication specific training sessions.	Difference between scores on a measure of capacity to give informed consent (measured by Adapted – Assessment of Capacity Questionnaire) at baseline, first re-assessment, and second re-assessment (post-intervention): Mean scores increased for all medication groups between baseline and second re-assessment. Epilepsy (n = 16) – baseline 4.69 (1.99), first re-assessment 4.81 (1.94), second re-assessment 6.38 (2.19). Haloperidol (n = 5) – baseline 4.20 (2.95), first re-assessment 4.40 (2.70), second re-assessment 6.60 (2.88). Metformin – baseline 4.71 (1.80), first re-assessment 4.57 (1.72), second re-assessment 7.14 (2.12). Analysis showed that there was a significant difference between scores at baseline, first and second re-assessment; ($F_{1.42, 35.55}$ = 180.60, $p < 0.01$; partial eta squared = 0.88). The results also indicated that there was no significant interaction effect between occasions (of assessment) and medication group; $F_{2.84, 35.55}$ = 4.21, $p > 0.01$. The between subjects effects (medication group) was also not significant; $F_{2, 25}$ = 0.054, $p > 0.01$. Post-hoc tests (using Bonferroni corrections): Difference between scores on a measure of capacity to give informed consent (measured by Adapted – Assessment of Capacity Questionnaire) at baseline assessment and at first re assessment: There was no significant difference in scores at baseline assessment (pre-intervention) and at first re-assessment (also pre-intervention) on a measure of capacity to give informed consent (measured by Adapted – Assessment of Capacity Questionnaire), $p > 0.01$ (no further data reported). Difference between scores on a measure of capacity to give informed consent (measured by Adapted – Assessment of Capacity Questionnaire) at baseline assessment (pre-intervention) and at second re-assessment (post-intervention): There was a significant difference in scores at	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	• Delivered by – Sessions delivered by lead author of paper. • Delivered to – Participants with mild to moderate learning disabilities. The sample were split into groups according to the medication which they were taking and sessions were provided in group format. Participants were told that their carers could also attend the sessions; however, none did so. • Duration, frequency, intensity, etc. – Participants received 3 sessions, no further details on length of sessions or frequency are reported. • Key components and objectives of intervention – Training sessions focused on reasons why medication was prescribed, risks and side-effects, the benefits of medication, and alternatives to medication. • Content/session titles – Session 1 – reasons for prescription of medication, physiological effects and possible side effects. Session 2 – Review of '… all the positive and negative things that could occur if the individual continued to take their medications.' (p868) Session 3 – Discussion of alternatives to medication, e.g. avoidance of alcohol or flashing lights for the group taking anti-epileptic medication. This session also appears to have included discussion of the Mental Capacity Act and capacity to consent with an emphasis on the importance of the individual being provided with the correct information about their medication and their rights	baseline assessment (pre-intervention) and at second re-assessment (post-intervention) on a measure of capacity to give informed consent (measured by Adapted – Assessment of Capacity Questionnaire), *p* < 0.01 (no further data reported). Difference between scores on a measure of capacity to give informed consent (measured by Adapted – Assessment of Capacity Questionnaire) at first re-assessment (pre-intervention) and at second re-assessment (post-intervention): There was a significant difference in scores on a measure of capacity to give informed consent (measured by Adapted – Assessment of Capacity Questionnaire) at first re-assessment (pre-intervention) and at second re-assessment (post-intervention), *p* < 0.01 (no further data reported). <u>Capacity to consent to medication –</u> NB. The authors judged a participant to have capacity to consent to their medication if they scored at least one point on each of the questions on the Adapted – Assessment of Capacity Questionnaire relevant to the medication they were taking. Baseline and first re-assessment (pre-intervention): n = 2 participants (2/28, 7%) were judged able to consent to their medication at baseline and first re-assessment (pre-intervention). Second re-assessment (post-intervention): n = 6 participants (6/28, 21%) were judged able to consent to their medication at second re-assessment (post-intervention). The authors report that this increase in the number of participants judged able to consent to their medications between baseline/first re-assessment and second re-assessment (i.e. after training) was not significant (Fisher's exact test *p* = 0.04).	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	to ask their doctor or other relevant practitioners for more information or clarification. 'It was stressed that each person who is deemed to be capacitous had the right to take or refuse their prescribed medications.' The authors note that no 'take-home information' was provided. (p868) • Location/place of delivery – Not reported. **Comparison intervention:** This is a before and after/pre-post study – the dependent variables were measured before and after the intervention was delivered. The guideline committee should note that it is, therefore, difficult to draw strong conclusions regarding the impact of the intervention. **Outcomes measured** – Service user related – • Knowledge regarding prescribed medications was measured using the Assessment of Capacity Questionnaire. • Capacity to consent to medication measured using the Assessment of Capacity Questionnaire. NB. The authors judged a participant to have capacity to consent to their medication if they scored at least 1 point on each of the questions on the Adapted – Assessment of Capacity Questionnaire relevant to the medication they were taking. NB. No further outcomes were measured.		

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	The Assessment of Capacity Questionnaire is comprised of 6 questions which are essentially the same except that the versions used in this study were adapted to make specific reference to the conditions which participants had and the symptoms which are a feature of these conditions. An example set of questions adapted for participants taking Haloperidol (psychotropic medication) is quoted below: ‘1. You sometimes feel angry. What has happened in the past when you get angry? 2. You sometimes feel angry. Can you tell me what things your doctor has tried so far to help to control your anger? 3. Your doctor suggested a treatment to help you control your anger. What did he do to help to reduce your anger? 4. The doctor gave you some tablets. Can you tell me some good things AND some bad things that could happen to you if you continue to take the tablets? 5(a). The doctor gave you some tablets to help to control your anger. What can you do now? 5(b). What do you think would happen if you said no to taking the tablets? 6. The doctor has suggested you take the tablets. What do you think you should say about taking the tablets now? Why do you think you should say this?’ (p867) **Follow-up:** Knowledge of medications and capacity to consent were measured at baseline, at a first re-assessment and		

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	at a second re-assessment (these re-assessments were conducted to determine whether '… the experience of first assessment and having time to consider information from baseline assessment would produce any significant changes…' p868). The effect of the intervention was evaluated by using data from the second re-assessment (before provision of training sessions) and data from a follow-up assessment collected 2 weeks post-intervention. **Costs?** No. Costs and resource information are not provided.		

3. Murphy J and Oliver T (2013) The use of Talking Mats to support people with dementia and their carers to make decisions together. Health and Social Care in the Community 21: 171–180

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
Study aim: To '… explore whether Talking Mats could help people with dementia and family carers feel more involved in decisions about managing their daily living than using their usual communication methods…' (p173). **Methodology:** Mixed methods – before and after outcome evaluation and observational interviews.	**Participants:** Service users and their families, partners and carers – people with dementia (specific diagnosis not reported) and their family carers. The authors do not report whether all of the participants were married couples. People who had a diagnosis of dementia were eligible if they were: '… aware of their diagnosis and be comfortable with the terminology involved … living at home and have a relative or friend (unpaid family carer) who is knowledgeable about how they are managing their daily living activities … a native speaker of	<u>Perceptions of involvement in discussions (whole sample)</u> – When participants were asked to rate their level of involvement for each discussion type (using the Involvement Measure), the mean score was significantly higher for discussions using Talking Mats than for discussions using usual methods of communication (Wilcoxon signed-rank test, z = -3.83, $p < 0.01$, $r = -0.45$). <u>Perceptions of involvement in discussions overall (i.e. not specific to discussion type, people with dementia compared to family carers)</u> – When participants were asked to rate their level of involvement overall (using the Involvement Measure), the mean score for carers was significantly higher than the mean score for people with dementia (Mann–Whitney test, z = -2.12, $p < 0.05$, $r = 0.35$). NB. These data are not reported in the narrative summary as	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
Country: United Kingdom – Scotland and the North of England (no further details provided). **Source of funding:** Charity/voluntary – Joseph Rowntree Foundation.	English … have sufficient vision to see picture symbols.' (p174). Of the people with dementia, 3 are described as having early stage dementia, 13 described as having moderate stage dementia, and 2 described as having late stage. It is not clear how this was determined or whether the authors considered this in relation to results. **Sample characteristics:** • Age – People with dementia mean age = 77 years (range 60 – 86); family carers mean age = 69 years (range 44–89). • Gender – People with dementia – females n = 8, males n = 10; family carers – females n = 13, males n = 5. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported, although authors report in the discussion section that participants were from 'varied backgrounds'. (p179) **Sample size:** N = 18. The authors report that 22 couples originally agreed to participate; however, 1 of person with dementia was unable to use the Talking Mats (no further details provided) and 2 people withdrew due to poor health.	they do not provide evidence regarding effectiveness of the intervention. <u>Level of satisfaction with discussions (whole sample) –</u> When participants were asked to rate their level of satisfaction for each discussion type (using the Involvement Measure), the mean score was significantly higher for discussions using Talking Mats than for discussions using usual methods of communication (Wilcoxon signed-rank test, z = -3.46, *p* < 0.01, *r* = 0.41). NB. The authors do not report analysis of difference in mean scores between people with dementia and their carers with respect to level of satisfaction with discussions. The authors report that four themes emerged from the feedback provided by people with dementia. Talking Mats helped the people with dementia to keep track of the conversation, and remember words which the authors report was seen as useful in enabling them to express their views more clearly: "The pictures are really clear; they helped me to remember when I couldn't find the right word." "… that is what I think, right in front of me; I don't have to rack my brain to remember." "… it is so difficult to tell [my wife] what I think when I can't remember the words, the pictures could help me a lot." (p177) Talking Mats reportedly helped the people with dementia to remember the activities that they were still able to do and those that they wanted to do: "I had forgotten all the things I like to do." (p 177)	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	Intervention category: Support for decision-making – Talking Mats. • Description – The authors describe Talking Mats as a low technology augmentative and alternative communication framework designed to support people with communication difficulties to express their views. People do so by placing cards representing a specific activity (based on simplistic symbols) below visual scales. • Delivered by – The information provided in the study suggests that discussions using Talking Mats do not require input from professionals. • Delivered to – People with dementia and their carers. • Duration, frequency, intensity, etc. – Talking Mats can be used on an ongoing basis. • Key components and objectives of intervention – Talking Mats can be used to discuss how well the person with dementia is managing with daily living activities. The activities represented by the cards focus on personal care (e.g. washing, and getting dressed); how well the person is managing physically (e.g. driving, getting in and out of bed, walking,); housework (e.g. cooking, doing the dishes, doing the laundry); and activities the person likes to do to (e.g. listening to music, reading a book or newspaper, watching TV).	Talking Mats helped the people with dementia to recognise the help that their carer provided: “I didn’t realise how much she (daughter) is doing in the house.” People with dementia were reported to find the use of Talking Mats as an enjoyable means of enhancing communication between themselves and their carer: “It was nice to talk about things. We never seem to do that anymore but the pictures really helped us do it.” (p 177) The authors also report that family carers felt that the use of Talking Mats meant that the person they cared for was more likely to listen to them and understand what they were saying: “I can talk away and she’s nodding away, but she’s not taking it in. At least with the mat she can see and hear what I am trying to say.” (p 178) Carers are also reported to believe that Talking Mats improved their own understanding of the wishes of the person with dementia: “Meals are a problem, I’m not sure if he likes what I give him, but it is so hard to know. We could use pictures of different foods and decide what we are going to have for tea each night.” (p 178) Carers are also reported to feel that Talking Mats improved the awareness of the person with dementia regarding the support that they were receiving from their family member: “She can see how much I actually do’. Reduction in confrontation and arguments …” “He can’t say he has forgotten what we agreed, it’s right there in the pictures in front of him.” (p178)	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	• Location/place of delivery – The authors note that Talking Mats can be used in any setting. **Comparison intervention:** Usual communication method. Participants were asked to discuss if the person with dementia was 'managing', 'needed assistance' or 'not managing' for each activity within the topic (i.e. the same topics and activities were discussed using both Talking Mats and usual communication methods); however, these discussions were not led/supported by use of the Talking Mats. **Outcomes measured:** Service user and family or caregiver related outcomes – Perceptions of involvement and satisfaction in discussions were measured using the Involvement Measure, which uses questions adapted from the Freedom of Choice Interview Schedule (Frossard et al. 2001), a measure designed specifically to determine how involved people with dementia and their family carers feel in situations where they have to consider aspects of care. The Involvement Measure is comprised of 5 questions: 'How many of the issues that are most important to you were covered?' 'How well do you think you were listened to?' 'How well do you think you were able to express your view?'		

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	‘Did you have enough time to express your view?’ ‘How involved in the conversation did you feel?’ (p176) Scores for these questions ranged from 1 – 4 (none/never; few/occasionally; most/usually; all/always). Scores were summed to produce a total measure of perception of involvement. The measure also includes a question on satisfaction with the discussion overall. Responses to this question were based on a 7-point Likert scale to produce a global satisfaction score (0 = not very well at all and 6 = very well indeed). The authors report that the measure was adapted to improve accessibility by using ‘plain English’ as well as visual clues. **Follow-up:** Qualitative data collected during discussion sessions, and questionnaires completed immediately after sessions. **Costs?** No. Cost and resource information not provided.		

4. Naughton M, Nulty A, Abidin Z et al. (2012) Effects of group metacognitive training (MCT) on mental capacity and functioning in patients with psychosis in a secure forensic psychiatric hospital: a prospective-cohort waiting list controlled study. BMC Research Notes 5: 302

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
Study aim: To evaluate the effects of group metacognitive training on ca-	**Participants:** Service users and their families, partners and carers – male patients meeting DSM-IV-TCR criteria for a psychotic disorder who were detained	Competence to consent to treatment measured using the MacArthur Competence Assessment Tool-Treatment –	**Overall assessment of internal validity:** −

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
pacity to consent to treatment, fitness to plead, global functioning, and symptoms of schizophrenia in patients in a secure forensic hospital. **Methodology:** Quantitative – prospective waitlist controlled study. **Country:** Ireland – Dublin – Central Mental Hospital. **Source of funding:** Not reported.	under both forensic and civil mental health legislation in a secure forensic psychiatric hospital. NB. The inclusion/exclusion criteria for the study are not clearly reported; however, the authors note that participants had been referred because of incomplete responses to anti-psychotic medication. They go on to state that 2 participants originally referred '… were not deemed suitable; one for security issues and the second as the patient was deemed to be highly functioning with good insight." (p4). Four of those originally referred refused to participate. **Sample characteristics – demographics:** • Age – Sample mean age = 36.7 years (SD 10.59); intervention mean age = 37.5 years (10.6 SD); control mean age = 35.62 (11.2 SD); (F = 0.02, df = 17, p >0.9). • Gender – All participants were male. • Ethnicity – Not reported; however, the authors report that all participants spoke 'adequate English' (p5). • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – The authors do not report on how old participants had been when they had been diagnosed as meeting DSM-IV-TCR criteria for psychotic disorders. Details on whether participants had any other health conditions are not provided. • Sexual orientation – Not reported.	Total scores on MacArthur Competence Assessment Tool-Treatment at baseline – There were no significant differences between groups in mean total scores on a measure of competence to consent to treatment at baseline; control mean score = 11.8 (4.3 SD), intervention mean score = 12.9 (4.1 SD); T = −0.6, p > 0.5. Total scores on MacArthur Competence Assessment Tool-Treatment after treatment or waiting list period – After treatment/waitlist period a large effect size in favour of the intervention was observed on a measure of competence to consent to treatment; d = −1.1419, p = 0.0041. This result was significant. Total scores on MacArthur Competence Assessment Tool-Treatment – change in scores between baseline and post-treatment/waiting list – Between baseline and post-treatment/waitlist period, a medium to large effect size in favour of the intervention was observed in change in total score on the MacArthur Competence Assessment Tool-Treatment; d = 0.7948 (95% CI −0.1503 to 1.74). This result was not significant (p > 0.1). Understanding at baseline – There were no significant differences between groups in mean scores on a measure of understanding at baseline; control mean score = 4.2 (1.3 SD), intervention mean score = 4.7 (1.2 SD); T = −0.9, p > 0.3. Understanding after treatment or waiting list period – After treatment/waitlist period a medium to large effect size in favour of the intervention was observed on a measure of understanding; d = 0.7341, p = 0.008. This result was significant. Understanding – change in scores between baseline and post-treatment/waiting list – Between baseline and post-treatment/waitlist period, a large effect size in favour of the intervention was observed in change in score on a measure of understanding; d = 1.3137 (95% CI 0.3118 to 2.3157). This result was significant (p = 0.009).	**Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	- Socioeconomic position – Not reported. **Sample characteristics – baseline data:** - Diagnosis – Intervention – Schizophrenia n = 7, Schizoaffective Disorder n = 3, Major Depression with Psychotic Features n = 1; Control Schizophrenia n = 8, Schizoaffective Disorder n = 0, Major Depression with Psychotic Features n = 0; Fisher's exact test = 3.2, *p* > 0.2. - Length of stay in Central Mental Hospital – intervention = 44 months (47.8 SD); control 48 months (55.5 SD); of stay (*F* = 0.71, *p* > 0.4). - Medications (n) – Intervention – Clozapine n = 8, 'other' n = 3; control Clozapine n = 3, 'other' n = 5; (χ^2 = 2.4 *df* = 1 *p* > 0.1). - Abnormalities of mental state – Positive symptoms of Schizophrenia – Intervention mean score = 11.4 (3.7 SD); control mean score = 14.0 (6.3 SD); *p* > 0.2. - Abnormalities of mental state – Negative symptoms of Schizophrenia – Intervention mean score = 17.7 (6. 7 SD); control mean score = 17.5 (4.7 SD); *p* > 0.9. - Abnormalities of mental state – General – Intervention mean score = 31.7 (8.6 SD); control mean score = 27.0 (6.6 SD); *p* > 0.2. - Abnormalities of mental state – Total – Intervention mean score = 60.7	Reasoning at baseline – There were no significant differences between groups in mean scores on a measure of reasoning at baseline; control mean score = 5.0 (1.9 SD), intervention mean score = 5.5 (2.0 SD); T = −0.5, *p* > 0.5. Reasoning after treatment or waiting list period – After treatment/waitlist period a large effect size in favour of the intervention was observed on a measure of reasoning; *d* = 1.4164, *p* = 0.023. This result was significant. Reasoning – change in scores between baseline and post-treatment/waiting list - Between baseline and post-treatment/waitlist period, a large effect size in favour of the intervention was observed in change in score on a measure of reasoning; *d* = 0.8404 (95% CI −0.1087 to 1.7895). This result was not significant (*p* > 0.1). Appreciation at baseline - There were no significant differences between groups in mean scores on a measure of appreciation at baseline; control mean score = 25.6 (1.6 SD), intervention mean score = 2.7 (1.5 SD); T = −0.3, *p* > 0.7. Appreciation after treatment or waiting list period - After treatment/waitlist period a very small effect size in favour of the intervention was observed on a measure of appreciation; *d* = 0.1333, *p* > 0.7. This result was not significant. Appreciation – change in scores between baseline and post-treatment/waiting list - Between baseline and post-treatment/waitlist period, a very small effect size in favour of the intervention was observed in change in score on a measure of appreciation *d* = 0.0221 (95% CI −0.8886 to 0.9329). This result was not significant (*p* > 0.9). <u>Difference between treatment and waiting list group marginal means (SEM, after adjustment for baseline values) on MacArthur Competence Assessment Tool – Treatment -</u> MacArthur Competence Assessment Tool – Treatment – total scores – After adjustment for baseline values, change in mean total score on the MacArthur Competence Assessment Tool – Treatment between baseline and follow-up was significantly greater for the intervention group than	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	(15.2 SD); control mean score = 58.8 (14.9 SD); $p > 0.7$. • General functional competence – Global Assessment of Functioning Scale – Intervention mean score = 50.6 (9.5 SD); control mean score = 54.6 (8.8 SD); $p > 0.3$. • Capacity to consent to treatment – MacArthur Competence Assessment Tool-Treatment – Intervention mean score = 12.9 (4.1 SD); control mean score = 11.8 (4.3 SD); $p > 0.5$. • Fitness to plead – MacArthur Competence Assessment Tool-Fitness to Plead – Intervention mean score = 25.5 (6.5 SD); control mean score = 23.9 (7.5 SD); $p > 0.6$. • Need for therapeutic security and admission to a secure forensic psychiatric hospital/triage security score – Intervention mean score = 30.6 (4.9 SD); control mean score = 29.1 (4.2 SD); $p > 0.3$. Risk factors for violence – HCR-20 – • H1 – previous violence – Intervention mean score = 2.00 (0.00 SD); control mean score = 2.00 (0.00 SD); $p > 0.9$. • H2 – young age at first violence – Intervention mean score = 1.00 (0.47 SD); control mean score = 1.25 (0.46 SD); $p > 0.2$. • H3 – relationship instability – Intervention mean score = 1.50 (0.71 SD); control mean score = 1.50 (0.76 SD); $p > 0.9$.	for the comparison group; intervention difference in marginal means (SEM) T2−T1 = +1.53 (0.86) vs. comparison difference in marginal means (SEM) T2−T1 = −1.88 (0.96); difference between treatment and waiting list group marginal means (SEM) = −3.4 (1.29); $p = 0.019$. MacArthur Competence Assessment Tool – Treatment – understanding – After adjustment for baseline values, change in mean score on the understanding domain of the MacArthur Competence Assessment Tool – Treatment between baseline and follow-up was significantly greater for the intervention group than for the comparison group; intervention difference in marginal means (SEM) T2−T1 = +0.44 (0.22) vs. comparison difference in marginal means (SEM) T2−T1 = −0.52 (0.25); difference between treatment and waiting list group marginal means (SEM) = −0.96 (0.34); $p = 0.011$. MacArthur Competence Assessment Tool – Treatment – reasoning – After adjustment for baseline values, change in mean score on the reasoning domain of the MacArthur Competence Assessment Tool – Treatment between baseline and follow-up was significantly greater for the intervention group than for the comparison group; intervention difference in marginal means (SEM) T2−T1 = +1.08 (0.47) vs. comparison difference in marginal means (SEM) T2−T1 = −1.10 (0.53); difference between treatment and waiting list group marginal means (SEM) = −2.18 (0.71); $p = 0.008$. MacArthur Competence Assessment Tool – Treatment – appreciation – After adjustment for baseline values, there were no significant differences between groups in change in mean score on the appreciation domain of the MacArthur Competence Assessment Tool – Treatment between baseline and follow-up; intervention difference in marginal means (SEM) T2−T1 = −0.06 (0.40) vs. comparison difference in marginal means (SEM) T2−T1 = −0.17 (0.43); difference between treatment and waiting list group marginal means (SEM) = −0.10 (0.60); $p > 0.8$.	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	• H4 – employment problems – Intervention mean score = 1.30 (0.82 SD); control mean score = 1.25 (0.89 SD); $p > 0.9$. • H5 – substance misuse problems – Intervention mean score = 1.40 (0.69 SD); control mean score = 2.00 (0.00 SD); $p = 0.023$. • H6 – major mental illness – Intervention mean score = 2.00 (0.00 SD); control mean score = 2.00 (0.00 SD); $p > 0.9$. • H7 – psychopathy – Intervention mean score = 0.00 (0.00 SD); control mean score = 0.00 (0.00 SD); $p > 0.9$. • H8 – early maladjustment – Intervention mean score = 1.00 (0.82 SD); control mean score = 1.13 (0.99 SD); $p > 0.7$. • H9 – personality disorder – Intervention mean score = 0.20 (0.42 SD); control mean score = 0.50 (0.53 SD); $p > 0.3$. • H10 – prior supervision failure – Intervention mean score = 1.60 (0.69 SD); control mean score = 1.25 (0.89 SD); $p > 0.1$. • C1 – lack of insight – Intervention mean score = 1.30 (0.48 SD); control mean score = 1.63 (0.52 SD); $p > 0.3$. • C2 – negative attitudes – Intervention mean score = 0.50 (0.71 SD); control mean score = 0.75 (0.89 SD); $p > 0.1$. • C3 – active symptoms – Intervention mean score = 1.25 (0.89 SD); control	Correlation between magnitude of baseline scores and magnitude of change (T2 – T1, all participants – including waiting list comparison group) on MacArthur Competence Assessment Tool – Treatment – MacArthur Competence Assessment Tool-Treatment – total score – There was a moderate negative correlation between magnitude of total score at baseline with magnitude of change in total scores on the MacArthur Competence Assessment Tool-Treatment; $r = -0.467$, $p = 0.05$. This result was significant. MacArthur Competence Assessment Tool-Treatment – understanding – There was a very weak negative correlation between magnitude of score at baseline with magnitude of change in score on the understanding domain of the MacArthur Competence Assessment Tool-Treatment; $r = -0.185$, $p > 0.4$. This result was not significant. MacArthur Competence Assessment Tool-Treatment – reasoning – There was a moderate negative correlation between magnitude of score at baseline with magnitude of change in score on the reasoning domain of the MacArthur Competence Assessment Tool-Treatment; $r = -0.717$, $p < 0.001$. This result was significant. MacArthur Competence Assessment Tool-Treatment – appreciation – There was a moderate negative correlation between magnitude of score at baseline with change in score on the appreciation domain of the MacArthur Competence Assessment Tool-Treatment; $r = -0.427$, $p > 0.7$. This result was not significant. The authors report narratively that when '… only those who had treatment were considered, the correlations between baseline and change were greater …' (p7); however, no data are reported to illustrate this finding.	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	mean score = 1.25 (0.89 SD); $p > 0.5$. - C4 – impulsivity – Intervention mean score = 0.13 (0.35 SD); control mean score = 0.13 (0.35 SD); $p > 0.05$. - C5 – unresponsive to treatment – Intervention mean score = 1.13 (0.83 SD); control mean score = 1.13 (0.83 SD); $p > 0.8$. - R1 – plans lack feasibility – Intervention mean score = 0.50(0.76 SD); control mean score = 0.50 (0.76 SD); $p > 0.3$. - R2 – exposure to destabilisers – Intervention mean score = 0.38(0.52 SD); control mean score = 0.38 (0.52 SD); $p > 0.05$. - R3 – lack of personal support – Intervention mean score = 0.38(0.74 SD); control mean score 0.38 (0.74 SD); $p = 0.039$. - R4 – non-compliance with remediation – Intervention mean score = 0.75 (0.89 SD); control mean score = 0.75 (0.89 SD); $p > 0.8$. - R5 – stress – Intervention mean score = 0.88 (0.64 SD); control mean score = 0.88 (0.64 SD); $p > 0.4$. **Sample size:** Intervention n = 11; control n = 8; total N = 29. **Intervention category:** Support for decision-making – metacognitive training. - Description – A manualised group-training programme designed to increase awareness of cognitive distortions and to encourage participants to	Correlation between number of treatment sessions and changes in outcome measures (T2-T1, all participants - including waiting list comparison group) on MacArthur Competence Assessment Tool – Treatment – MacArthur Competence Assessment Tool – Treatment – total score – There was a moderate positive correlation between number of treatment sessions and change in total score on the MacArthur Competence Assessment Tool – Treatment ($r = +0.556$, $p = 0.016$). This result was significant. MacArthur Competence Assessment Tool-Treatment – understanding – There was a strong positive correlation between number of treatment sessions change in scores on the understanding domain of the MacArthur Competence Assessment Tool-Treatment; $r = +0.644$, $p = 0.004$. This result was significant. MacArthur Competence Assessment Tool-Treatment – reasoning – There was a moderate positive correlation between number of treatment sessions change in scores on the reasoning domain of the MacArthur Competence Assessment Tool-Treatment; $r = +0.540$, $p = 0.021$. This result was significant. MacArthur Competence Assessment Tool-Treatment – appreciation – There was a weak positive correlation between number of treatment sessions and change in score on the appreciation subscale. This result was not significant ($r = +0.284$, $p > 0.3$). Fitness to plead measured using the MacArthur Competence Assessment Tool-Fitness to Plead – Total scores on MacArthur Competence Assessment Tool-Fitness to Plead – at baseline – There were no significant differences between groups in mean scores on a measure of fitness to plead at baseline; control mean score = 23.9 (7.5 SD), intervention mean score = 25.5 (6.5 SD); $T = -0.5$, $p > 0.6$.	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	'… critically reflect on, complement and alter their current repertoire of problem-solving skills.' (p3). Its aim is to reduce symptoms and risk of relapse. • Delivered by – The intervention was delivered by a psychiatrist and a clinical nurse specialist, who the authors report were qualified as recommended by the handbook (no further details reported and it is not clear whether other practitioners would be considered suitable). Training for these practitioners consisted of reading modules and handbook and supervision by senior clinician involved in the study. • Delivered to – All participants in this study all met DSM-IV-TR criteria for psychotic disorders and had been detained in a secure forensic psychiatric hospital; however, it is not clear whether the intervention is intended for use exclusively with this population. • Duration, frequency, intensity, etc. – Sessions delivered twice a week for a total of 8 weeks. Each module takes 2 sessions to complete. • Key components and objectives of intervention – The training programme is focuses on the 2 basic principles of knowledge translation (cognitive biases), and demonstration of the negative consequences of cognitive biases. These are explained and demonstrated using examples, and	Total scores on MacArthur Competence Assessment Tool-Fitness to Plead – after treatment or waiting list period – After treatment/waitlist period, a medium effect size in favour of the intervention was observed on a measure of fitness to plead; *d* = 0.5808, *p* > 0.2. This result was not significant. Total scores on MacArthur Competence Assessment Tool-Fitness to Plead – change in scores between baseline and post-treatment/waiting list – Between baseline and post-treatment/waitlist period, a small to medium effect size in favour of the intervention was observed in change in total score on MacArthur Competence Assessment Tool-Fitness to Plead *d* = 0.4225 (95% CI −0.4981 to 1.3431. This result was not significant (*p* > 0.3). Fitness to plead – understanding at baseline – There were no significant differences between groups in mean scores on a measure of understanding (fitness to plead) at baseline; control mean score = 9.8 (3.8 SD), intervention mean score = 9.8 (3.5 SD); T = −0.04, *p* > 0.9. Fitness to plead - understanding after treatment or waiting list period – After treatment/waitlist period no effects were observed on a measure of understanding (fitness to plead); *d* = 0.0, *p* > 0.3. Fitness to plead – understanding – change in scores between baseline and post-treatment/waiting list – Between baseline and post-treatment/waitlist period, a medium to large effect size in favour of the intervention was observed in change in score on a measure of understanding (fitness to plead); *d* = 0.7106 (95% CI −0.2277 to 1.6489). This result was not significant (*p* > 0.1). Fitness to plead – reasoning – at baseline – There were no significant differences between groups in mean scores on a measure of reasoning (fitness to plead) at baseline; control mean score = 7.1 (1.9 SD), intervention mean score = 7.4 (1.6 SD); T = −0.3, *p* > 0.7.	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	exercises targeting each bias are discussed within the group. Participants are encouraged to recount personal examples and have group discussion of methods of countering biases '… provide corrective experiences in a relaxed and supportive atmosphere, yielding obvious advantages over mere didactic information giving. Patients are taught to recognise and counter the biases that are important in schizophrenia, thus allowing them to arrive at more appropriate inferences and avoiding automatic "cognitive traps" ' (p3). Each module concludes with learning goals and discussion of a case in which a cognitive bias resulted in the escalation of psychotic symptoms. • Location/place of delivery – In this study the intervention being evaluated was delivered in a secure forensic psychiatric hospital. NB. The authors report that of the 11 participants in the intervention group only 5 were considered to have 'fully attended' (15 or 16 sessions), while 6 were considered to have 'partially attended' (fourteen or fewer sessions). **Comparison intervention:** Waitlist. **Outcomes measured** – service user related – • Abnormalities of mental state measured using the Positive and Negative Syndrome Scale for Schizophrenia –	Fitness to plead – reasoning – after treatment or waiting list period – After treatment/waitlist period, a large effect size in favour of the intervention was observed on a measure of reasoning (fitness to plead); $d = 0.8799$, $p > 0.05$. This result was not significant. Fitness to plead – reasoning – change in scores between baseline and post-treatment/waiting list – Between baseline and post-treatment/waitlist period, a large effect size in favour of the intervention was observed in change in score on a measure of reasoning (fitness to plead) $d = 1.0406$ (95% CI 0.0716 to 2.0095). This result was not significant ($p > 0.05$). Fitness to plead – appreciation – at baseline – There were no significant differences between groups in mean scores on a measure of appreciation (fitness to plead) at baseline; control mean score = 8.3 (3.5 SD), intervention mean score = 8.6 (2.7 SD); $T = -0.03$, $p > 0.7$. Fitness to plead – appreciation – after treatment or waiting list period – After treatment/waitlist period, a very small effect size in favour of the intervention was observed on a measure of appreciation (fitness to plead); $d = 0.155$, $p > 0.7$. This result was not significant. Fitness to plead – appreciation – change in scores between baseline and post-treatment/waiting list – Between baseline and post-treatment/waitlist period, a very small effect size in favour of the control group was observed in change in score on a measure of appreciation (fitness to plead) $d = -0.0471$ (95% CI −0.9579 to 0.8637). This result was not significant ($p > 0.9$). Difference between treatment and waiting list group marginal means (SEM, after adjustment for baseline values) on the MacArthur Competence Assessment Tool-Fitness to Plead – MacArthur Competence Assessment Tool-Fitness to Plead – total scores – After adjustment for baseline values, there was no significant difference between groups	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	positive, negative, general, and total scores (rated by treating psychiatrists as part of periodic routine assessments, Kay et al. 1987). - Competence to consent to treatment measured using the MacArthur Competence Assessment Tool-Treatment (Grisso et al., 1997). - Fitness to plead measured using the MacArthur Competence Assessment Tool-Fitness to Plead (Hope et al. 1997). - General functional competence measured using the Global Assessment of Functioning Scale (rated by treating psychiatrists as part of periodic routine assessments). **Follow-up:** Follow-up took place around 3 months after the end of the treatment/waitlist period. **Costs?** No. Costs and resource information not reported.	in change in mean total score on the MacArthur Competence Assessment Tool – Fitness to Plead between baseline and follow-up; intervention difference in marginal means (SEM) T2−T1 = 3.8 (1.6) vs. comparison difference in marginal means (SEM) T2−T1 = 0.9 (1.9); difference between treatment and waiting list group marginal means (SEM) = −2.9 (2.5); *p* > 0.2. MacArthur Competence Assessment Tool-Fitness to Plead – understanding – After adjustment for baseline values, there was no significant difference between groups in change in mean score on the MacArthur Competence Assessment Tool – Fitness to Plead – understanding domain between baseline and follow-up; intervention difference in marginal means (SEM) T2−T1 = 2.19 (0.49) vs. comparison difference in marginal means (SEM) T2−T1 = 0.86 (0.57); difference between treatment and waiting list group marginal means (SEM) = −1.33 (0.75); *p* > 0.05. NB. Reported as significant by authors. MacArthur Competence Assessment Tool-Fitness to Plead – reasoning – After adjustment for baseline values, change in mean score on the MacArthur Competence Assessment Tool – Fitness to Plead – reasoning domain between baseline and follow-up was significantly greater for the intervention group than for the comparison group; intervention difference in marginal means (SEM) T2−T1 = 0.48 (0.54) vs. comparison difference in marginal means (SEM) T2−T1 = −1.29 (0.63); difference between treatment and waiting list group marginal means (SEM) = 1.77 (0.82); *p* = 0.049. MacArthur Competence Assessment Tool-Fitness to Plead – appreciation – After adjustment for baseline values, there was no significant difference between groups in change in mean score on the MacArthur Competence Assessment Tool – Fitness to Plead – appreciation domain between baseline and follow-up; intervention difference in marginal means (SEM) T2−T1 = 0.74 (0.74) vs. comparison differ-	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
		ence in marginal means (SEM) T2−T1 = 0.73 (0.63); difference between treatment and waiting list group marginal means (SEM) = 0.010 (0.98); *p* > 0.09. <u>Correlation between number of treatment sessions and changes in outcome measures (T2-T1, all participants – including waiting list comparison group) the MacArthur Competence Assessment Tool-Fitness to Plead –</u> MacArthur Competence Assessment Tool – Fitness to plead – understanding – There was a weak positive correlation between number of treatment sessions and change in scores on the understanding domain of the MacArthur Competence Assessment Tool – Fitness to plead; *r* = +0.250, *p* > 0.3. This result was not significant. MacArthur Competence Assessment Tool – Fitness to plead – reasoning – There was a moderate positive correlation between number of treatment sessions and change in scores on the reasoning domain of the MacArthur Competence Assessment Tool – Fitness to plead; *r* = +0.410, *p* > 0.05. This result was not significant. MacArthur Competence Assessment Tool – Fitness to plead – appreciation – There was a very weak positive correlation between number of treatment sessions and change in scores on the appreciation domain of the MacArthur Competence Assessment Tool – Fitness to plead; *r* = +0.159, *p* > 0.5. This result was not significant. MacArthur Competence Assessment Tool – Fitness to plead – total scores – There was a weak positive correlation between number of treatment sessions and change in total scores on the MacArthur Competence Assessment Tool – Fitness to plead; *r* = 0.236, *p* > 0.3. This result was not significant. <u>Abnormalities of mental state measured using the Positive and Negative Syndrome Scale for Schizophrenia</u> Total scores at baseline – There were no significant differences between groups in mean total scores on a measure	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
		of positive and negative symptoms of Schizophrenia at baseline; control mean score = 58.8 (14.9 SD), intervention mean score = 60.7 (15.2 SD); T = −0.3, *p* > 0.7. Total scores after treatment or waiting list period – After treatment/waitlist period, a small to medium effect size in favour of the intervention was observed on a measure of positive and negative symptoms of Schizophrenia; *d* = −0.4393, *p* > 0.3. This result was not significant. Total scores – change in scores between baseline and post-treatment/waiting list – Between baseline and post-treatment/waitlist period, a medium effect size in favour of the intervention was observed in change in total score on the Positive and Negative Syndrome Scale for Schizophrenia; *d* = −0.5388 (95% CI −1.4655 to 0.3879. This result was not significant (*p* > 0.2). Positive symptoms at baseline – There were no significant differences between groups in mean scores on a measure of positive schizophrenia symptoms at baseline; control mean score = 14.0 (6.3 SD), intervention mean score = 11.4 (3.7 SD); T = 1.1, *p* > 0.2. Positive symptoms after treatment or waiting list period – After treatment/waitlist period, a small to medium effect size in favour of the intervention was observed on a measure of positive schizophrenia symptoms; *d* = −0.493, *p* > 0.4. This result was not significant. Positive symptoms – change in scores between baseline and post-treatment/waiting list – Between baseline and post-treatment/waitlist period, a very small effect size in favour of the control group was observed in change in score on a measure of positive schizophrenia symptoms *d* = 0.1993 (95% CI −0.7136 to 1.1122). This result was not significant (*p* > 0.6). Negative symptoms at baseline – There were no significant differences between groups in mean scores on a measure of negative symptoms of schizophrenia at baseline; control mean score = 17.5 (4.7 SD), intervention mean score = 17.7 (6.7 SD); T = 0.1, *p* > 0.9.	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
		Negative symptoms after treatment or waiting list period – After treatment/waitlist period, a medium to large effect size in favour of the intervention was observed on a measure of negative symptoms of schizophrenia; *d* = −0.6882, *p* > 0.1. This result was not significant. Negative symptoms – Between baseline and post-treatment/waitlist period, a medium to large effect size in favour of the intervention group was observed in change in score on a measure of negative schizophrenia symptoms *d* = −0.7388 (95% CI −1.6793 to 0.2017). This result was not significant (*p* > 0.1). General symptoms at baseline – There were no significant differences between groups in mean scores on a measure of general symptoms at baseline; control mean score = 27. 0 (6.6 SD), intervention mean score = 31.7 (8.6 SD); T = −1.4, *p* > 0.2. General symptoms after treatment or waiting list period – After treatment/waitlist period, a large effect size in favour of the intervention was observed on a measure of general symptoms after treatment or waiting list period; *d* = −0.0994, *p* > 0.8. This result was not significant. General symptoms – change in scores between baseline and post-treatment/waiting list – Between baseline and post-treatment/waitlist period, a medium to large effect size in favour of the intervention group was observed in change in score on a measure of general symptoms of schizophrenia *d* = −0.7606 (95% CI −1.7028 to 0.1817). This result was not significant (*p* > 0.1). <u>Change in marginal means on the Positive and Negative Syndrome Scale for Schizophrenia</u> – Total scores on the Positive and Negative Symptoms of Schizophrenia scale – There was no significant difference in change in marginal means (T2-T1) on total scores on a measure of positive and negative symptoms of Schizophrenia; intervention marginal mean = −0.7 (4.1 SD); control marginal mean = 6.6 (4.8); difference in marginal means = 7.3 (6.4), *p* > 0.2.	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
		Positive symptoms of Schizophrenia – There was no significant difference in change in marginal means (T2-T1) on a measure of positive symptoms of Schizophrenia; intervention marginal mean = 1.7 (1.3 SD); control marginal mean = 1.9 (1.5 SD); difference in marginal means = 0.23 (2.0 SD), *p* > 0.9. Negative symptoms of Schizophrenia – There was no significant difference in change in marginal means (T2-T1) on a measure of negative symptoms of Schizophrenia; intervention marginal mean = −1.0 (1.5 SD); control marginal mean = 2.9 (1.7 SD); difference in marginal means = 3.9 (2.3), *p* > 0.05. General symptoms – There was no significant difference in change in marginal means (T2-T1) on a measure of general symptoms of Schizophrenia; intervention marginal mean = −0.7 (2.1 SD); control marginal mean = 2.1 (2.5); difference in marginal means = 3.8 (3.4 SD), *p* > 0.2. Correlation between number of treatment sessions and changes in outcome measures (T2-T1, all participants including waiting list comparison group) on the Positive and Negative Syndrome Scale for Schizophrenia – The authors report narratively that number of treatment sessions did not correlate with change in scores on any of the Positive and Negative Symptoms of Schizophrenia scales. General functional competence measured using the Global Assessment of Functioning Scale – Functional competence – at baseline – There were no significant differences between groups in mean scores on a measure of functional competence at baseline; control mean score = 54.6 (8.7 SD), intervention mean score = 50.6 (9.5 SD); T = 0.9, *p* > 0.3. Functional competence – after treatment or waiting list period – After treatment/waitlist period, a large effect size in	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
		favour of the intervention was observed on a measure of functional competence after treatment or waiting list period; *d* = 1.0546, *p* = 0.021. This result was significant. Functional competence – change in scores between baseline and post-treatment/waiting list – Between baseline and post-treatment/waitlist period, a large effect size in favour of the intervention was observed in change in score on a measure of functional competence *d* = 1.2263 (95% CI 0.2356 to 2.2169). This result was significant (*p* = 0.012). Global Assessment of Function – change in 'raw' scores between baseline and post-treatment/waitlist period (unadjusted) on the Global Assessment of Functioning Scale At post-treatment/waitlist period there was a significant difference in unadjusted scores on a measure of global function; intervention mean score = 57.2 (9.8 SD), comparison mean score = 48.0 (6.9 SD); ANOVA = 5.0, df = 1, *p* = 0.035. Participants in the intervention group also had a significantly greater change in score (unadjusted) on this measure; intervention change in score = +6.6 points (12.0 SD); control change in score = −6.6 points (SD 8.7); ANOVA = 7.0, df = 1, *p* = 0.017. Global Assessment of Function – There was a significant difference in change in marginal means (T2-T1) on a measure of global functioning; intervention marginal mean = 5.4 (2.6); control marginal mean = −4.9 (3.1); difference in marginal means = −10.3 (4.1), *p* = 0.024. Correlation between number of treatment sessions and changes in outcome measures (T2-T1, all participants – including waiting list comparison group) the Global Assessment of Functioning Scale – Global Assessment of Function – There was a moderate positive correlation between number of treatment sessions and change in score on the Global Assessment of Functioning scale, which was significant (r = +0.592, *p* = 0.008).	

5. Turner D, MacBeth A, Larkin A et al. (2017) The relationship between the ‘jumping to conclusions’ bias and treatment decision-making capacity in psychosis: A participant-blind randomised controlled experiment (unpublished)

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
Study aim: To test the hypothesis that meta-cognitive therapy would improve treatment related capacity and that this would be mediated by changes in the ‘jumping to conclusions’ bias in patients with psychosis. **Country:** United Kingdom – Scotland. **Methodology:** Quantitative evaluation – randomised controlled trial. **Source of funding:** No external funding provided.	**Participants:** Service users – Inpatients and outpatients with psychosis under the care of 2 NHS health boards in Scotland. Individuals were eligible if they - spoke English; were aged between 16 and 65 years; had diagnosed schizophrenia, schizoaffective disorder, delusional disorder, brief psychotic disorder or a psychotic disorder Not Otherwise Specified; and had the capacity to consent to participation in the study. Individuals were excluded if they – had psychotic symptoms resulting from a general medical condition or substance misuse disorder; had a moderate or severe learning disability; had experienced a deterioration in condition suggesting that participation in the study could be harmful; or were involved in ongoing legal proceedings / forensic mental health services. The authors state that as the ‘… primary outcome was treatment decision-making capacity, no minimum or maximum symptom threshold or stage of illness was specified.’ (Authors, p4). They also note that inpatients were recruited via both acute and rehabilitation inpatient psychiatric services and that outpatients were recruited via community mental health teams and psychological therapies teams. **Sample characteristics:**	MacArthur Competency Assessment Tool for Treatment – Understanding – Participants in the intervention group demonstrated better understanding at post-treatment in relation to capacity to make treatment decisions (as measured by the MacArthur Competency Assessment Tool for Treatment – understanding scale) than those in the control group (after controlling for baseline scores on this measure). This result was not significant (*F* = 2.06, *p* value not reported). The effect size was small to medium (*d* = 0.49). MacArthur Competency Assessment Tool for Treatment – Appreciation – Participants in the intervention group demonstrated better appreciation at post-treatment in relation to capacity to make treatment decisions (as measured by scores on the MacArthur Competency Assessment Tool for Treatment – appreciation scale) than those in the control group (after controlling for baseline scores on this measure). This result was significant (*F* = 6.45, *p* < 0.05). The effect size was large (*d* = 0.87). The authors note that a significant degree of negative skew was displayed in data for this outcome at baseline and post-treatment across groups that may have violated ANCOVA assumptions. The data met assumptions for a Kruskall-Wallis H test and a sensitivity analysis was conducted. The result was ‘... consistent with the main ANCOVA in showing a significant effect favouring...’ (p8) the intervention (χ2 = 0.11, *p* <.05). MacArthur Competency Assessment Tool for Treatment – Reasoning – Participants in the intervention group demonstrated better reasoning at post-treatment (as measured by scores on the MacArthur Competency Assessment Tool for Treatment – reasoning scale) than those in the control group (after controlling for baseline scores on this measure). This result was not significant (*F* = 3.95, *p* = .055). The effect size was medium to large (*d* = 0.68)	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	Age – Whole sample – 44.7 years (12.8 SD); intervention – 45.3 years (13.0 SD); control – 44 years (12.9 SD). Gender – Whole sample – female n = 6, male = 31; intervention – female n = 5, male n = 14; control – female n = 1, male n = 17. Ethnicity – Whole sample – white n = 37, other ethnicity n = 0; intervention – white n = 19, other ethnicity n = 0; control – white n = 17, other ethnicity n = 0. Religion/belief – Not reported. Disability – Not reported. Long-term health condition – No conditions other than schizophrenia, schizoaffective disorder, psychosis Not Otherwise Specified are reported. Sexual orientation – Not reported. Socioeconomic position – Not reported. Clinical characteristics at baseline: Patient status – Whole sample – inpatient n = 11, outpatient n = 26; intervention – inpatient n = 5, outpatient n = 14; control – inpatient n = 6, outpatient = 12. Diagnosis – Schizophrenia – Whole sample – n = 26 (70%); intervention – n = 12 (63%); control – n = 14 (78%). Schizoaffective – Whole sample – n = 5 (14%); intervention – n = 3 (16%); control – n = 2 (11%). Psychosis Not Otherwise Specified – Whole sample – n = 6 (16%); intervention – n = 4 (21%); control – n = 2 (11%). Duration of illness –	MacArthur Competency Assessment Tool for Treatment – Total – Participants in the intervention group demonstrated better capacity to make treatment decisions at post-treatment (as measured by total scores on the MacArthur Competency Assessment Tool for Treatment) than those in the control group (after controlling for baseline scores on this measure). This result was significant (*F* = 7.78, *p* < 0.05). The effect size was large (*d* = 0.96). Hospital Anxiety and Depression Scale – Anxiety – Participants in the intervention group had higher levels of anxiety at post-treatment (as measured by scores on the Hospital Anxiety and Depression Scale – Anxiety subscale) than those in the control group (after controlling for baseline scores on this measure). This result was not significant (*F* = 2.21, *p* value not reported). The effect size was very small (*d* = −.18). Hospital Anxiety and Depression Scale – Depression – As the intervention group had significantly higher levels of depression at baseline than those in the control group (as measured by scores on the Hospital Anxiety and Depression Scale – Depression subscale, *p* = 0.022), the authors conducted an analysis of mean change on this measure as adjusting for this difference with ANCOVA would have violated the assumption of independence of covariate and treatment effect. This analysis demonstrated that the increase in levels of depression for participants was not significantly greater for those in the intervention group than those in the control group. The effect size was small (*p* value not reported, *d* = .30). Hospital Anxiety and Depression Scale – Total scores – Participants in the intervention group had higher levels of distress at post-treatment (as measured by scores on the Hospital Anxiety and Depression Scale – total score) than those in the control group (after controlling for baseline scores on this measure). This result was not significant (*F*	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	0–1 years – Whole sample – n = 3 (8%); intervention – n = 3 (16%); control – n = 0 (0%). 1–3 years – Whole sample – n = 3 (8%); intervention – n = 2 (11%); control – n = 1 (6%). 3–5 years – Whole sample – n = 2 (5%); intervention – n = 1 (5%); control – n = 1 (6%). 5–10 years – Whole sample – n = 2 (5%); intervention – n = 1 (5%); control – n = 1 (6%). Over 10 years Whole sample n = 27 (73%); intervention n = 12 (63%); control n = 15 (83%). Symptom severity – Positive and Negative Syndrome Scale – Positive – Whole sample – mean = 17.2 (7.1 SD); intervention – mean = 17.2 (8.1 SD); control – mean = 17.2 (6.1 SD). Positive and Negative Syndrome Scale Negative – Whole sample – mean = 15.1 (5.2 SD); intervention – mean = 13.7 (4.4 SD); control – mean = 16.6 (5.8 SD) Positive and Negative Syndrome Scale General – Whole sample – mean = 36.2 (7.4 SD); intervention – mean = 38.1 (7.2 SD); control – mean = 34.3 (7.3 SD) Positive and Negative Syndrome Scale Total – Whole sample – mean = 68.8 (16.5 SD); intervention – mean = 69.5 (16.8 SD); control – mean = 68.1 (16.7 SD).	= 2.21, *p* value not reported). The effect size was medium (*d* = −.51). Bias and cognitive distortion – Participants in the intervention group demonstrated lower levels of bias and cognitive distortions at post-treatment (as measured by total scores on the Cognitive Biases Questionnaire for Psychosis) than those in the control group (after controlling for baseline scores on this measure). This result was not significant (*F* = .35, *p* value not reported). The effect size was small (*d* = .20). 'Jumping to conclusions' bias – Participants in the intervention group demonstrated lower levels of bias at post-treatment (as measured by scores on the Cognitive Biases Questionnaire for Psychosis – 'jumping to conclusions' subscale) than those in the control group (after controlling for baseline scores on this measure). This result was not significant (*F* = .33, p value not reported). The effect size was small (*d* = .20). 'Jumping to conclusions' bias – Participants in the intervention group demonstrated lower levels of bias at post-treatment (as measured by the beads task) than those in the control group (after controlling for baseline levels of bias). This result was significant (*F* = 7.35, *p* < 0.05). The effect size was large (*d* = .93). Data gathering behaviour as a mediator of group allocation on capacity – Mediation analysis (Baron and Kenny method, pre-specified) showed that post-treatment data gathering behaviour (as measured by the beads task) significantly mediated the effect of group allocation on post-treatment capacity to make treatment decisions (as measured by total scores on the MacArthur Competency Assessment Tool for Treatment) at post-treatment, with a medium effect size (*d* = 0.64, *p* < .05), and accounted for 38.7% of treatment effects. However, the authors note that	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	Hospital Anxiety and Depression Scale Total – Whole sample – mean = 13.30 (7.2 SD); intervention – mean = 15.4 (8.2 SD); control – mean = 11.1 (5.4 SD) The authors report that there were no significant differences between groups (t-test and chi-squared tests). **Sample size:** Total sample N = 37; intervention n = 19; control n = 17. **Intervention:** Intervention category – Support for decision-making. Description – A single session of meta-cognitive training designed to address the 'jumping to conclusions' bias. The session was designed to provide participants with a 'best of' meta-cognitive training that raises awareness of the disadvantages of making decisions based on limited information. The session was derived from modules of the 2007 metacognitive training manual by Moritz et al. that address the 'jumping to conclusions' bias. Administered by – Researcher. Administered to – Patients with a diagnosis of schizophrenia, schizoaffective disorder, delusional disorder, brief psychotic disorder, or a psychotic disorder Not Otherwise Specified. Duration, frequency, etc. – Single session of 1 hour. Components/domains – The intervention '… aimed to repeatedly engage the participant in applying an approach contrary	the second step of the analysis did not meet the requirements described by Baron and Kenny as the result of this was not significant (*p* < .06). Post-treatment data gathering behaviour also mediated the effect of group allocation (with small to medium effect sizes) on the understanding scale (*d* = 0.45, 63% mediated); the appreciation scale (*d* = 0.55, 35.7% mediated); and the reasoning scale (*d* = 0.59, 28.8% mediated). These results were not significant. Mediation analysis using the Preacher and Hayes method (post-hoc) showed that post-treatment data gathering behaviour (as measured by the beads task) significantly mediated the effect of group allocation on post-treatment capacity to make treatment decisions (as measured by total scores on the MacArthur Competency Assessment Tool for Treatment) at post-treatment, with a medium effect size (d = 0.64, *p* < .05), and accounted for 38.7% of treatment effects. Post-treatment data gathering behaviour also mediated the effect of group allocation (with small to medium effect sizes) on the understanding scale (*d* = 0.45, 63% mediated); the appreciation scale (*d* = 0.55, 35.7% mediated); and the reasoning scale (*d* = 0.59, 28.8% mediated). These results were significant.	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	to the JTC bias while reflecting on the pitfalls of JTC.' (Authors, p6). The session is comprised of 11 key components including examples of the 'jumping to conclusions' bias (e.g. daily life, politics, medicine, and conspiracy theories), worksheet exercises and tasks focusing on misinterpretations using images, and suggested tactics to address the bias. Location/place of administration – Not reported. It appears that the intervention is delivered in a group setting although this is not reported specifically. **Comparison intervention:** Attention control – The control group received a talk on the localisation of brain function and brain processing in different sensory modalities. The control intervention was designed to match the experimental intervention according to modality, duration, and non-specific factors not addressing thinking biases (single, 1-hour session, delivered using PowerPoint). **Outcomes measured:** Service user related outcomes – the primary outcome measure was competency to make treatment decisions measured using the MacArthur Competency Assessment Tool for Treatment. The measure is clinician-rated on the basis of a semi-structured interview schedule that covers 4 domains – understanding information relevant to treatment; appreciation of diagnostic and treatment information; reasoning ability regarding treatment options; and expressing choice regarding treatment. Higher scores on each scale indicate		

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	greater capacity in that domain. The scale does not result in a total overall score; however, the authors report that they calculated this to '… align with previous research …' (Authors, p6). The reliability of the scale for the sample was calculated to be α = 0.80. Secondary outcomes were – Distress – measured using the Hospital Anxiety and Depression Scale (HADS, 14 item self-report measure of anxiety and depression symptoms, higher scores indicate greater levels of anxiety/depression). The reliability of the scale for the sample was calculated to be α= 0.83. 'Jumping to conclusions' bias – measured using the Cognitive Bias Questionnaire for Psychosis (CBP-Q), a 30-item self-report measure of 'jumping to conclusions' bias and 4 cognitive distortions. The reliability of the scale for the sample was calculated to be α= 0.89. 'Jumping to conclusions' bias – primarily measured using a computerised version of the beads task. This assesses bias by recording how much information participants seek before making a decision (total number of beads requested before making a decision) on the origin of the bead [one of two jars] '…The total number of beads a person requests before making their decision ... was taken as an index of data-gathering. Participants who made a decision after only 1 or 2 beads		

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	were presented were deemed to demonstrate the jumping to conclusions (JTC) decision-making bias.' (Authors, p6). Severity of psychosis – measured using the Positive and Negative Syndrome Scale. Clinician-rated assessment of the positive, negative, and general symptoms of psychosis, as well as a total score of the symptoms of psychosis. Greater severity of symptoms is indicated by higher scores. The reliability of the scale for the sample was calculated to be $\alpha = 0.88$. **Follow-up:** Follow-up assessments were completed immediately after delivery of intervention. **Costs?** No. Costs and resource information are not reported.		

6. Woltmann EM, Wilkniss SM, Teachout A et al. (2011) Trial of an electronic decision support system to facilitate shared decision making in community mental health. Psychiatric Services 62: 54–60

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To examine the feasibility of using an electronic decision support system to improve communication between service users and practitioners in mental health decision-making and to determine the impact of the system on outcomes.	**Participants:** • Service users and their families, partners and carers – 'mental health consumers' (participants had a primary diagnosis of schizophrenia or schizoaffective disorder, bipolar disorder, major depressive disorder, or post-traumatic stress disorder. • Professionals/practitioners – case managers working at 1 of 3 clinics provided by the agency.	Possible scores for each item on both service user and practitioner questionnaires ranged from 1 to 5 (higher scores indicate greater agreement with the statement). Case manager satisfaction with the care planning process questionnaire – *p* values and R^2 values adjusted for clustering. Regression for each item on the questionnaire included length of time working with case manager as a covariate due to randomisation failure. The authors report narratively that the '… regression results for the individual items included length of time working with case manager	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Methodology: Quantitative – cluster randomised controlled trial. **Country:** United States – no further details reported. **Source of funding:** Voluntary/charity – The West Family Foundation and the Segal Family Foundation.	Only limited details are provided regarding the clinics and it is not clear what criteria were used to select these clinics or whether any inclusion/exclusion criteria were used. The authors note that 2 of the clinics provided '… traditional case management and community support …' while the other '… provided slightly more intensive services, because it previously provided assertive community treatment and continued to serve the same population.' (p55). The authors also report that the agency which provided the 3 clinics espouse a '… mission to help mental health clients maintain autonomy over their lives and achieve recovery-oriented goals.' (p55). **Sample characteristics – 'mental health consumers':** • Age – Intervention mean age = 47 years (9 SD); control mean age = 46 years (11 SD); NS. • Gender – Intervention – female n = 15 (38%), male n = 25 (62%); control – female n = 12 (30%), male = 28 (70%); NS. • Ethnicity – Intervention – White n = 14 (35%), African American n = 23 (58%), Latino n = 3 (8%), control – White n = 13 (33%); African American n = 25 (63%); Latino n = 2 (5%); NS. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported.	as a covariate, because of randomization failure. In all cases these results were nonsignificant and had minimal effect on the overall result. Thus for brevity they are not shown … although the β for intervention status, *p* value, and R^2 reported are from models including length of time with case manager.' (p58). Multiple linear regression, controlling for case manager age showed that intervention status significantly predicted a better summary score overall on the case manager satisfaction questionnaire (intercept = 3.29, β = .62, adjusted *p* = .01). Case manager age was not significant. The authors report that around 30% of the variance in summary score was explained by the model. Communication – "My client was able to tell me important information about himself or her-self that I did not know before we discussed the care plan" – Multiple linear regression, controlled for case manager age, showed that intervention status significantly predicted a higher summary score (intercept = 2.82, β = 1.01, adjusted *p* = .001). The model explained approximately 22% of the variance in the summary score (R^2 = .22). Flow – "I feel that the way I complete the care plan with my client is too cumbersome and hard to use" – Multiple linear regression, controlled for case manager age, showed that intervention status significantly predicted a lower summary score (intercept = 2.87, β = –.82, adjusted *p* = .042). The model explained approximately 16% of the variance in the summary score (R^2 = .16). Time - "Creating the care plan in this way and reviewing it with my client takes up too much time" – Multiple linear regression, controlled for case manager age, showed that intervention status significantly predicted a lower summary score (intercept = –1.04, β = 2.97, adjusted *p* = .026). The model explained approximately 24% of the variance in the	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	- Sexual orientation – Not reported. - Socioeconomic position – Not reported. - Primary diagnosis – Intervention – Schizophrenia or Schizoaffective disorder n = 24 (60%), Bipolar disorder n = 10 (25%), Major depressive disorder n = 6 (15%), Posttraumatic stress disorder n = 0 (0%), 'Other' n = 0 (0%); control – Schizophrenia or Schizoaffective disorder n = 24 (63%), Bipolar disorder n = 5 (13%), Major depressive disorder n = 6 (16%), Posttraumatic stress disorder n = 1 (3%), 'Other' n = 2 (5%); NS. - Current substance abuse or dependence – Intervention n = 8 (20%); control n = 8 (21%); NS. - Length of time working with case manager – Intervention mean = 3.4 years (3.0 SD); control mean = 1.4 (1.4 SD); *p* = 0.03. NB. The authors report that data for some characteristics were missing for 2 people because the case manager left the agency before filling out the case manager questionnaire. **Sample characteristics – practitioners:** - Age – Intervention mean 47 years (12 SD); control mean 31 years (7 SD); *p* < 0.001. - Gender – Intervention – female n = 8 (80%), male n = 2 (20%); control – female n = 6 (67%), male = 3 (33%); NS.	summary score ($R^2 = .24$). <u>Organisation of information – "The process of creating a care plan was easy for me to get the right information about what my client needed"</u> – Multiple linear regression, controlled for case manager age, showed that intervention status significantly predicted a higher summary score (intercept = 3.40, β = .65, adjusted *p* = .018). The model explained approximately 15% of the variance in the summary score ($R^2 = .15$). <u>Credibility as a clinical tool – "I think that the care plan my client and I created is realistic"</u> – Multiple linear regression, controlled for case manager age, showed that intervention status predicted a higher summary score. This result was not significant (intercept = 3.82, β = .43, adjusted *p* = .130). The model explained approximately 9% of the variance in the summary score ($R^2 = .09$). <u>Credibility as a clinical tool – "I am concerned that the care plan does not address something I feel is important for my client to work on</u> – Multiple linear regression, controlled for case manager age, showed that intervention status predicted a lower summary score (intercept = 2.45, β = −.15, adjusted *p* = .470). This result was not significant. The model explained less than 1% of the variance in the summary score ($R^2 = < .01$). <u>Service user satisfaction with care planning process questionnaire</u> – Multiple linear regression showed that the length of time which a service user had been with their case manager had a statistically significant (but clinically insignificant) negative effect — '… the longer clients were with their case mangers (in months), the more dissatisfied they were (β = –.003, adjusted *p* < .001). The fit of the model was not significant and explained little of the variance in score.' NB. As this result does not demonstrate the impact of the intervention, it has not been included in the	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	• Ethnicity – Intervention – White n = 4 (40%), African American n = 6 (60%), Latino n = 0 (0%), control – White n = 4 (44%); African American n = 4 (44%); Latino n = 1 (11%); NS. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. • Years worked at clinic – Intervention mean = 7 years (5 SD); control mean = 3 years (2 SD); *p* = 0.04. • Years in mental health field – Intervention mean = 12 years (10 SD); control mean = 5 years (4 SD); *p* = .05. • Master's degree – Intervention n = 5 (50%); control n = 5 (56%); NS. NB. The authors report that data were only available for 9 case managers in the control group, as 1 case manager had gone on leave before completing the demographic questionnaire. **Sample size:** • Total – N = 100. • 'Mental health consumers' – total sample n = 80; intervention n = 40; control n = 40. • Practitioners – total sample n = 20; intervention n = 10; control = n = 10.	narrative summary. Client satisfaction with the care planning process overall (mean summary scores) – For client satisfaction, there was no difference between groups regarding mean summary scores (measured using the client satisfaction questionnaire; intervention = 3.88 [± .54]; control mean = 3.78 [± .56]). Communication – "I was able to tell my counselor important information about me that he or she did not know before we discussed my care plan." – Multiple linear regression, showed that intervention status predicted a higher summary score (intercept = 4.20, β = −.10, *p* =.87). This result was not significant. The model explained less than 1% of the variance in the summary score (R^2 = .003). Involvement in decision-making – "I did not feel that my opinion counted for much when decisions were made about my care plan" – Multiple linear regression, showed that intervention status predicted a higher summary score (intercept = 1.96, β = −.15, *p* = .18). This result was not significant. The model explained approximately 2% of the variance in the summary score (R^2= .02). Communication – "I feel that my counselor listened to my opinion." – Multiple linear regression, showed that intervention status significantly predicted a higher summary score (intercept = 4.41, β = .11, *p* = .38). This result was not significant. The model explained approximately 1% of the variance in the summary score (R^2 = .01). Involvement in decision-making "My care plan is about working on areas of my life that are important to me to address." – Multiple linear regression showed that intervention status significantly predicted a higher summary score (intercept = 4.29, β = .23, *p* = .20). This result was not significant. The model explained approximately 3% of the variance in the summary score (R^2 = .03).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Intervention category: Support for decision-making – electronic support system for shared decision-making in mental healthcare. - Description – The authors describe the electronic decision support system as a 3-step process that '…inverts the usual care planning procedures.' (p55). Service users use a touchscreen-enabled computer to identify their top priorities and thoughts about services. This information is then sent to the case manager who does the same. These 2 records are then merged by the programme which produces a graphic to be used in a shared decision-making session. - Delivered by – The tool does not require a third party to facilitate use of the system. - Delivered to – 'Mental health consumers' and case managers. - Duration, frequency, intensity, etc. – The study does not include details on how long it takes to complete a record, and if it is intended for regular use. However, the authors note that participants in the intervention group completed their care plans using the tool at least 3 months before their regular 6-month case planning date in order to ensure that results were not biased. The intervention group did go on to complete their plan at the scheduled 6-month point. Case managers received a manual and a 1-	Involvement in decision-making "I wish I had more of an opportunity to discuss something on my mind with my counselor before making my care plan." – Multiple linear regression showed that intervention status significantly predicted a higher summary score (intercept = 2.91, β = −.19, *p* = .001). The model explained approximately 7% of the variance in the summary score (R^2 = .07). Service user informed about decisions made – "I did not understand why all of the things included in my care plan were there." – Multiple linear regression, showed that intervention status predicted a higher summary score (intercept = 2.36, β = −.16, *p* = .75). This result was not significant. The model explained less than 1% of the variance in the summary score (R^2 = .004). Clear management plan – "I am not exactly sure what I will be working on with my counselor in the next couple of months." – Multiple linear regression showed that intervention status predicted a higher summary score (intercept = 2.80, β = −.31, *p* = .40). This result was not significant. The model explained approximately 2% of the variance in the summary score (R^2 = .02). Service user knowledge of care plan goals (n = 69/80, 86% contacted; control n = 36, 90% of group; intervention n = 33, 83% of group) – Participants in the intervention group had a significantly higher mean proportion of plan goals recalled than those in the comparison group; intervention 75%±28% vs. control 57%±32%; z= –2.367, *p* = .02. NB. The authors were only able to contact 86% of service users who had participated. Service user incorrect recall of care plan goals (n = 69/80, 86% contacted; control n = 36, 90% of group; intervention n = 33, 83% of group) – There were no significant differ-	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	hour training session in use of the tool. Service users do not appear to have received any training. - Key components and objectives of intervention – priorities and views on services. No further details reported. - Location/place of administration – The authors do not report on the location in which the tool was or is intended to be used. **Comparison intervention:** Treatment as usual. Clients and case managers in the control group completed care plans together at the 6-month point at which they were usually due using the usual method of completion. The authors note that the usual care planning process includes the use of a case manager completed electronic medical record used for billing purposes and to '… theoretically help case managers create recovery-oriented care plans.' (p55). They go on to report that there was significant heterogeneity in how these care plans were completed, noting that this was to be expected in real-world case management. **Outcomes measured – service user and practitioner related:** - Case manager satisfaction with each care planning encounter was measured using a bespoke questionnaire. This is comprised of 6 statements relating to case manager–service user communication using the tool – time, flow, credibility as a clinical tool, and	ences between groups in mean proportion of incorrect recall of goals; intervention 17%±16% vs. control 20%±16%. *p* value not reported. NB. The authors were only able to contact 86% of service users who had participated.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	organisation of information. The statements are rated on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). The authors report Cronbach's alpha of .74 for the entire scale. • 'Client' satisfaction with each care planning encounter was measured using a bespoke questionnaire. This is comprised of 7 statements rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). These items were designed to assess overall satisfaction with a 'mental health encounter' – case manager–client communication, decision-making involvement, service user informed about decisions made, clear management plan. The authors report Cronbach's alpha of .62 for the entire scale. • Service user recall of care plans was assessed 2 to 4 days after care planning sessions. 'The researcher first asked the client to note which goal areas appeared in the care plan. The client was then provided with a list of goal areas not already indicated by the client and asked whether they were in the care plan. For each area correctly identified in either manner, the client was asked to relate what his or her individualized goals or objectives or shared decisions (as applicable) were within each quality-of-life area.' (p56).		

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Follow-up: Unclear, the authors report that case managers and clients completed relevant questionnaires ‘immediately’ after study participation and it is not clear if they mean immediately after care planning sessions. Service user recall of care plans was assessed after 2 to 4 days. **Costs?** No. Costs and resource information not reported.		

7. Boyle G (2013) Facilitating decision-making by people with dementia: is spousal support gendered? Journal of Social Welfare and Family Law 35: 227–243

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To explore the social process of every day decision-making by couples living with dementia. In particular, to identify the different strategies used by spouses to support decision-making by their partners with dementia. **Methodology:** Qualitative – observation and interviews. **Country:** United Kingdom. Large metropolitan local authority in the north of England. **Source of funding:** Other – Economic and Social Research Council.	**Participants:** Service users and their families, partners and carers – couples where 1 person has a dementia diagnosis. **Sample characteristics:** • Age – Ranged from 40 years to 80 years. • Gender – 12 women, 9 men with dementia. • Ethnicity – Predominantly white British but also 1 South Asian couple (precise ethnic group anonymised). • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. Severity of dementia was informally assessed by the author (e.g. via observation of ability to carry out activities of daily living). This is reported to have revealed that some participants had 'more advanced dementia'. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** Twenty-one couples (42 participants).	Key strategies used by carer spouses to support decision-making included: Discussion and consultation – The most common mode of support was for the carer spouse to discuss relevant areas of decision-making with their partner – although barriers to being able to do this included forgetfulness, perceived indecisiveness, lack of understanding and loss of conversational ability. In this context, the carer spouse adapted their approach to take account of their partner's perceived difficulties. For example, adjusting the timing of and time for discussions and consultation (minimising to account for forgetfulness or maximising to allow for the gradual development of understanding). Spouse carers also used repetition and explanation to reinforce/ clarify information. They also limited choices in order to simplify decision-making, for example a husband showing his wife 2 different pizza options for dinner – using the visual aid of showing her the pizza boxes (from the freezer). In some cases husband carers were making decisions on their partner's behalf even when their partner had capacity – this is because the husband had 'always' made decisions (described as 'habituated decision-making', as a result of being married so long). Some spouse carers (mainly husbands) also admitted talking for their partner even when this was clearly unnecessary, for example at general practitioner appointments (the husband felt the wife couldn't explain things quickly enough).	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		Facilitating communication – When they had limited speech and/ or reduced capacity, carer spouses made a particular effort to include their partner in conversation. They also looked to non-verbal cues (facial expressions). Some husbands clearly facilitated their wives voices when their wives had difficulty communicating; whereas when the wives were perfectly capable of communicating, the husband often dominated through a habituated style of communication. Supervising, guiding and monitoring – This related to managing activities of daily living, not just decision-making, '... such support was aimed at promoting both decisional capacity and executional autonomy ...' (Authors, p234). NB. The findings about supporting executional autonomy are not extracted because they are not within the scope of NCCSC research question 2 on decision-making. It was clear that some spouse carers imposed their will on their partners, directing them towards preferred outcomes. At times, they explained it was in their partner's interest, for example one man insisting his partner accompany him on a daily walk when this clearly was not her preferred choice (he thought it would benefit her physical wellbeing). Another example was a man telling his wife to do housework when her preferred choice was to pursue a hobby. Emotional/ loving support – A wife emphasised how love and trust are key to managing every day decision-making, particularly as her husband (with dementia) completely trusts her. Ability to make decisions – Spouse carers tended to say that their partner's ability to make decisions had deteriorated, although the person with dementia felt their decisional abilities were relatively unchanged. For example, "Steve said his wife found it difficult to make even basic	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		decisions: ‘Yes, decisions are not easy for her. Choices are not easy, she’s happy with something laid down, without having to make up her mind about something or decide.’ However, as his wife had decided herself that she did not want to go to a day centre and gave a coherent argument why this was not desirable or necessary for her it was evident that she was able to make major decisions." (Participant, p237). According to the Mental Capacity Act 'all practicable steps' should be taken to enable individuals to make decisions before they are deemed to lack capacity. Most spouse carers adhered with this in terms of the support provided to make decisions (although they were largely unaware of the Mental Capacity Act itself). Spouse carers often used individualised, perceptive approaches to communicating with their partners so they could be involved in making decisions. They timed decision-making conversations to allow for forgetfulness and simplified explanations to aid understanding. Specific strategies – ‘The carer-spouses frequently supported their partners to express a choice or view by repeating questions to determine their authentic views and being receptive to indicators of their preferences. For example, they identified their partners’ valid choices if they initially said 'yes' when they meant 'no' and detected non-verbal signs of their likes and dislikes.’ (Authors, p237). So the spouse carers helped to enhance the decisional abilities of their partners with dementia – to understand, weigh up the relevant information and express a choice. However, not all were like this. Negative support limited the involvement of people living with dementia in decision-making. Some carer spouses were overly directive, constraining their partners' scope for ‘… authentic decision making …’ (Authors, p238). They also sometimes made decisions on behalf of their partners, even though they were capable of making the decision themselves, depriving	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		them of autonomy (more often the husband carers). This was mainly the smaller decisions, whereas both men and women excluded their partners with dementia from decision-making about big issues, for example attending a day centre (a wife decided this on behalf of her partner who clearly had capacity to decide for himself). This was often explained by the partners having other disabilities (leading to communication problems) but these clearly did not affect their capacity to make or contribute to a decision. So certainly for smaller decisions, wives were more facilitative.	

8. Goldsmith L, Woodward V, Jackson L et al. (2013) Informed consent for blood tests in people with a learning disability. Journal of Advanced Nursing 69: 1966–1976

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The aim of the study was to examine the ways in which informed consent for routine blood tests was obtained from people with a learning disability. **Methodology:** Qualitative – focused ethnography. **Country:** United Kingdom. **Source of funding:** Other – researchers based at academic institutions.	**Participants:** Service users and their families, partners and carers – all participants had a learning disability. **Sample characteristics:** • Age – 27–65 years. • Gender – Not reported. • Ethnicity – Not reported. • Disability – People with learning disability. • Long-term health condition – Learning disability. • Socioeconomic position – Half (50%) lived in a shared house (supported living), with the remainder either living at home with parents, living independently with support, or living alone with informal family support. Twelve of the 14 participants were single.	<u>The patient in the healthcare context</u> – subthemes: Attitude to having a blood test, feeling about going to the doctors, knowledge of healthcare system, relationship and communication with the healthcare professional and role of supporter Consultations involve social chat, explanation of procedure, and reason for blood test and often involved humour. For the majority the experience of going to the doctors was routine and held no fear. Some expressed strong views about their healthcare and appeared unwilling to tolerate a poor level of care. In general, there was a good deal of trust in health professionals. Some participants who attended the surgery independently explained that communication was not always easy. <u>Information and knowledge</u> – subthemes: presentation of health information, knowledge of blood tests in general, purpose of blood test and procedure. Information, if any, given during the blood test consulta-	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Sample size: Phase 1 involved observation of 6 participants with a learning disability having a routine blood test in general practice, followed by semi-structured interviews with 14 participants with a learning disability in Phase 2.	tions was verbal, and there were no examples of any alternative presentation such as a leaflet in accessible format. Some participants did not appear to understand why they had had a blood test; some guessed, although others clearly understood. The consent process – subthemes: seeking consent and expressing content. Sometimes both elements (procedure and purpose) were mentioned and the patient indicated understanding using non-verbal communication. In some consultations, there appeared to be little or no explicit attempt to obtain consent from the patient. The responses from participants when expressing consent were fairly minimal, and it was difficult to judge whether they were genuinely giving their informed consent. There was a range of ways the healthcare professionals approached the blood test and inconsistency in the level of information giving and seeking of consent. Behavioural characteristics – subthemes: Anxiety, bravado, fear, pain, relief, resistance. Participants exhibited behavioural cues as well as verbal expressions, before and after the procedure. Despite anxiety, there was much evidence of bravado prior to and during the procedure. Eventually, participants appeared to resign themselves to having the procedure, despite their apprehension. Strategies and coping mechanisms – subthemes: distraction tactics, establishing rapport, reassurance, use of humour or teasing. Throughout the consultations, there were various strategies used by both patients and health staff to deal with apparent nervousness and apprehension.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		'The self' – subthemes: self-identity, self-image, how I would like to be treated, decision-making. There was a tendency for some participants to try and impress with their reading ability, their level of independence and general capabilities; dismissing others who were less able.	

9. Stovell D, Wearden A, Morrison AP et al. (2016) Service users' experiences of the treatment decision-making process in psychosis: a phenomenological analysis. Psychosis 8: 31 –323

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To explore the treatment decision-making experiences of individuals with psychosis, and their implications for increasing service users' autonomy through clinical practice and research. **Methodology:** Qualitative – interpretative phenomenological analysis. **Country:** United Kingdom. **Source of funding:** Other – researchers based at academic institutions.	**Participants:** Service users and their families, partners and carers – 7 service users with multiple experiences of treatment for psychosis. **Sample characteristics:** • Age – mean age 49, (range 38–58). • Gender – 4 males and 3 females. • Ethnicity – all 7 participants were White British. • Disability – psychosis. • Long-term health condition – 5 had experienced hospitalisation with psychosis. • Socioeconomic position – none were in paid employment. **Sample size:** N = 7.	A need to feel listened to – Nearly all participants described experiences of disempowerment arising from feeling that they had not been listened to during treatment decision-making. • Importance of listening with respect, compassion and empathy. Participants' experiences of disempowerment included feeling that professionals were not listening, did not believe them, did not take their distress seriously and lacked compassion. A number of participants noted the positive contrast when they did feel heard. • Disempowerment by system and process. A number of participants described experiencing the treatment system as disempowering and de-humanising, feeling insignificant. • Feelings related to power. Most participants described having experienced feelings of disempowerment within treatment decision-making situations such as tribunals, being turned away from services when feeling suicidal or being sectioned. Psychotic experiences, treatment and stigma – experiences of psychosis seemingly affected treatment decision-making situations for participants both directly, via symptoms and medication; and indirectly, with influence of past treatment experiences, negative beliefs about psychosis,	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		low self-worth and perceptions of being negatively judged by others. • Reduction in agency and self-efficacy with distressing psychosis – psychotic experiences eroded participants' agency and self-efficacy in treatment decision-making directly, through the severity of their distress, undermining influence of hallucinations and feeling physically unwell. • Influence of treatment-related experiences and beliefs – participants approaches to treatment decision-making were influenced by their past experiences of, and beliefs about, treatment. • Power of negative constructions of mental illness – participants articulated many taken-for-granted meanings or social constructions around psychosis. They made associations between psychosis and being not normal and these sometimes reduced their confidence to raise concerns about their treatment. • Stigma, shame and low self-worth – the effects of self-stigma and low self-worth on treatment decision-making were more immediately apparent for some. • Feeling negatively judged by others – some participants described feeling negatively judged by professionals, in relation to their actions, choices and treatment decision-making capabilities. <u>Communication and support</u> – participants described experiences of disempowerment in treatment decision-making where they had not felt adequately informed or supported, or had difficulty communicating their needs within the context of unequal power dynamics. • Power dynamics, from the implicit to the coercive – participants expressed variously the view that psychiatrists hold immutable power, have authority over their patients, are of higher status and are the main drivers of treatment decision-making.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		- Power dynamics in sharing and use of knowledge – participants felt excluded from the content of multi-disciplinary discussions about them; the rationale for decisions; and information about psychosis, medication and other treatment options. - Importance of self-representation – being able to communicate their needs to clinicians during treatment decision-making was very important to most participants, but also frequently challenging because of psychosis-related distress, effects of medication and difficulties with assertiveness or self-expression. Differing conceptions of recovery – Participants seemed to vary in their degree of recovery orientation, that is, in how far they sought autonomy, considered a range of influences on their wellbeing, prioritised their values and goals and maintained a hopeful outlook. - Seeking autonomy – all participants expressed preferences for at least some level of autonomy in their treatment. - Relationship to the medical model – a key influence on participants' feelings of empowerment appeared to be their relationship to the medical model. - Seeking treatment congruent with values and goals – all participants spoke about their values and goals in relation to treatment decision-making. - Hope, an influence and an outcome in treatment decision-making – all participants felt hopeless, at times, in relation to treatment decision-making, due variously to highly restrictive decisions made entirely by others, negative messages imparted by clinicians, limited intervention options and persistently being offered treatment that was antithetical to the participants' understanding of their experience.	

Research question 3. Assessment of mental capacity:

- 3.1 – What interventions, tools and approaches are effective and cost-effective in supporting the assessment of mental capacity?
- 3.2 – What are the views and experiences of people who may lack mental capacity, their families and carers and others interested in their welfare on the acceptability of interventions, tools and approaches to support the assessment of mental capacity?

Effectiveness data

1. Aydin Er R and Sehiralti M (2014) Comparing assessments of the decision-making competencies of psychiatric inpatients as provided by physicians, nurses, relatives and an assessment tool. Journal of Medical Ethics 40: 453–457

Research aims.	**PICO (population, intervention, comparison, outcomes)**	**Findings.**	**Validity ratings.**
Study aim: To compare the evaluations provided by physicians, nurses and family members with the results of the MacArthur Competence Assessment Tool-Treatment with respect to their agreement regarding the decision-making competence of psychiatric inpatients. **Methodology:** Cross-sectional – descriptive comparative study of assessments in decision-making. **Country:** Turkey. **Source of funding:** Other – This study was supported by Kocaeli University Scientific Research Projects Unit (Project number: 2008/13).	**Participants:** • Service users and their families, partners and carers – 83 patients participated in the study, relatives of 65 patients. • Professionals/practitioners – 8 physicians and 5 nurses responsible for the care of the patients participated in the study. **Sample characteristics:** • Age – The 83 patients who participated in this study were between 18 and 63 years of age, with a mean age of 35.06±11.07 years (median = 33.0). • Gender – 60.2% were male. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – All patients had psychiatric illness, based on the diagnostic criteria, 39.8% of the patients had a mood disorder, 27.7% had a psychotic disorder, 18.1% had an anxiety disorder, and 14.5% had alcohol/substance dependence. • Long-term health condition – Based on the diagnostic criteria, 39.8% of	<u>Competence to make treatment decision of psychiatric patients (MacArthur Competence Assessment Tool-Treatment scores of the psychiatric patients)</u> – It was found that 73.5% of patients in the study were incompetent. Patients living alone demonstrated greater competence in decision-making than patients who lived with their families (χ^2 = 5888; p = 0.028). There were no statistically significant relationships between demographic variables, such as gender, age, education level and work status and decision-making competence. Patients hospitalised for the first time, and those who were hospitalised voluntarily, were more competent in decision-making than patients who had been previously hospitalised or those who had been hospitalised involuntarily (χ^2 = 8.310; p = 0.016 and χ^2 =8.292; p = 0.002). Other clinical characteristics do not result in a significant difference in decision-making competence. <u>The relationships among evaluations made by the physician, nurse, patient's relative and MacArthur Competence Assessment Tool-Treatment</u> – There was moderate agreement between the evaluations of the physicians and nurses (κ = 0.526, p = 0.000), but poor agreement between the evaluations of either the nurses or physicians	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	the patients had a mood disorder; 27.7% had a psychotic disorder; 18.1% had an anxiety disorder; and 14.5% had alcohol/substance dependence. - Sexual orientation – Not reported. - Socioeconomic position – Not reported. **Sample size:** N = 83. **Outcomes measured:** Service user related outcomes – competence to make treatment decision of psychiatric patients, and the relationships among evaluations made by the physician, nurse, patient's relative and MacArthur Competence Assessment Tool-Treatment. **Costs?** No cost information reported.	and those of the relatives (κ = 0.267, *p* = 0.003; κ = 0.318, *p* = 0.000). The competence evaluation carried out using MacArthur Competence Assessment Tool-Treatment statistically differed from the evaluations of the nurses, physicians and relatives, respectively ($\chi^2 = 9.247$, $p = 0.010$; $\chi^2 = 6.303$, $p = 0.0043$; $\chi^2 = 7.635$, $p = 0.022$). More than half the patients evaluated by the MacArthur Competence Assessment Tool-Treatment as incompetent in decision-making were either partially or fully competent. The assessments of the psychiatric nurses were in better agreement with the MacArthur Competence Assessment Tool-Treatment results than the assessments of either the physicians or relatives.	

2. Carling-Rowland A, Black S, McDonald L et al. (2014) Increasing access to fair capacity evaluation for discharge decision-making for people with aphasia: a randomised controlled trial. Aphasiology 28: 750–765

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
Study aim: To develop and test the effectiveness of a communicatively accessible capacity evaluation tool with communication training supports; thus, allowing healthcare professionals to evaluate more equitably the capacity of people living with aphasia to consent to be admitted to long-term care.	**Participants:** - Service users and their families, partners and carers – Study had 32 participants with aphasia. - Professionals/practitioners – Study had 32 social workers as participants along with 3 speech language pathologists. **Sample characteristics:** - Age – People with aphasia – ages ranged from 42 to 77 years (M 61.9	<u>Capacity determination of people with aphasia</u> – The results showed that when using the Capacity to Make Admissions Decisions questionnaire, 1 evaluator found a competent person with aphasia lacking in capacity, and 12 of the evaluators were unable to determine capacity. Using the communicatively accessible version of the questionnaire, the Communication Aid to Capacity Evaluation, 100% of the evaluators were able to accurately determine capacity.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
Methodology: Quantitative – randomised controlled trial. **Country:** Canada. **Source of funding:** Government – This work was supported by the Brill Chair of Neurology, Ontario Graduate Scholarship, Peterborough K.M. Hunter Graduate Studentship, Government of Ontario/Paul and Adele Deacon and the Government of Ontario/Heart and Stroke Foundation of Ontario Graduate Scholarships in Science and Technology.	years; SD 10.2). Social work evaluators – Their ages ranged from 27 to 66 years, (M 42 years). Age of speech and language pathologists not mentioned. • Gender – Participants with aphasia: men – 18; women – 14 All social work evaluators were women Gender of speech and language pathologists not mentioned • Ethnicity – Participants with aphasia: Caucasian – 25; Asian – 5; Black – 2. Ethnicity of social workers and speech language pathologists is not reported. • Religion/belief – Not reported. • Disability – All participants with aphasia had a diagnosis of stroke apart from one with a subdural haematoma. Fewer than 10% of the participants had mild to moderate expressive language impairments, 2 participants reported a hearing loss. • Long-term health condition – All participants with aphasia had a diagnosis of stroke apart from one with a subdural haematoma. Fewer than 10% of the participants had mild to moderate expressive language impairments, 2 participants reported a hearing loss. • Sexual orientation – Not reported. • Socioeconomic position – All participants with aphasia completed a minimum of Grade 10 education, and over half of the participants completed college or university education	Social worker evaluators communication skills – The results showed that the social worker evaluators in the experimental group, following the communication training and with the use of the Communication Aid to Capacity Evaluation, had significantly better communication skills, Revealing Competence ($F_{2, 29}$ = 12.03, p = .002), which in turn increased the people with aphasias' abilities to Transfer Information ($F_{2, 29}$ = 10.51, p = .003). Three of the 4 constructs in the Measure of Skill in Supported Conversation and Measure of Participation in Conversation showed a large effect size: Acknowledging Competence, d = .88; Revealing Competence, d = 1.13; Transaction, Cohen's d = .99. The construct of 'Interaction' showed a moderate effect size (d = .52). Social worker evaluators confidence in capacity determination – The group x time result, which compared the 2 groups (experimental vs. control) across 2 administrations, showed that the increase in confidence to determine capacity using Communication Aid to Capacity Evaluation with communication training as compared to Capacity to Make Admissions Decisions was highly significant ($F_{2, 29}$ = 13.511, p = .001). Effect size d = 1.3021 (95% CI – 0.538 to 2.0662) Perspectives of people with aphasia – The results for the 2 questions regarding comprehension were found not to be statistically significant. The question regarding 'Communicating Answers' did reveal a statistically significant difference, t (16) = -5.39, p > 0.000. The paired samples t-test demonstrated a significant difference in the levels of frustration pre-and post-test as a result of the intervention, t (16) = -3.598, p = .002. Post hoc analysis – Results of logistical regression analysis showed that neither severity levels of language deficits,	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	with occupations ranging from a provincial government minister to a roofer. **Sample size:** - Total – 32 participant pairs (people with aphasia paired with social worker evaluators) completed the study protocol, 17 participant pairs in the experimental group and 15 in the control group. Three speech language pathologists also participated in the study. - Intervention – 17 participant pairs (people with aphasia paired with social worker evaluators) were in the experimental group. - Control – 15 participant pairs (people with aphasia paired with social worker evaluators) were in the control group. **Intervention category:** Tools to support assessment of mental capacity – Communication Aid to Capacity Evaluation. - Description – The Communication Aid to Capacity Evaluation is a communicatively accessible version of the 'The Capacity to Make Admissions Decisions' and incorporates relevant legal constructs contained in the Health Care Consent Act. - Delivered by – Not reported. The copies and training DVD for the intervention, were given to social worker evaluators. Any questions they had regarding administration and communication techniques were answered.	nor social worker evaluators' experience were significant predictors of the social worker evaluators' ability to determine capacity, expressive language impairments $p = .643$, receptive aphasia $p = .200$, social worker evaluators' experience $p = .612$. There was a significant difference in communication skills of social worker evaluators contributing to an inability to determine capacity between the two groups ($F_{2, 29} = 6.17$, $p = .019$).	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	They were given a further week to familiarise themselves with the Communication Aid to Capacity Evaluation and to review the training DVD. • Delivered to – Social worker Evaluators in the intervention group. • Duration, frequency, intensity, etc. – Not reported. • Key components and objectives of intervention – To measure the effectiveness of the Communication Aid to Capacity Evaluation with communication training as a capacity evaluation tool for people with aphasia. Does the use of Communication Aid to Capacity Evaluation result in more accurate determinations of capacity? Do improved communication skills increase the confidence of Social Worker Evaluators in their determinations of capacity? Components – pictorial and written support to explain capacity evaluation, long-term care, and the process of appeal; information required to demonstrate understanding of an admission to long-term care versus another living environment and an appreciation of the foreseeable consequences of a decision; a training DVD focusing on the effective administration of the Communication Aid to Capacity Evaluation and communication techniques. Content/session titles – The Communication Aid to Capacity Evaluation is a communicatively accessible version of the Capacity to Make Admissions Decisions and incorporates relevant		

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	legal constructs contained in the Health Care Consent Act. The first third of the Communication Aid to Capacity Evaluation includes pictorial and written support to explain capacity evaluation, long-term care, and the process of appeal. The latter two-thirds illustrate the information required to demonstrate understanding of an admission to long-term care versus another living environment and an appreciation of the foreseeable consequences of a decision. The pictures and text, combined with communication strategies, provides a vehicle for the patient to communicate complex information non-verbally, and for the evaluator to verify that information. A training DVD focusing on the effective administration of the Communication Aid to Capacity Evaluation and communication techniques. • Location/place of delivery – Not reported. **Comparison:** Control group social work evaluators were emailed general information on aphasia. **Outcomes measured:** Service user related outcomes – capacity determination of people with aphasia; social worker evaluators' communication skills; social worker evaluators' confidence in capacity determination; and perspectives of people with aphasia.		

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	Follow-up: Around two weeks post-intervention. **Costs?** No cost information is provided.		

3. Feng BS, Person C, Phillips-Sabolet J et al. (2014) Comparison between a standardized questionnaire and expert clinicians for capacity assessment in stroke clinical trials. Stroke 45: e229–e232

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
Study aim: The study aims to compare a standardised questionnaire (modified, stroke-specific, version of the Aid to Capacity Evaluation) and expert clinicians' capacity assessments. **Methodology:** Prospective pilot study comparing 3 different capacity evaluations performed in a single group of stroke patients. **Country:** United States – Texas. **Source of funding:** Government – National Institutes of Health Clinical and Translational Award.	**Participants:** Service users and their families, partners and carers – Study participants were patients diagnosed with stroke. **Sample characteristics:** • Age – Mean – 67.8 years and standard deviation +/- 14.9 • Gender – 18 males and 12 females • Ethnicity – African-American – 12 (40%); Caucasian – 11 (36.7%); Asian – 1 (3.3%); Hispanic – 6 (20%). • Religion/belief – Not reported. • Disability – All patients were diagnosed with either an ischemic or hemorrhagic stroke. Thirty-seven per cent exhibited aphasia and neglect, whereas the remaining participants lacked these deficits. • Long-term health condition – All patients were diagnosed with either an ischemic or hemorrhagic stroke. Thirty-seven per cent exhibited aphasia and neglect, whereas the remaining participants lacked these deficits. • Sexual orientation – Not reported. • Socioeconomic position – Only education of participants were reported: No schooling 2 (6.9%); some high	<u>Frequency (percentage) of Capacity Decision by Aid- to-Capacity Evaluation, Psychiatrist, and Neuropsychologist</u> The Aid to Capacity Evaluation, neuropsychologist, and psychiatrist determined many patients lacked decision-making capacity: 70% (21/30), 52% (15/29), and 28% (8/29), respectively. <u>Sensitivity and specificity of the Aid to Capacity Evaluation</u> The Aid to Capacity Evaluation demonstrated high sensitivity: 93.8% (95% CI, 69.8 to 99.8) compared with neuropsychologist and 100% (95% CI, 63.1 to 100) compared with psychiatrists. The Aid to Capacity Evaluation demonstrated low specificity: 53.8% (95% CI, 25.1 to 80.8) compared with neuropsychologist and 42.9% (95% CI, 21.8 to 66.0) compared with psychiatrists. <u>Positive predictive value and negative predictive value of the Aid to Capacity Evaluation</u> Positive predictive value = 40% (95% CI 19.1 to 64) compared with psychiatrist and 71.4% (95% CI 47.8 to 88.7) compared to neuropsychologists. The Aid to Capacity Evaluation had a high negative predictive value to detect intact capacity versus clinicians; misclassifying only 1 patient capable when clinicians recorded incapacity (false-negative rate of 6.2%).	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	school 8 (27.6%); High school diploma/GED 11 (37.9%); some college 4 (13.8%); College degree 3 (10.3 %); Advanced degree 1 (3.5%). **Sample size:** N = 30. **Outcomes measured:** Service user related outcomes – all patients underwent 3 independent capacity assessments: comparison between Aid to Capacity Evaluation and capacity assessment by psychiatrist and neuropsychologist was done. Measurements – Modified, stroke-specific, version of the Aid to Capacity Evaluation performed by a trained research assistant; capacity evaluation performed by a psychiatrist; neuropsychological examination followed by administration of the Neuropsychological Assessment Battery Judgment subtest and Complex Ideational Material and Syntactic Processing subtests from the Boston Diagnostic Aphasia Examination. **Costs?** No cost information reported.		

4. Gregory R, Roked F, Jones L et al. (2007) Is the degree of cognitive impairment in patients with Alzheimer's disease related to their capacity to appoint an enduring power of attorney? Age and Ageing 36: 527–531

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
Study aim: To investigate the capacity to create an Enduring Power of Attorney as determined by a clinical assessment is significantly related to	**Participants:** Service users and their families, partners and carers – Participants with a DSM-IV diagnosis of Alzheimer's disease were recruited from the Old Age Psychiatric service at the Queen Elizabeth Psychiatric Hospital, Birmingham, United Kingdom.	<u>Association between capacity and level of cognitive impairment/Mini Mental State Examination score</u> – There was a significant association between level of cognitive impairment and capacity to create an Enduring Power of Attorney ($\chi^2 = 35.15$, $p < 0.0001$). Mini Mental State Examination score was found to be significantly different in patients with capacity and patients without ($U = 103.0$, $p < 0.0001$).	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
a degree of cognitive impairment, and whether Mini Mental State Examination (Folstein et al. 1975) score is a good predictor of a patient's capacity. To examine whether any socio-demographic factors (age, gender, education, and qualifications), are related to a patient's capacity to create an Enduring Power of Attorney. **Methodology:** Cross-sectional – quantitative descriptive cross-sectional study. **Country:** United Kingdom – Birmingham. **Source of funding:** Not reported.	**Sample characteristics:** - Age – Median age was 80.0 years (IQR 75–85, range 37). - Gender – 49 (66%) were female and 25 (34%) were male. - Ethnicity – Not reported. - Religion/belief – Not reported. - Disability – All Participants with a DSM-IV diagnosis of Alzheimer's disease. Twenty patients (27%) were classed as suffering from severe cognitive impairment, 27 (36.5%) were moderate and 27 (36.5%) mildly cognitively impaired. - Long-term health condition – All Participants with a DSM-IV diagnosis of Alzheimer's disease. Twenty patients (27%) were classed as suffering from severe cognitive impairment, 27 (36.5%) were moderate and 27 (36.5%) mildly cognitively impaired. - Sexual orientation – Not reported. - Socioeconomic position – Median age of leaving school was 14.0 years (IQR 14 -15, range 10). Sixty-three patients (85%) had not received any formal qualifications while in education. **Sample size:** N = 74. **Outcomes measured:** Service user related outcomes – association between capacity and level of cognitive impairment/ Mini Mental State Examination score; association between capacity and socio-demographic factors; predictors of	Association between capacity and socio-demographic factors – There were no associations between socio-demographic factors such as age, gender, qualifications, age of leaving school and capacity to create an Enduring Power of Attorney. Predictors of capacity – Logistic regression showed that Mini Mental State Examination score was the only variable to significantly predict capacity (OR = 1.6, 95% CI 1.3 to 2.0). Mini Mental State Examination score correctly classified 83.8% of the patients. Receiver operating characteristic analysis (Sensitivity, Specificity, Positive predictive value, Likelihood ratio) – The area under the curve for the Mini Mental State Examination score as a test to identify incapacity to create an Enduring Power of Attorney was 0.921 (95% CI 0.863 to 0.979). Optimal sensitivity and specificity were obtained using a cut-off Mini Mental State Examination score of 18: sensitivity 86.2% (95% CI 67.4 to 95.5), specificity 82.2% (95% CI 67.4 to 91.5). Positive predictive value 75.8% (95% CI 57 to 88%), Negative predictive value 90.2% (95% CI 76 to 97%). Likelihood ratio for a positive result (LR+ve) = 4.84 (95% CI 2.54 to 9.24); likelihood ratio for a negative result (LR -ve) = 0.16 (95% CI 0.06 to 0.42).	

Research aims.	PICO (population, intervention, comparison, outcomes)	Findings.	Validity ratings.
	capacity; receiver operating characteristic analysis (sensitivity, specificity, positive predictive value, and likelihood ratios). **Costs?** No costs information reported.		

5. Lai JM, Gill TM, Cooney LM et al. (2008) Everyday decision-making ability in older persons with cognitive impairment. American Journal of Geriatric Psychiatry 16: 693–696

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To demonstrate the reliability and validity of the Assessment of Capacity for Everyday Decision-Making, an instrument to evaluate everyday decision-making. **Methodology:** Cross-sectional – assesses the reliability and validity of an instrument. **Country:** United States. **Source of funding:** Other – This work was supported by the Robert Wood Johnson Foundation, the NIA (T32AG1934 (JML), K24AG021507 (TMG), P30-AG10124 (JHK)), the Alzheimer's Association (IIRG-05-14532 (KAH)), the Donaghue Foundation (#02-102	**Participants:** Service users and their families, partners and carers – Participants were 39 persons with very mild to moderate cognitive impairment and 13 cognitively intact caregivers. **Sample characteristics:** • Age – Patients (n = 39) had a mean age of 81, caregivers (n = 13) had a mean age of 62. • Gender – Not reported. • Ethnicity – Forty-nine (94%) of the 52 total participants were White. • Religion/belief – Not reported. • Disability – All participants were treated for cognitive difficulties – Thirty-six of the 39 (92%) participants had a diagnosis of dementia (50% Alzheimer's disease, 3% vascular dementia, and 47% unspecified type), and 3 had mild cognitive impairment. • Long-term health condition – Thirty-six of the 39 (92%) participants had a diagnosis of dementia (50% Alzheimer's disease, 3% vascular dementia, and 47% unspecified type), and 3 had mild cognitive impairment.	<u>Reliability of the Assessment of Capacity for Everyday Decision-Making</u> – Inter-scorer reliability (n = 15) – intraclass correlation coefficients of 0.72, 0.69, and 0.65, respectively, for understanding, appreciation, and reasoning. Percentage agreement for choice was 93%. For patients and caregivers combined (n = 52), the internal consistency of the Assessment of Capacity for Everyday Decision-Making abilities was also good, with Cronbach alpha values of 0.92, 0.88, and 0.84, respectively, for understanding, appreciation, and reasoning. <u>Distribution of Assessment of Capacity for Everyday Decision-Making Ability Scores</u> – Performance of patients (n = 39) and caregivers (n = 13) on measures of everyday decision-making performance were compared. Overall, both groups were equally capable of articulating a choice. They differed in their abilities to understand, appreciate, and reason. NB. Higher Scores represent better performance on the ability measure. Ability to understand – Only 15 patients (38%) achieved an understanding score above the lowest score observed in the caregiver group. Patients – Mean = 5.2 (SD 3.2); Caregivers – Mean = 9.8 (SD 0.6). Ability to appreciate – Six patients (15%) scored in the	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
(EHB)), a Greenwall Faculty Scholar Award (JHK), and the Ware Alzheimer Program (JHK).	• Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** People with 'very mild to moderate cognitive impairment' n = 39; caregivers n = 13 ('cognitively intact'). **Outcomes measured:** service user related outcomes – reliability and validity of the new tool Assessment of Capacity for Everyday Decision-making; reliability of the Assessment of Capacity for Everyday Decision-Making; distribution of Assessment of Capacity for Everyday Decision-Making Ability Scores; correlates of Everyday Decision-making Performance. **Costs?** No cost information provided.	highest category (7–8) for appreciation, whereas, all caregivers scored within the highest category. 22/39 patients (56%) demonstrated inadequate (score = 0) recognition of proxy reported functional problems. Patients – Mean = 3.5 (SD 2.0); Caregivers – Mean = 7.9 (SD 0.3). Ability to reason – Performance on reasoning ability was similar to appreciation, with only 6 patients (15%) achieving scores in the highest range (9 or 10). It was also observed total scores above 5 points in this ability for 30 patients (77%), reflecting the higher scores found from questions testing comparative reasoning and logical consistency. Patients – Mean = 6.3 (SD 2.1); Caregivers – Mean = 10 (SD 0) Ability to express a choice – Patients – Mean = 1.9 (SD 0.3); Caregivers – Mean = 2 (SD 0). <u>Correlates of Everyday Decision-making Performance – No significant correlation between Assessment of Capacity for Everyday Decision-Making performance and the variables of age, gender, or education level</u> – Mini Mental State Examination scores had a moderate to strong correlation with all 3 decision-making abilities (0.48 ≤ rs ≤0.60, all *p* <0.002). Trails B and Controlled Oral Word Fluency Test showed a moderate association with Assessment of Capacity for Everyday Decision-Making understanding and reasoning performance (0.33≤ rs ≤0.59, all *p* <0.04). Three tests (Trails A and B, COFL) demonstrated no correlation with Assessment of Capacity for Everyday Decision-Making appreciation scores (0.06≤ rs ≤0.25 *p* >0.08). Each Assessment of Capacity for Everyday Decision-Making ability measure was associated with its corresponding measure on the MacArthur Competence Assessment Tool-	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		Treatment: appreciation rs = 0.38 (*p* =0.02), reasoning rs =0.50 (p=0.001), understanding rs = 0.63 (*p* < 0.001), and expressing a choice rs = 0.71 (*p* < 0.001).	

6. Mills W, Regev T, Kunik M et al. (2014) Making and Executing Decisions for Safe and Independent Living (MED-SAIL): development and validation of a brief screening tool. American Journal of Geriatric Psychiatry 22: 285–293

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The purpose of the study was to describe the development and preliminary validation of the Making and Executing Decisions for Safe and Independent Living (MED-SAIL), a brief screening tool for capacity to live safely and independently in the community. **Methodology:** Prospective preliminary validation study. **Country:** United States. **Source of funding:** Other – Grants received from the Greenwall Foundation Bioethics Small Grants Program; the Atlantic Philanthropies; the John Hartford Foundation Awards for Effective Leadership to Improve Care to Older	**Participants:** Service users and their families, partners and carers – Forty-nine community-dwelling older adults. **Sample characteristics:** • Age – Mean (SD) – 76 years (10.9). • Gender – Females – 28 (57.1%); Males – 21 (42.8%). • Ethnicity – Black, non-Hispanic – 42 (85.7); White, non-Hispanic – 5 (10.2); Asian or Pacific Islander – 2 (4.1). • Religion/belief – Not reported. • Long-term health condition – Participants have moderate to advanced cognitive impairment, clinically important functional declines, but mild to no depressive symptoms. The comprehensive capacity assessment clinic determined that 25% (N =12) of the participants had no capacity, 71% (N = 35) had partial capacity, and 4% (N =2) had full capacity. • Sexual orientation – Not reported. • Socioeconomic position – Education – Primary school or less – 11 (22.4). Some high school – 16 (32.7). High school diploma/GED – 10 (20.4).	Internal consistency – Cronbach's alpha coefficients first scenario, a = 0.77, second scenario, a = 0.78, mean score across the 2 scenarios, a =0.85. Discriminant validity – Making and Executing Decisions for Safe and Independent Living tool did not have a significant relationship with physical function (ADLs) and depression (PHQ-9). Convergent validity – Pearson's correlations indicated significant positive correlations for Making and Executing Decisions for Safe and Independent Living and the Independent Living Scale (r = 0.573, *p* < 0.001) and Instrumental Activities of Daily Living (r = 0.440, *p* < 0.01). The correlation between Making and Executing Decisions for Safe and Independent Living and the St. Louis University Mental Status Examination was not significant at the *p* less than or equal to 0.05 level. Criterion-based validity – A Mann-Whitney test revealed significant differences between the no capacity group (M =3.25, SD =1.60) and partial/full capacity group (M = 6.11, SD =1.99) classification using the Making and Executing Decisions for Safe and Independent Living tool (U(48) =60.5, Z = 0.38, *p* < 0.0001). Accuracy of Making and Executing Decisions for Safe and Independent Living tool as a screening tool by examining	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Adults Practice Change Fellowship Program; the Houston Veterans Affairs Health Services Research and Development Center of Excellence; and the National Institute on Aging.	Some college/trade school – 8 (16.3). College degree or higher – 4 (8.1). **Sample size:** N = 49. **Outcomes measured:** Service user related outcomes – reliability, criterion-based validity, concurrent validity, and accuracy of classification for Making and Executing Decisions for Safe and Independent Living. The researchers evaluated the tool using two of seven scenarios developed through focus groups. These were " … the door to your home is locked and you do not have a key … you run out of a medication that you take regularly … you are at home and suddenly there is a fire in your kitchen … you notice that the cut on your foot is not healing and has become infected … someone calls you saying you've won $100,000 and all they need from you is your social security number to verify your identity … you are driving to the grocery store and you get a flat tire … your heating unit [air conditioner] breaks down and it is very cold [hot] outside." (p 287) The authors report that those administering the tool selected the two scenarios from this list which they felt were most appropriate to the person. **Costs?** No cost information reported.	sensitivity, specificity, and the Area Under the Curve – Receiver Operating Characteristic analysis revealed an area under the curve value of 0.864, (95% confidence interval: 0.84 - 0.99), which indicates good accuracy in distinguishing between no capacity and partial/full capacity. The authors provided a metric associated with potential cut points for Making and Executing Decisions for Safe and Independent Living tool scoring, including sensitivity, specificity, negative predictive value, and positive predictive value across the range of possible Making and Executing Decisions for Safe and Independent Living tool scores. In the discussion section, it is reported that the authors chose a mean Making and Executing Decisions for Safe and Independent Living cut-off score of 5.0 across 2 scenarios to maximise sensitivity. Making and Executing Decisions for Safe and Independent Living tool cut-off score of 5. Sensitivity – 0.92; specificity – 0.70; positive predictive value – 0.50; negative predictive value – 0.96. Using Bayesian analysis to examine effect of prevalence on positive predictive value, the authors determined that with the prevalence of no capacity at 25% for the current sample, an older adult with a Making and Executing Decisions for Safe and Independent Living score of less than 5 has a 79% probability of having no capacity.	

7. Moye J, Karel MJ, Edelstein B et al. (2007) Assessment of capacity to consent to treatment. Clinical Gerontologist 31: 37–66

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The study reports on the development of a tool to assess capacity to consent to treatment. The authors also present statistical data in an attempt to determine reliability and validity of the tool. **Country:** United States – Boston and Salt Lake City. **Methodology:** Diagnostic accuracy study. **Source of funding:** • Government – National Institute of Aging. • Other – Western Institute of Biomedical Research.	**Participants:** Service users and their families, partners and carers – The study sample was comprised of 2 groups – individuals with a clinical diagnosis of dementia or schizophrenia (recruited from an outpatient clinic at a Veterans Affairs centre in Boston); and a '... healthy comparison group ...' (p46) recruited from primary care clinics at a Salt Lake City Veterans Affairs centre. To be included in the study, individuals had to be aged 60 years or over; speak English as their first language; and be able to participate in a 1-hour interview (ability determined by a clinician with whom the person was familiar). For recruitment to the 'healthy' comparison group, individuals were excluded if they had a clinical diagnosis of dementia or schizophrenia, or if they scored lower than 26 on the Mini Mental State Examination (Folstein et al. 1975). **Sample characteristics:** • Age – Dementia group range = 65 to 88 years (M = 77.97, SD = 6.38); schizophrenia group range = 60 to 93 years (M = 70.85, SD = 8.68); comparison group range = 61 to 83 years (M = 74.35, SD = 6.38). • Gender – All participants were male. • Ethnicity – All participants were White. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – No con-	NB. Only data relating to reliability and validity of tool are reported here (e.g. no data on treatment choices made, prevalence of capacity, or values identified as most important by participants). Inter-rater reliability of decisional ability items (agreement between scores generated by raters in the study and those generated by an independent rater, using the scoring manual, examined through comparison of n = 10 patient protocols) – Total scores – There was a very strong positive correlation between total scores generated by raters for the study and those generated by an 'independent' rater (*r* = .90). This result was significant (*p* < .001). NB. Total score did not include scores on the communicating a choice subscale. Understanding – There was a very strong positive correlation between scores generated by raters for the study and those generated by an 'independent' rater on the understanding subscale (*r* = .90). This result was significant (*p* < .001). Appreciation – There was a very strong positive correlation between scores generated by raters for the study and those generated by an 'independent' rater on the appreciation subscale (*r* = .89). This result was significant (*p* < .01). Reasoning – There was a strong positive correlation between scores generated by raters for the study and those generated by an 'independent' rater on the reasoning subscale (*r* = .68). This result was significant (*p* < .05). Communicating a choice – There was a very strong positive correlation between scores subscale by raters for the study and those generated by an 'independent' rater on	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	ditions, other than clinically diagnosed dementia or schizophrenia, are reported. No details regarding duration of these conditions are reported. - Sexual orientation – Not reported. - Socioeconomic position – Not reported. **Sample size:** Total N = 59. Dementia group n = 20; schizophrenia group n = 20; comparison group n = 19. **Intervention category:** Tools to support assessment of mental capacity – consent to medical treatment. - Description – The Assessment of Capacity to Consent to Treatment interview – a tool developed to assess capacity to consent to treatment. - Delivered by – Unclear. The authors report that trained research assistants administered the Assessment of Capacity to Consent to Treatment interview in this study; however, it is not clear whether those who are likely to administer the interview in real-world situations require training. - Delivered to – Individuals with a neurocognitive or neuropsychiatric deficit (the sample of this study is comprised of people with dementia, people with schizophrenia, and a 'healthy' comparison group and the authors do not provide examples of specific groups with whom the tool could be used. - Duration, frequency, intensity, etc. – Not reported.	the understanding subscale (*r* = .98). This result was significant (*p* < .001). Inter-rater reliability examined by vignette – There were very strong positive correlations between scores generated by raters for the study and those generated by an 'independent' rater for vignette one (*r* = .95; *p* < .001), and vignette two (*r* = .83; *p* < .01). These results were significant. There was a strong positive correlations between scores generated by raters for the study and those generated by an 'independent' rater for vignette three (r = .76; *p* < .05). This result was significant. <u>Internal consistency of decisional ability items (across all three vignettes)</u> – Excellent internal consistency was demonstrated for the decisional ability related items (n = 56, drawn from the use of three vignettes with patients with dementia and schizophrenia) used in the Assessment of Capacity to Consent to Treatment interview (α = .96). Understanding – Excellent internal consistency was demonstrated for the decisional ability related items on the understanding subscale (α = .91; 26 items). Appreciation – Good internal consistency was demonstrated for the decisional ability related items on the appreciation subscale (α = .88; 12 items). Reasoning – Good internal consistency was demonstrated for the decisional ability related items on the reasoning subscale (α= .82; 12 items). Communicating a choice – Questionable internal consistency was demonstrated for the decisional ability related items on the communicating a choice subscale (α= .66; 6 items).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	- Key components and objectives of intervention – the first stage of the Assessment of Capacity to Consent to Treatment interview is described by the authors as a '... values interview to elicit values and preferences relevant to medical decisions.' (p40). The next stage uses hypothetical vignettes (or descriptions of proposed treatment) to assess decision-making ability in relation to appreciation, reasoning, understanding and communication of choice. - Location/delivery setting – The authors report that although the tool was developed for research purposes, it can be adapted for use in clinical settings. While the research version (used in this study) uses hypothetical vignettes, these can be substituted in clinical settings for descriptions of a proposed treatment. **Comparison:** The Assessment of Capacity to Consent to Treatment interview was evaluated by examining internal consistency, inter-rater reliability, association of scores with cognitive test performance, association of scores with clinician ratings, and differences in scores between patients where some degree of impairment is likely (people with dementia and schizophrenia) and a 'healthy' comparison group.	Internal consistency examined by vignette – Excellent internal consistency was demonstrated for vignette three (α = .91, 22 items). Good internal consistency was demonstrated for vignette one (α = .88, 16 items) and vignette two (α = .88, 18 items). Validity − Association between Assessment of Capacity to Consent to Treatment interview total score and Mini Mental State Examination total score – There was a moderate positive correlation between Assessment of Capacity to Consent to Treatment interview total score and Mini Mental State Examination total score (*r* = .47). This result was significant (*p* < .01). Association between Assessment of Capacity to Consent to Treatment interview total score and Brief Symptom Inventory total score – There was a weak positive correlation between Assessment of Capacity to Consent to Treatment interview total score and Brief Symptom Inventory total score (*r* = .25). This result was not significant (*p* value not reported). Association between Assessment of Capacity to Consent to Treatment interview total score and Brief Symptom Inventory subscales score – The authors report narratively that correlations between Assessment of Capacity to Consent to Treatment interview total score and Brief Symptom Inventory subscales (anxiety, depression, paranoia, and psychosis) were not significant. Association between Assessment of Capacity to Consent to Treatment interview capacity ratings and primary care clinician capacity ratings – There was moderate agreement between Assessment of Capacity to Consent to Treatment interview capacity ratings and primary care clinicians ratings of capacity in people with dementia and schizophrenia (κ = .44, n = 20/27, 74%). This result was significant (*p* < .01).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		Correlation between Assessment of Capacity to Consent to Treatment interview total score and primary care clinician ratings of subscale scores – There was a moderate positive correlation between Assessment of Capacity to Consent to Treatment interview and primary care clinician scores for reasoning (*r* = .41). This result was significant (*p* < .05). The authors report narratively that correlations between Assessment of Capacity to Consent to Treatment interview scores and primary care clinician scores for appreciation, communicating a choice, and understanding were not significant. Association between Assessment of Capacity to Consent to Treatment interview capacity ratings and capacity ratings by ‘experienced clinicians’ (3 clinicians produced ratings by consensus) – There was moderate agreement between Assessment of Capacity to Consent to Treatment interview capacity ratings and ‘experienced clinicians’ capacity ratings (κ = .50, n = 9/12, 75%). This result was significant (*p* < .05). Correlation between Assessment of Capacity to Consent to Treatment interview total score and ‘experienced clinicians’ ratings of subscale scores (3 clinicians produced ratings by consensus) – There was a strong positive correlation between Assessment of Capacity to Consent to Treatment interview and ‘experienced clinician’ scores for understanding (r = .73). This result was significant *p* < .01). There was a very strong positive correlation between Assessment of Capacity to Consent to Treatment interview and ‘experienced clinician’ scores for reasoning (r = .87). This result was significant *p* < .01). <u>Mean Group Differences on Decisional Ability Subscales for Vignette Three</u> – Understanding disorder – Individuals in the dementia and schizophrenia groups showed worse	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		performance than those in the 'healthy' comparison group on the understanding disorder subscale; dementia group mean score = 4.25 (1.83 SD), schizophrenia group mean score = 4.65 (2.18 SD), comparison group mean score = 6.11 (1.29 SD). This result was significant (*p* < .05). Post hoc analysis using Bonferroni correction also showed that individuals in the dementia and schizophrenia groups showed worse performance on this measure than those in the comparison group. This result was also significant (*p* < .05). Understanding treatments – Individuals in the dementia and schizophrenia groups showed worse performance than those in the 'healthy' comparison group on the understanding treatments subscale; dementia group mean score = 9.95 (4.71 SD), schizophrenia group mean score = 9.80 (4.68 SD), comparison group mean score = 13.16 (2.71 SD). This result was significant (*p* < .05). Post hoc analysis using Bonferroni correction also showed that individuals in the dementia and schizophrenia groups showed worse performance on this measure than those in the comparison group. This result was also significant (*p* < .05). Appreciation distrust – Individuals in the dementia and schizophrenia groups showed worse performance than those in the 'healthy' comparison group on the appreciation distrust subscale; dementia group mean score = 3.75 (0.55 SD), schizophrenia group mean score = 2.50 (1.50 SD), comparison group mean score = 3.95 (0.23 SD). This result was significant (*p* < .05). Post hoc analysis using Bonferroni correction also showed that individuals in the schizophrenia group showed worse performance on this measure than those in the comparison group and those in the dementia group. This result was also significant (*p* < .05). Appreciation foresight – Individuals in the dementia and schizophrenia groups showed worse performance than	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		those in the 'healthy' comparison group on the appreciation foresight subscale; dementia group mean score = 2.60 (1.35 SD), schizophrenia group mean score = 2.25 (1.41 SD), comparison group mean score = 3.63 (0.68 SD). This result was significant (*p* < .05). Post hoc analysis using Bonferroni correction also showed that individuals in the dementia and schizophrenia groups showed worse performance on this measure than those in the comparison group. This result was also significant (*p* < .05). Reasoning rational – Individuals in the dementia and schizophrenia groups showed worse performance than those in the 'healthy' comparison group on the reasoning rational subscale; dementia group mean score = 2.75 (1.41 SD), schizophrenia group mean score = 2.50 (1.47 SD), comparison group mean score = 3.89 (0.32 SD). This result was significant (*p* < .05). Post hoc analysis using Bonferroni correction also showed that individuals in the dementia and schizophrenia groups showed worse performance on this measure than those in the comparison group. This result was also significant (*p* < .05). Reasoning values – Individuals in the dementia and schizophrenia groups showed worse performance than those in the 'healthy' comparison group on the reasoning values subscale; dementia group mean score = 2.60 (1.27 SD), schizophrenia group mean score = 1.85 (1.23 SD), comparison group mean score = 3.74 (0.93 SD). This result was significant (*p* < .05). Post hoc analysis using Bonferroni correction also showed that individuals in the dementia and schizophrenia groups showed worse performance on this measure than those in the comparison group. This result was also significant (*p* < .05). Naming choices – Individuals in the dementia and schizophrenia groups showed worse performance than those in the 'healthy' comparison group on the naming choices sub-	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		scale; dementia group mean score = 1.45 (0.83 SD), schizophrenia group mean score = 1.25 (0.85 SD), comparison group mean score = 1.95 (0.23 SD). This result was significant (*p* < .05). Post hoc analysis using Bonferroni correction also showed that individuals in the schizophrenia group showed worse performance on this measure than those in the comparison group. This result was also significant (*p* < .05). Communicating a choice – Individuals in the dementia and schizophrenia groups showed worse performance than those in the 'healthy' comparison group on the communicating a choice subscale; dementia group mean score = 1.85 (0.49 SD), schizophrenia group mean score = 1.65 (0.75 SD), comparison group mean score = 2.00 (0.00 SD). This result was significant (*p* < .05). There was no association between performance on any of the subscales and – prior history of the medical condition (t = .69; ns); having made similar decisions previously (t = 1.37; ns).	

8. Sugano K, Okuyama T, Lida S et al. (2015) Medical decision-making incapacity among newly diagnosed older patients with haematological malignancy receiving first line chemotherapy: a cross-sectional study of patients and physicians. PLoS ONE 10: e0136163

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The purpose of this study was to identify the frequency of decision-making incapacity among newly diagnosed older patients with haematological malignancy receiving first-line chemotherapy, to examine factors associated with inca-	**Participants:** Service users and their families, partners and carers – Patients aged 65 years or over with a primary diagnosis of malignant lymphoma or multiple myeloma were recruited. **Sample characteristics:** - Age – The mean (±SD) and median age of the study population were 73.9 (±5.7) and 74 years, respectively, range (65–90 years).	Frequency of incapacity – Of the 114 patients who completed the Structured Interview for Competency Incompetency Assessment Testing and Ranking Inventory-Revised, 28 (25%, 95% CI 17% to 32%) patients were judged to be incompetent to some extent. Factors associated with incompetency – univariate analysis – Compared to participants who were competent, patients judged to be incompetent were more likely to be older, and to have more severe cognitive impairment and lower education level:	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
pacity and assess physicians' perceptions of patients' decision-making incapacity. **Methodology:** Cross-sectional – survey. **Country:** Japan. **Source of funding:** Government – This study was supported, in part, by a Grant-in-Aid for Cancer Research [grant number H22-009 to T.A.] from the Japanese Ministry of Health, Labor and Welfare, and a Grant-in Aid for Challenging Exploratory Research [grant number 23659264 to T.A.] from the Japanese Ministry of Education, Culture, Sports, Science and Technology.	• Gender – 64 males (55.7%) and 50 (44.3%) females. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – 71% of the subjects had malignant lymphoma and the remaining 28.9% had multiple myeloma. Eleven per cent of patients had performance status of 3 or 4. • Long-term health condition – 71% of the subjects had malignant lymphoma and the remaining 28.9% had multiple myeloma. • Sexual orientation – Not reported. • Socioeconomic position – 23.5% of participants were employed full time/part time and 59.1% had education high school or higher. **Sample size:** N = 114. **Outcomes measured:** Service user related outcomes – frequency of incapacity; factors associated with incompetency; physicians' recognition of patient incompetency. **Costs?** No. Cost information not reported.	Age – Competent (n = 86) – mean (73.1) SD (5.6); Incompetent (n = 28) – mean (76.6) SD (5.5) *p* < 0.01. Cognitive impairment – Competent (n = 86) – mean (26.2) SD (2.7); Incompetent (n = 28) – mean (23.7) SD (4.1) *p* < 0.01. Other factors such as performance status, depression, gender, diagnosis, education and household size did not reach statistical significance between competent and incompetent participants. Factors associated with incompetency: logistic regression analysis – Older patients and those with more severe cognitive impairment (i.e. lower Mini Mental State Examination score) had higher odds of being classified as incompetent according to the Structured Interview for Competency Incompetency Assessment Testing and Ranking Inventory-Revised: Age – Beta (0.92) SE (0.04) *p* value (0.03) Adjusted OR (1.10) 95% CI 1.01 to 1.19). Cognitive impairment – Beta (-0.18) SE (0.08) *p* value (0.02) Adjusted OR (0.84) 95% CI 0.73 to 0.97). Physicians' recognition of patient incompetency – Total 3 patients (3%, 95% CI 0% to 6%) were judged to be incompetent by physicians and these 3 patients were also considered to be incompetent by the SICIATRI-R. Cohen's kappa was -0.54, indicating that agreement was no greater than what would be expected by chance.	

9. Brown PF, Tulloch AD, Mackenzie C et al. (2013) Assessments of mental capacity in psychiatric inpatients: a retrospective cohort study. BMC Psychiatry 13: 115

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To '… evaluate how frequently mental capacity is assessed in psychiatric inpatients, whether the criteria for determining capacity set out in the MCA are used in practice, and whether this has increased with the introduction of the MCA.' (p1). **Methodology:** Audit – the authors' extracted data from the South London and Maudsley NHS Foundation Trust Biomedical Research Centre Case Record Interactive Search. **Country:** United Kingdom, England – South London and Maudsley NHS Foundation Trust. **Source of funding:** Not reported.	**Participants:** Service users and their families, partners and carers – Patients admitted to a psychiatric ward between 01/05/2006 and 31/01/2010 – inpatient admissions to an older adult, child or adolescent mental health, forensic psychiatry, rehabilitation service, and mental health in learning disability service psychiatric ward, or one of the South London and Maudsley NHS Foundation Trusts specialist referral units (e.g. affective disorders, eating disorders, psychosis). Data for patients under the age of 16 were excluded due to the scope of the Mental Capacity Act. For patients with multiple admissions during the study period, each admission was counted and considered separately. **Sample characteristics:** • Age – Total – 16–25 years n = 2629 (14.8%), 26–35 years n = 4368 (24.6%), 36–45 years n = 5184 (29.2%), 46–55 years n = 2800 (15.7%), 56–65 years n = 1188 (6.7%), 66–75 years n = 776 (4.4%) 76 years or older n = 799 (4.5%). Those with a documented capacity assessment 16–25 years n = 295 (11.3%), 26–35 years n = 335 (7.7%), 36–45 years n = 376 (7.2%), 46–55 years n = 228 (8.1%) 56–65 years n = 150 (12.7%), 66–75 years n = 151	Instances in which a documented capacity assessment took place – Documented capacity assessments took place for 9.8% of all admissions (1732/17744; 95% CI 9.3 to 10.2%). Mental capacity assessments were suggested by a clinical team member for a further 2.4% of admissions (423/17744); however, there is no record to show whether such an assessment took place. For informal admissions; capacity assessments were documented in only 4% of cases (433/10608); for patients admitted under Sections 4, 5, or 136 of the Mental Health Act, capacity assessments were documented in 9.8% of cases (68/703); for patients admitted under Section 2 of the Mental Health Act, capacity assessments were documented in 14.3% of cases (332/2326); for patients admitted under Section 3 of the Mental Health Act, capacity assessments were documented in 13.6% of cases (507/3740); for patients admitted under Section 3 of the Mental Capacity Act and detained for more than three months, capacity assessments were documented in 16.0% of cases (353/2201); and for patients admitted under a forensic section of the Mental Capacity Act, capacity assessments were documented in 25.1% of cases (92/367). The authors also report in their discussion section that for those admissions in which a person was detained (for over three months) under Section 3, a capacity assessment was documented in only 23% of cases (353/1539). Frequency of capacity assessment by type of admission is not recorded for other statuses. Frequency of capacity assessments (May 2006 to January 2010) – Change between May 2006 and January 2010 – In	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	(19.3%) 76 years or older n = 197 (24.7%). • Gender – Total – female n = 8147 (45.9%), male n = 9597 (54.1%). Those with a documented capacity assessment female n = 824 (10.1%), male n = 908 (9.5%). • Ethnicity – Total – White European n = 10511 (59.2%); Black African n = 1913 (10.8%); Black Caribbean n = 1567 (8.8%); Black other n = 1946 (11.0%); East Asian n = 410 (2.3%); South Asian n = 337 (1.9%), Mixed, other n = 1060 (6.0%). Those with a documented capacity assessment – White European n = 865 (8.2%); Black African n = 269 (14.1%); Black Caribbean n = 211 (13.5%); Black other n = 212 (10.9%); East Asian n = 35 (8.5%); South Asian n = 29 (8.6%), Mixed, other n = 111(10.5%). • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – No conditions other than mental health diagnosis at admission are reported. • Sexual orientation – Not reported. • Socioeconomic position – Marital Status – Single – Total n = 11164 (64.6%); those with a documented capacity assessment n = 1077 (9.4); Married/civil partnership – Total n = 2,283 (12.9%); those with a documented capacity assessment n = 244 (10.7%); divorced/separated – Total n = 2,182 (12.3%); those with a documented capacity assessment n = 188	May 2006, capacity assessments were conducted for 5% of admissions. By January 2010, this had increased to over 17%. Time-series regression demonstrated a significant increase of around 0.3 percentage points per month in the proportion of assessments carried out over the course of the study (regression coefficient = 0.294 [95% CI 0.258 to 0.328], $p < 0.0001$). There was no evidence of autocorrelation (Durbin-Watson statistic = 2.22). Immediately after the introduction of the Mental Capacity Act (November 2007), there was no step-wise increase in the proportion of inpatients assessed for capacity immediately (regression coefficient = 0.59, [95% CI −1.21 to 2.39], $p = 0.5$). <u>Practitioners who conducted capacity assessments (n = 1732)</u> – Doctors (n = 1227/1732, 70.7%) Approved social worker or approved mental health practitioner (308/1732, 17.8%). Nurse (103/1732, 6.0%) Multidisciplinary team members (34/1732, 2.0%). Unknown (60/1732, 3.5%). <u>Reason for capacity assessment (n = 1732)</u> – Psychiatric admission n = 752 (43.4%). Psychiatric treatment including ECT n = 435 (25.1%). Aftercare and accommodation n = 111 (6.4%). Physical health interventions n = 174 (10.1%). Legal issues n = 59 (3.4%). Finances, contracts, Lasting Power of Attorney, Advance Directive n = 75 (4.4) Other n = 126 (7.3%).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	(8.6%); widowed – Total n = 658 (3.7%); those with a documented capacity assessment n = 141 (21.4%); not-known – Total n = 1157 (6.5%); those with a documented capacity assessment n = 82 (7.1%). Diagnosis – - Organic and Developmental Disorders – Total n = 903 (5.1%); those with a documented capacity assessment n = 236 (26.0%). - Schizophrenia – Total n = 3,902 (22.0%); those with a documented capacity assessment n = 547 (14.0%). - Schizoaffective and other Psychotic Disorders 2,102 (11.9%); those with a documented capacity assessment n = 268 (12.7%). - Bipolar Disorder – Total n = 1,972 (11.1%); those with a documented capacity assessment n = 232 (11.8%). - Depression and Neurotic Disorders 3,246 (18.3%); those with a documented capacity assessment n = 211 (6.5%). - Personality Disorders – Total n = 909 (5.1%); those with a documented capacity assessment n = 55 (6.1%). - Substance Misuse Disorders – Total n = 3,582 (20.2%); those with a documented capacity assessment n = 109 (3.0%). - Eating Disorders and Other Behavioural Disorders 247 (1.4%); those	In their discussion section, the authors also report that for forensic wards, 87% of capacity assessments related to capacity to consent to treatment. Instances in which Mental Capacity Act criteria for determining capacity are reported (n = 1732) – Mental Capacity Act criteria in relation to determination of capacity were recorded in 254 admissions (14.7%). Before the introduction of the Mental Capacity Act these criteria were recorded in 11.5% of admissions. This increased to 15.5% after the introduction of the act. This increase was not significant ($\chi2 = 3.718$, *p* = 0.052). Time series analysis also showed an increase of 0.13 percentage points per month; however, this increase was not significant (95% CI −0.007 to 0.268, *p* = 0.06). Use of a form to document mental capacity assessments – A form was used to document capacity assessments in eight admissions (0.5%). Prevalence of incapacity (n = 1732) – Prevalence of incapacity – In cases in which a capacity assessment was conducted, 1101 admissions were recorded as lacking capacity (63.6%, 95% CI 61.3 to 65.8); 612 admissions were recorded as having capacity (35.1%); and 19 admissions (1.1%) did not report whether the person was assessed as having capacity or reported what the authors describe as 'ambiguous' outcome such as 'fluctuating capacity'. The proportion of admissions lacking capacity varied by diagnosis (see Table 3) with organic and developmental disorders showing the highest prevalence (82.2% and 67.1% respectively). Table 4 shows the proportion of psychiatric admissions found to lack capacity according to MHA status.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	with a documented capacity assessment n = 20 (8.1%). - Unknown – Total n = 881 (5.0%); those with a documented capacity assessment n = 54 (6.1%). Service – - General Adult Services – Total n = 11,957 (67.4%); those with a documented capacity assessment n = 1,074 (9.0%). - PICU – Total n = 564 (3.2%); those with a documented capacity assessment n = 108 (19.0%). - MHOA – Total n = 1,390 (7.8%); those with a documented capacity assessment n = 328 (23.7). - CAMHS – Total n = 255 (1.4%); those with a documented capacity assessment n = 28 (11.0%). - Specialist – Total n = 746 (4.2%); those with a documented capacity assessment n = 81 (10.9%). - Learning Disabilities – Total n = 60 (0.3%); those with a documented capacity assessment n = 24 (40.0%). - Addictions – Total n = 2,527 (14.2%); those with a documented capacity assessment n = 16 (0.6%). - Forensic – Total n = 177 (1.0%); those with a documented capacity assessment n = 62 (35.0%). - Rehab – Total n = 68 (0.4%); those with a documented capacity assessment n = 11 (16.2%). Mental Health Act Status –	<u>Proportion of assessments found to lack capacity by diagnosis (NB These data do not appear to be internally consistent)</u> – Organic and Developmental 236 (26.0) 194 82.2 (77.3-87.1) Schizophrenia 547 (14.0) 367 67.1 (63.1-71.0) Schizoaffective/Other Psychotic 268 (12.7) 163 60.8 (54.9-66.7) Bipolar Disorder 232 (11.8) 160 69.0 (63.0-75.0) Depression and Neurotic Disorders 211 (6.5) 111 52.6 (45.8-53.4) Personality Disorders 55 (6.1) 16 29.1 (16.7-41.5) Substance Misuse Disorders 109 (3.0) 47 43.1 (33.7-52.6) Eating and other Behavioural Disorders 20 (8.1) 6 30.0 (8.0-52.0) Unknown 54 (6.1) 37 68.5 (55.7-81.3) Total 1,732 1,101 63.6 (61.3-65.8) <u>Proportion of assessments found to lack capacity by MHA status (MHA status at time of assessment)</u> Informal – with documented capacity assessment n = 637; number assessed to lack capacity n = 320 (50.3; 95% CI 46.3 to 54.1). Section 4/5/136 – with documented capacity assessment n = 186; number assessed to lack capacity n = 149 (80.1, 95% CI 74.3 to 85.9). Section 2 – with documented capacity assessment n = 324; number assessed to lack capacity n = 274 (84.6%, 95% CI 80.6 to 88.5). Section 3 – with documented capacity assessment n = 507; number assessed to lack capacity n = 342 (67.5%, 95% CI 63.4 to 71.5). Criminal section – with documented capacity assessment n = 78; number assessed to lack capacity n = 16 (20.5%, 95% CI to 11.3 to 29.7).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	• Informal Total n = 10608 (59.8%); those with a documented capacity assessment n = 433 (4.1%). • Section 4/5/136 Total n = 703 (34.0%); those with a documented capacity assessment n = 68 (9.8%). • Section 2 Total n = 2326 (13.1%); those with a documented capacity assessment n = 332 (14.3%). • Section 3 Total n = 3740 (21.1%); those with a documented capacity assessment n = 507 (13.6%). • Section 3 detained for >three months Total n = 2,201 (12.4%); those with a documented capacity assessment n = 353 (22.9%). • Forensic Total n = 367 (2.1%); those with a documented capacity assessment n = 92 (25.1%). **Sample size:** N = 17744.	The authors also report in their discussion section that for those admissions in which a person was detained under Section 3 (for over 3 months), a capacity assessment was documented in only 23% (353/1539). Frequency of capacity assessment by type of admission is not recorded for other statuses. Frequency of findings of incapacity – When analysis by month was conducted, this demonstrated that the frequency with which admissions were determined to lack capacity decreased by 0.4 percentage points per month. This result was significant (regression coefficient −0.427, 95% CI −0.623 to −0.230, *p* = 0.0001).	

10. Emmett C, Poole, Bond J et al. (2013) Homeward bound or bound for a home? Assessing the capacity of dementia patients to make decisions about hospital discharge: comparing practice with legal standards. International Journal of Law and Psychiatry 36: 73–82

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To '… comment on how assessments of residence capacity are actually performed on general hospital wards compared with legal standards for the assessment of capacity set out in the Mental Capacity Act, 2005 (MCA).'	**Participants:** • Service users and their families, partners and carers – Interviews were conducted with elderly patients and their families who had been admitted to an acute or rehabilitation ward. Focus groups were also held with a small number of carers and members of staff from a voluntary agency currently supporting these individuals.	The authors report that three themes emerged from the data. These related to the 'type' of assessment (use of a functional approach as set out in legislation), the level of formality of assessments, and the extent to which information provided to patients as part of the assessment was 'relevant'. Approaches to assessment – functional or outcomes driven – The authors report that while the majority of practitioners understood the requirements for assessment of	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
(p73). **Methodology**: Qualitative – focus groups and interviews (and an 'analysis' of key ward-based interactions) and events involving the whole range of health and social care professionals, people with dementia and their families. These included routine activities such as 'consultant-led ward rounds, MDT meetings, case conferences and discharge planning meetings, as well as more informal interactions. Patients' medical records were also reviewed.' (p76). It is assumed that interviews were conducted with the same patients with whom case study analysis was undertaken; however, this is not clearly stated by the authors. **Country:** United Kingdom, England – Newcastle/North Tyneside. Fieldwork was conducted with patients and staff working in elderly wards (acute and rehabilitation) in 2 hospitals in the north of England.	• Professionals/practitioners – Interviews were conducted with a range of practitioners working in elderly care wards. This included junior and senior physicians and psychiatrists, variously qualified nursing staff (including a psychiatric liaison nurse), an Independent Mental Capacity Advocate, occupational therapists, a physiotherapist, and social workers. Focus groups were also held with a similar range of hospital-based staff; however, these also included general practitioners and psychologists as well as an assessor for nursing home placements, a care home manager and a chaplain with experience in the care of people with dementia. **Sample characteristics:** • Age – Not reported. • Gender – Not reported. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** Total sample size unclear. Interviews were conducted with n = 29 patients, n = 28 nominated family members, and n = 35 practitioners. Focus groups were also conducted with n = 22	capacity set out in the Mental Capacity Act, the 'statutory' approach was not always clear in practice. They highlight in particular the failure to provide and identify relevant information and how this was used to '… test the person's recall, understanding and ability to weigh matters up before communicating a decision.' (Authors, p77). They cite a description of practice provided by a social worker and note that their approach would lead to the provision of information that was irrelevant to the assessment as well as a failure to provide information on certain '… things the person (arguably) ought to know to make a capacities decision with respect to place of residence, such as his or her requirements (if any) for assistance, which would not necessarily be covered.' (Authors, p77). The authors also highlight examples of practice in which assessments tended to take an outcomes-based approach rather than a functional approach. They note that this was an issue when people with dementia or a cognitive impairment were being assessed: "I think this is an interesting issue around capacity, I think quite often capacity is used, or the issue around capacity is used, as a basis for saying that somebody's made a decision that you don't agree with yeah ... [Later in the interview]...I mean the difficulty thing is, like I say is about the unwise decision if it's difficult knowing sometimes whether somebody has been able to process the information and make a wise decision, make a capacitated decision or whether in fact they haven't been able to analyse it. I think that's quite difficult some- times but if you know your patient well enough you can generally judge that." "....erm then it comes down to that thing of whether it's an unwise decision but one made with a full understanding of the risks, or whether it's, you know, a decision, you know and completely no insight what the problems may be, what the consequences are and I think that's when you start to	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Source of funding: Other – National Institute for Health Research.	healthcare professionals (in 3 groups); and n = 3 carers and n = 2 voluntary agency staff members (in 1 group).	get very concerned about somebody's capacity to make decisions.” (Participant, p77). The authors go on to report that when practitioners did not agree with service users’ decisions, they interpreted this as evidence of a lack of capacity. They also state that best interests decisions were often made regardless of whether the person had capacity. They conclude that the concepts of ‘best interests’ and ‘risks’ clearly shaped capacity assessments when the person had dementia. The authors report that junior nursing staff, in particular, appeared to have difficulties and were more likely to be risk-averse. Nursing staff were also identified as a group for whom taking a functional approach was difficult because of the likely longer-term relationship they had developed with the person. The authors conclude that practitioners find it difficult to reconcile the desire to enable service users to make autonomous decisions with the instinct to protect others from the effects of ‘risky’ discharge decisions; consequently, capacity assessments are often subsumed into wider discussions regarding risk and harm. Formality of assessments – The authors report that practitioners took both formal and informal approaches to capacity assessments. They note that these often ‘… occurred over a period of time and involved gleaning information from various sources, which then fed into the overall capacity assessment. This was often referred to as having a ‘holistic view’ of the patient. It might involve, for instance, an OT home visit, the result of which would be fed into the assessment process to form a general picture of the patient's capacity.’ (Authors, p78). They go on to suggest that such an assessment and/or visit ‘… might either be used to inform judgements about the patient's functional ability to weigh things up, or it might encourage an outcomes approach to the assessment of	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		capacity: if the home visit went badly, but the patient still said he or she wished to go home, it might be presumed that this was in itself a marker of incapacity.' (Authors, p78). The authors report that these 'informal' assessments often took place during ward rounds that patients were often 'assessed' in this way on multiple occasions, and that assessments only became formalised after an extended period of time. With regards to 'formal' assessments, the authors report that these took the form of '… conversational exchanges between the patient and the assessor with questions about home-life, reasons for the current admission, the patient's feelings and their expectations concerning the future.' (Authors, p78). The authors go on to note that practitioners then made judgements on the basis of whether the persons response was 'reasonable', they also note that these assessments tended to be shaped by more general and informal observations made by members of the team over an extended period of time. They cite a description made by a consultant as evidence of this: 'You get a feeling about people's general capacity, but then…if a decision is being taken or being made or about to be taken, I think then we'll be slightly more specific about going to the patient and actually exploring the issues in more depth. So I think there's a gut feeling and then sort of you know hopefully, I think it mainly comes about if there's conflict or if there's concerns that we investigate that further by sort of direct questioning.' (Participant, p78). The authors conclude that the assessment of capacity was not routine, particularly when service users did not make their preferences known. They go on to suggest that this reliance on informal assessments may be indicative of a	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		failure by professionals to understand the required functional approach to capacity assessments. They suggest that more formal assessments may only occur when there is conflict between service users and practitioners, citing one professional as evidence of this: “But I don't feel that it happens in real life really. I don't, I think if the MDT and the patient's relatives decide that they should, that their level of requirement is that they might need care, I don't feel that we do assess their capacity if they just kind of, if patients are placid as you call it, if there's no big objection if they're not saying loudly ‘I want to go home’ then I don't feel that on a routine basis that we assess their capacity to agree with us, we only assess their capacity if they don't.” (Participant, p79). <u>Understanding information relevant to the decision</u> – The authors report that the information provided to service users varied in relation to the amount provided and its relevance. They note ‘questionable’ practice in which practitioners cited a service user’s inability to remember previous conversations and general confusion as evidence of a lack of capacity to be able to make a decision on place of residence: “… for some people it's actually very straightforward: they plainly don't have capacity because they can't remember, you know, anything. They don't know where they are, they think they're at home, they think I'm their daughter, you know they think they still live with their mother, you know things that are plainly not true and they plainly, even when we treated [the] medical problem, they plainly do not, cannot understand or retain relevant information about the home situation so then it's easy to make a decision that they don't have capacity and then we can make a best interests decision.” (Participant, p79).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		The authors also conclude that practitioners do not always clearly present information to service users in discussions regarding admission to residential care, citing concerns raised by one consultant that there may be a tendency to use euphemisms when discussing a long-term placements (e.g. 'a bit more care'). <u>Conclusions</u> – In their discussion section, the authors conclude that practitioners find it difficult to reconcile the requirements to enable service users to make autonomous decisions and to protect others from the effects of a 'risky' discharge decisions and they note that capacity assessments are often subsumed into wider discussions regarding risk and harm. The authors suggest that their research demonstrates that legal standards are not always met during assessments of capacity and that these can be used selectively as a means of achieving the 'best' solution. They go on to recommend that a more specific test be used when assessing capacity to make a decision on residence after discharge from hospital. They suggest that ability to understand, retain, weigh and communicate information in relation to: reasons for hospital admission; proposed post-discharge living arrangements; post-discharge needs and proposed support; and the persons and services who are willing and able to support them.	

11. Manthorpe J, Samsi K, Rapaport J (2014) Dementia nurses' experience of the Mental Capacity Act 2005: A follow-up study. Dementia 13: 131–143

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: This study is based on follow-up interviews from another study. The authors report that the '… overall aim of this part of the study was	**Participants:** Professionals/practitioners – dementia nurses. **Sample characteristics:** • Age – 50–59 years n = 8; 45–49	<u>Assessment of mental capacity</u> – The authors report that the nurses were having to deal with capacity (and assessment) related issues as a result of the frequency with which carers were asking them for advice on whether their relative still had capacity to make a decision and who could assess this.	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
to explore participants' understanding, over time, their practice experience of the implementation of the MCA and their reflections of change in nursing practice. More specifically, this related to what challenges, if any, they faced in everyday practice and whether any expectations in relation to the MCA had been met.' (p133). **Methodology:** Qualitative – interviews. **Country:** United Kingdom – England. **Source of funding:** Not reported.	years n = 1; 'late 30s' n = 1; 70 years n = 1. - Gender – female n = 14; male = n 1. - Ethnicity – Not reported. - Religion/belief – Not reported. - Disability – Not reported. - Long-term health condition – Not reported. - Sexual orientation – Not reported. - Socioeconomic position – Not reported. **Sample size:** N = 15.	They go on to report that nurses suggested that carers did not always understand that capacity was decision-specific: "Usually when we start having that conversation [carers] will say things like, 'well [my mum] doesn't know what she's doing, she can't make decisions'. When you actually sit down and say 'well, actually she can, she can decide that she doesn't want jam on her toast', that's a decision, however small. It's quite a long way down the road before you can say that somebody doesn't have that capacity." (Participant, p136). The authors also report that the nurses had concerns regarding the accuracy of assessments made by other practitioners and that in cases where the person's capacity to refuse a service was being queried assessments were '… inaccurate or risk-averse …' (Authors, p136). The authors suggest that the nurses' experience of capacity assessments also varied in terms of the practitioners involved. They report that nurses had concerns regarding the use of private medical assessments in assessing capacity to appoint a Lasting Power of Attorney as this person did not have knowledge of the individual.	

12. McDonald A, Dawson C, Heath B (2008) The impact of the Mental Capacity Act 2005 on social workers' decision making: a report for SCIE. Norwich: University of East Anglia

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors aimed to explore the '... impact of the Mental Capacity Act on assessments of capacity and best interests decision-	**Participants:** Professionals/practitioners – Social workers and a social work assistant working with older people with dementia. Interviewees were based in 1 of 5 community teams in 1 of 3 geographical areas. Two of these individuals were also members of a hospital based mental	NB. The authors also report on comments made by a service user and carer 'reference group' (convened by the regional Alzheimer's Group) on the research; however, these have not been extracted by the NCCSC as they were not generated as part of this research study.	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
making and their integration into record-keeping and care planning.' (p3). **Country:** United Kingdom, England – Norfolk. **Methodology:** Qualitative – semi-structured interviews in which interviewees were asked to describe examples from their practice in which an assessment of mental capacity was involved. The authors also made observations of practice. **Source of funding:** Voluntary/Charity – Social Care Institute for Excellence.	health team. One interviewee was an Approved Social Worker. Length of time qualified varied between 2 months and 15 years. **Sample characteristics:** • Age – Not reported. • Gender – Female n = 12; male n = 2. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** N = 14.	Significance of diagnosis – The authors report that practitioners understood that having a diagnosis of dementia did not necessarily mean that a person lacks capacity to make a decision. The authors go on to report that referrals to obtain a mental health assessment (in order to meet the first requirements of the test of capacity) were often drawn out, and that general practitioners were sometimes reluctant to make referrals. They note that those social workers who were co-located within a mental health team benefitted from easier access to mental health practitioners. The authors report that those social workers with less experience were more likely to seek input from mental health practitioners when assessing capacity; however, they note that this was not an attempt to pass on responsibility but instead was an attempt to 'corroborate' their own views on whether the person has capacity. Inter-professional working – The authors report that most interviewees felt that the Mental Capacity Act had increased their confidence, and to empower them to challenge assumptions where necessary. Discussions with other professionals, particularly Community Psychiatric Nurses were seen as helpful in assessing capacity. Some participants raised capacity to consent to information sharing protocols as an issue, and there were concerns that other practitioners, and general practitioners in particular, did not understand the requirements of the Mental Capacity Act in relation to assessments: "I do think that social workers seem to be the only ones who have any knowledge of the Act – GPs seem to have no concept of it." (Participant, p16). The authors also note that general practitioners sometimes	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		only provided '... brief diagnostic letters which unhelpfully 'crystallised' situations ... in one case, a GP's letter to a solicitor that the client 'had dementia and so was not capable of making a Power of Attorney' closed down discussion of whether the client was able to choose whether her neighbour or a family member was the most appropriate person to help her deal with her financial affairs.' (Authors, p16). The authors also report that collaboration with mental health services was minimal (e.g. with consultant psychiatrists), with the exception of those social workers co-located in a hospital-based team. <u>Social workers' approaches to assessing mental capacity</u> – The authors report that social workers' '… approaches to assessing mental capacity … can be conceptualised as a sub-set of approaches to the assessment and management of risk.' (Authors, p18). They go on to report that while social workers may not have 'explicitly' followed the requirements of the Mental Capacity Act in assessing whether an individual was unable to make a decision, demonstrated understanding of the concepts and were able to describe examples in which they had applied these in their practice. Interviewees were also reported to accept the principle of presumption of capacity and to understand that there may be fluctuations in capacity. The authors note that interviewees tended to use an '… aggregate of different assessments over a period of time …' (Authors, p18) to reach their 'final' conclusion on whether the person had 'capacity or not'. The authors also note that participants tended to distinguish between capacity to make 'significant' decisions (e.g. financial or place of residence) and 'day-to-day' decisions. They report that the majority of assessments related to a	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		single issue (usually admission to residential care, although this was often '… combined with financial issues.' (Authors, p18). The authors go on to report that while a dementia diagnosis was not always the determining factor in the examples discussed by interviewees, 'medical opinion' could sometimes take precedence. They cite one example in which a social worker's suggestion that a person with dementia should enter into a Power of Attorney was overridden because a general practitioner stated that the person lacked capacity 'because of their dementia'. The authors report that while interviewees attempted to take a functional approach to assessment, they still appeared to be influenced by an outcomes model. They report that interviewees 'properly' provided information about reasonably foreseeable consequences (e.g. on the health risks resulting from living in insanitary conditions, or in living alone when there was a high risk of falling) but go on to note that when the person with dementia did not come to the same conclusion as the social worker regarding such issues, some practitioners suggested that this in itself was evidence of a lack of capacity. Some interviewees were also reported to be concerned about the amount of information provided, particularly when more significant decisions were being made. They also note that this could lead to professional conflict, for example in a case in which there was thought to be a high risk of infection due to insanitary conditions in the persons home: "I think he (the doctor) felt she had the right to make that choice. I felt it wasn't necessarily a fully informed choice because you know, that is a very unpleasant death." (Participant, p19).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		The authors also report that there was little evidence of proactive attempts to communicate and involve people in the assessment process. They note that in one case a participant had reportedly considered asking a speech therapist to assist them, there were no other instances in which alternatives to verbal communication had been considered. They go on to report that care home managers were reported to use observation as a means of assessment and that the Mini Mental State Examination was sometimes used. <u>Recording</u> – The authors report that interviewees had concerns about how to effectively and appropriately record their assessments. Interviewees were also reported to have stated that they were now more careful when recording assessments as a result of the requirements set out in the Mental Capacity Act. <u>Impact of the Mental Capacity Act on social work roles</u> – The authors suggest that interviewees' interpretation of the Mental Capacity Act enabled them to assume different 'roles'. In relation to assessment, they identified 'legal representatives' who valued the structured approach to decision-making and incorporated this into their recording practice; and 'protectors' who focused on risk and were reportedly more likely to '… interpret incapacity as an inability to foresee and to take precautions against obvious risks.' (Authors, p33). The authors conclude by suggesting that interviewees believed the legal framework provided by the Mental Capacity Act to be empowering.	

13. Murrell A and McCalla L (2016) Assessing decision-making capacity: The interpretation and implementation of the Mental Capacity Act 2005 amongst social care professionals. Practice 28: 21–36

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To explore how capacity assessments are being carried out by social care practitioners and ultimately to provide an indication on how coherence (in assessing capacity) in practice can be maximised and the aims and principles of the *Mental Capacity Act 2005* upheld. **Methodology:** Qualitative – semi-structured interviews. **Country:** United Kingdom – county in south-west England. **Source of funding:** Not reported.	**Participants:** Professionals/practitioners – Social care practitioners with experience of using the Mental Capacity Act. **Sample characteristics:** • Age – Not reported. • Gender – Not reported. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Although not relating to the respondents, the client groups experienced by the social care practitioners included people living with dementia, learning disabilities or various forms of mental distress. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** N = 6.	Knowledge and confidence – All participants were involved in assessing decision-making capacity on a regular basis, ranging from fortnightly to 3 monthly. The client group they worked with was predominantly people with dementia, with some cases involving people experiencing other forms of mental distress or a learning disability. Decision-making situations were around care needs, accommodation and finance. All participants had received county council delivered training on the Mental Capacity Act. The theoretical knowledge held on the Mental Capacity Act varied and in some cases was fairly limited. Participants demonstrated that their knowledge on the criteria for assessing decision-making capacity was more thorough compared with those given on the principles of the Mental Capacity Act. Participants acknowledged the responsibility that assessing capacity entails and the potential impact on people's lives. Some said they assess capacity multiple times to make sure the assessment was accurate and others said they would never assess capacity entirely on their own and that they would consult other professionals, especially mental health specialists. Identifying the relevant information – One participant said that when they were assessing capacity they tried to identify how orientated a person is and whether they have insight into their care needs, but as the researchers note, this is not enough to determine capacity under the Mental Capacity Act (which employs a functional test assessing whether a person can understand, retain and weigh up the relevant information). Merging capacity and best interests decisions – The responses showed that in complex situations it became difficult to carry out an objective assessment of capacity '… without speculating about the likely outcome of the decision …' (Authors, p29).	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		The researchers note that what the assessor perceives to be in the person's best interests shouldn't influence the capacity assessment (because the person has the right to make an unwise decision. Also capacity assessment and analysis of best interests are separate processes). There was also often a focus on what the person's wishes were rather than first establishing whether they had capacity, '… although a person's wishes and preferences are very important, they do not play an express part when assessing capacity.' (Authors, p29). Multiple roles and competing demands – One participant highlighted the subjective nature of capacity assessments and said that at times it conflicted with their role in assessing eligibility for services: "...if you are the assessor for say a care plan or the assessor for someone whether they need residential or home-based care and you're going to someone and saying: 'Actually, I think in my assessment your needs should be best met within a residential setting', and they actually don't want that, well then I think that puts you in a difficult position to be the person who carries out a capacity assessment and there is some conflict of interests there." (Participant, p30). The researchers note that the assessor is not the decision-maker – they only take on that role if the person lacks capacity. The value of the Mental Capacity Act – Most participants said that disagreements and disputes from family members added to the difficulties in assessing capacity – and they said that the Mental Capacity Act helped to counteract these challenges: "I went to see the person, I went to see this per- th-the family were very insistent that, you know, their Mother required a nursing home and she wasn't able to stay at	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		home anymore- and to sort of explain to the family that, you know, we can't just go arranging placements for people and capacity comes into it. You know, so then, you know, you've got some legal sort of back up really haven't you? To a process to follow which the family, you know, you need to make them understand that this is what we have to do." (Participant, p31). The problem is that participants seemed to value the Mental Capacity Act for the purposes of protecting people's best interests more than protecting their right to make their own decision. Implications for practice – The study found that the interplay with other assessments (such as eligibility) affected how decision-making capacity assessments are made, whereas they should be clearly distinguished. The researchers suggest that a key message for this local authority is that the forms for decision-making capacity assessments and best interests decisions should be separate (currently they are on the same form). Additional training and support – Participants were aware of the responsibility of assessing decision-making capacity and they were mindful of carrying out thorough assessments often involving other professionals. They also valued being able to observe the practice of other practitioners. In this sense the study supports the concept of integrating training within the workplace and also of giving practitioners the opportunity to discuss the difficulties they face promoting reflection, feedback and mutual support.	

14. Roy A, Sarus J, Roy A et al. (2011) Improving recording of capacity to consent and explanation of medication side effects in a psychiatric service for people with learning disability: audit findings. Journal of Intellectual Disabilities 15: 85–92

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors aimed to '… examine the practice of psychiatrists	**Participants:** Professionals/practitioners – The authors analysed the case notes of consultant psychiatrists working as part	**Standards measured:**	**Overall assessment of internal validity:** −

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
in a large learning disability service in recording capacity to consent to treatment and side effect discussion, and the impact of measures aimed at improving this.' (p85). **Methodology**: Audit – the authors describe their methodology as a '… retrospective case note audit …' (p87). **Country:** United Kingdom, England – no further details reported. **Source of funding:** Not reported.	of a psychiatric service providing support to adults with intellectual disabilities. NB. No further details on the individuals to whom the case notes relate or the practitioners who had created them are reported. **Sample characteristics:** • Age – Not reported. • Gender – Not reported. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** Total sample size unclear. At each cycle (data collected at 3 points) of the audit the authors' collected 26 sets of case notes from each of the 6 teams. It is not clear whether any of these notes related to the same individual or how many practitioners were involved with each case.	• Use of rubber stamp (measured at third cycle of audit – 2009, target = use of rubber stamp in 90% of outpatient encounters). • Confirmed discussion about capacity to consent to treatment/assessment of capacity to consent to treatment (measured at cycles 1, 2, and 3 of audit, 2007–2009, target = discussion recorded in more than 90% of outpatient encounters). • Confirmed discussion about adverse effects of medication (measured at cycles 1, 2, and 3 of audit, 2007–2009, target = discussion recorded in more than 90% of outpatient encounters). The authors report that the 'baseline' stage of the audit (conducted in 2007) prompted the local audit committee to make 3 recommendations aimed at improving recording practice. These were implemented over the following 12 months at which point the survey was repeated. The committee recommended that - notes were more abbreviated; that appointments were longer in order to ensure that more accurate notes could be taken in order to better reflect the consultation; that a computer-based information system was used. Standard 1 – Use of rubber stamp (third cycle of audit – 2009, target = use of rubber stamp in 90% of outpatient encounters) – In 2009, the rubber stamp was used in only 94 sets of case notes in total (60%). Compliance ranged between 4% and 100% for individual teams. Team 1 = The rubber stamp was used in 20/26 sets of case notes (77%); team 2 = The rubber stamp was used in 1/26 sets of case notes (4%); team 3 = The rubber stamp was used in 26/26 sets of case notes (100%); team 4 = The rubber stamp was used in 26/26 sets of case notes (100%); team 5 = The rubber stamp was used in 18/26	**Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		sets of case notes (69%); team 6 = The rubber stamp was used in 3/26 sets of case notes (12%). NB. The rubber stamp is stamped on to case notes. The stamp is a visual checklist to record (yes/no) whether a capacity assessment has taken place; whether informed consent had been sought; whether a best interest decision had been taken; and whether side effects of medication had been explained. <u>Standard 2 – Confirmed discussion about capacity to consent to treatment/assessment of capacity (cycles 1, 2, and 3 of audit (2007–2009), target = discussion recorded in more than 90% of outpatient encounters</u> 2007 – In 2007, discussions about capacity to consent to treatment were confirmed in only 46 sets of case notes in total (30%). Compliance ranged between 12% and 46% for individual teams. Team 1 = 3 (12%); team 2 = 7 (27%); team 3 = 9 (34%); team 4 = 9 (34%); team 5 = 6 (23%); team 6 = 12 (46%). 2008 – In 2008, discussions about capacity to consent to treatment were confirmed in only 51 sets of case notes in total (33%). Compliance ranged between 30% and 39% for individual teams. Team 1 = 8 (31%); team 2 = 9 (35%); team 3 = 8 (31%); team 4 = 8 (30%); team 5 = 10 (39%); team 6 = 8 (31%). 2009 – In 2009, discussions about capacity to consent to treatment were confirmed in only 81 sets of case notes in total (51%). Compliance ranged between 19% and 96% for individual teams. Team 1 = 20 (77%); team 2 = 9 (35%); team 3 = 16 (61%); team 4 = 25 (96%); team 5 = 6 (23%); team 6 = 5 (19%). Percentage increases between 2008 and 2009 – Percentage increases between 2008 and 2009 – Between 2008 and 2009, there was a total percentage increase of 59% in	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		confirmed discussions about capacity to consent to treatment. Change ranged between −40% and 150% for individual teams. Team 1 = 150%; team 2 = 0%; team 3 = 100%; team 4 = 213%; team 5 = -40%; team 6 = -38%. Change in rates of recording between 2007 and 2009 – Overall, the rate of recording improved from a total of 30% in 2007 to a total of 51% in 2009 (*p* = 0.000006). This result was significant. Standard 3 – Confirmed discussion about adverse effects of medication (cycles 1, 2, and 3 of audit (2007–2009), target = discussion recorded in more than 90% of outpatient encounters) 2007 – In 2007, discussions about adverse effects of medication were confirmed in 118 sets of case notes in total (76%). Compliance ranged between 69% and 88% for individual teams. Team 1 = 19 (73%); team 2 = 18 (69%); team 3 = 18 (69%); team 4 = 23 (88%); team 5 = 21 (81%); team 6 = 19 (73%). 2008 – In 2008, discussions about adverse effects of medication were confirmed in 105 sets of case notes in total (67%). Compliance ranged between 62% and 77% for individual teams. Team 1 = 17 (65%); team 2 = 20 (77%); team 3 = 18 (69%); team 4 = 16 (62%); team 5 = 17 (65%); team 6 = 17 (65%). 2009 – In 2009, discussions about adverse effects of medication were confirmed in 110 sets of case notes in total (71%). Compliance ranged between 23% and 88% for individual teams. Team 1 = 21 (81%); team 2 = 22 (85%); team 3 = 318 (69%); team 4 = 23 (88%); team 5 = 6 (23%); team 6 = 20 (77%). Percentage increases between 2008 and 2009 – Between 2008 and 2009, there was a total percentage increase of	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		5% in confirmed discussions about adverse effects of medication. Change ranged between −65% and 44% for individual teams. Team 1 = 24%; team 2 = 10%; team 3 = 0%; team 4 = 44%; team 5 = -65%; team 6 = 18%. Impact of use of rubber stamp on adherence to standards – The authors hypothesised that use of the rubber stamp would lead to greater adherence to standards 2 and 3. They report in their narrative findings for 2009 only, noting that the rubber stamp was used in 94 sets of case notes (60%); and that a recording of the person's capacity had been made in 81 sets of notes (52%). Their analysis showed that capacity was more likely to be recorded in cases in which the rubber stamp was used (OR = 13.5, *p* < 0.0001). This result was significant. Impact of use of rubber stamp on adherence to standards – The authors hypothesised that use of the rubber stamp would lead to greater adherence to standards 2 and 3. Using data for 2009 only, analysis showed that capacity was more likely to be recorded in cases in which the rubber stamp was used (OR = 13.5). This result was significant (*p* < 0.0001).	

15. Shah A, Banner N, Newbigging K et al. (2009) The early experience of consultant psychiatrists in application of the Mental Capacity Act: issues for black and minority individuals. Ethnicities and Inequalities in Health and Social Care 2: 4–10

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors aimed to examine the experiences of consultant psychiatrists regarding the early implementation of the Mental Capacity Act. The findings reported in this paper focus specifically on equalities	**Participants:** Professionals/practitioners – Consultant psychiatrists. The paper reports on 2 studies. The first surveyed a range of consultant psychiatrists working in the fields of general psychiatry, as well as child and adolescent psychiatry, forensic psychiatry, learning disability psychiatry, and liaison psychiatry. The second	Consultants views regarding the proportion of patients assessed for decision-making capacity belonging to Black and minority ethnic groups (consultant responses) – 'Nil' – Study 1 n = 28 (38%); study 2 n = 13 (28%) 'Some' – Study 1 n = 33 (45%); study 2 n = 25 (54%) 'Half' – Study 1 n = 4 (5%); study 2 n = 2 (4%) 'Most' – Study 1 n = 1 (1%); study 2 n = 1 (2%) 'All' – Study 1 n = 0 (0%); study 2 n = 0 (0%) 'Did not know' – Study 1 n = 8 (11%); study 2 n = 5 (11%)	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
issues. **Methodology:** Survey – postal survey. **Country:** United Kingdom – England and Wales. **Source of funding:** - Government – Department of Health. - Voluntary/charity agency – Social Care Institute for Excellence.	study focused only on consultants working in old age psychiatry. No further details in relation to the characteristics of respondents are provided. **Sample characteristics:** - Age – Not reported. - Gender – Not reported. - Ethnicity – Not reported. - Religion/belief – Not reported. - Disability – Not reported. - Long-term health condition – Not reported. - Sexual orientation – Not reported. - Socioeconomic position – Not reported. **Sample size:** The authors used the Royal College of Psychiatrists' database to identify relevant practitioners. For study 1, the authors identified 955 potential participants. Thirteen per cent of these practitioners responded (n = 126); however, only 12% of responses were usable as 13 questionnaires were returned unanswered. For study 2, the authors identified 186 potential participants. Twenty-nine per cent of these responded (n = 57); however, only 27% of responses were usable as 5 questionnaires were returned unanswered.	Total number of respondents – study 1 n = 74 (100%); study 2 n = 46 (100%) Consultants views on whether consideration is given to culture and ethnicity in the assessment of decision-making capacity (consultant responses, study 1 – 'other' specialties) – Yes – n = 69 (87%). No – n = 9 (11%). Did not know – n = 1 (1%). Total number of respondents – n = 79 (100%). Consultants views on whether consideration is given to religion in the assessment of decision-making capacity (consultant responses, study 1 – 'other' specialties) – Yes – n = 63 (80%). No – n = 16 (20%). Did not know – n = 0 (0%). Total number of respondents – n = 79 (100%). Consultants views on whether consideration is given to culture and ethnicity in the assessment of decision-making capacity (consultant responses, study 2 – old age psychiatry) Yes – n = 41 (83%). No – n = 6 (13%). Did not know – n = 1 (2%). Total number of respondents – n = 48 (100%). Consultants views on whether consideration is given to religion in the assessment of decision-making capacity (consultant responses, study 2 - old age psychiatry) - Yes – n = 38 (79%). No – n = 9 (19%). Did not know – n = 1 (2%). Total number of respondents – n = 48 (100%). Consultants recollections on the use of interpreters with	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		patients who lacked fluency in English or where English was not their first language – 'Nil' – Study 1 n = 28 (40%); study 2 n = 9 (24%). 'Some' – Study 1 n = 9 (13%); study 2 n = 8 (22%). 'Half' – Study 1 n = 0 (0%); study 2 n = 0 (0%). 'Most' – Study 1 n = 4 (6%); study 2 n = 2 (5%). 'All' – Study 1 n = 17 (24%); study 2 n = 15 (41%). 'Did not know' – Study 1 n = 12 (17%); study 2 n = 3 (8%). Total number of respondents – Study 1 n = 31 (100%); study 2 n = 70 (100%). Consultants recollections on regarding the types of interpreter used – Professional – Study 1 n = 41 (79%); study 2 n = 26 (81%). Clinical staff – Study 1 n = 3 (6%); study 2 n = 1 (3%). Non-clinical staff – Study 1 n = 3 (6%); study 2 n = 3 (9%). Relatives or friends – Study 1 n = 2 (4%); study 2 n = 1 (3%). Did not know – Study 1 n = 3 (6%); study 2 n = 0 (0%). Total number of respondents – Study 1 n = 52 (100%); study 2 n = 31 (100%).	

16. Shah A, Banne N, Heginbotham C et al. (2010) The early experience of old age psychiatrists in the application of the Mental Capacity Act 2005: a pilot study. International Psychogeriatrics 22: 147–157

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To '… examine the experience of consultants in Old Age Psychiatry in the early implementation of the Mental Capacity Act pertaining to local policy and training in the application of the Mental Capacity Act, the assessment of	**Participants:** Professionals/practitioners – consultants in old age psychiatry. **Sample characteristics:** • Age – Not reported. • Gender – Not reported. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported.	NB. Only findings relating to the assessment of decision-making capacity have been extracted. Local training and policy – Over 75% of consultants in old age psychiatry said there was a local trust policy on capacity to consent and this policy was used. Reported proportions of patients who have a routine assessment of decision-making capacity (n = number of consultant responses) Nil, 1 (2%) Some, 9 (17%) Half, 9 (17%) Most, 13 (25%) All, 10 (19%) did not know 7 (14%).	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
decision-making capacity, the determination of best interests, and the use of the least restrictive option and restraint.' (p147). **Methodology:** Survey. **Country:** United Kingdom – England. **Source of funding:** Government – Department of Health.	• Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** Fifty-two responses (out of 196) distributed questionnaires. **Outcomes measured:** Service outcomes – Some service outcome data is gathered, namely numbers of decision-making capacity assessments conducted, numbers recorded, and proportion of staff undergoing training.	Reported proportions of patients who have the assessment of capacity to consent documented – (n = number of consultant responses) Nil, 0 (0%) Some, 16 (33%) Half, 9 (19%) Most, 8 (17%) All, 6 (13%) did not know, 9 (19%). Issues for which decision-making capacity was assessed – Personal care – Routinely assessed, 19 (43%), Not routinely, 23 (57%), did not know, 2 (5%) Healthcare – Routinely assessed, 39 (80%), Not routinely, 8 (16%), did not know, 2 (4%) Social care – Routinely assessed, 33 (70%), Not routinely, 12 (26%), did not know, 2 (4%) Financial welfare – Routinely assessed, 42 (86%), Not routinely, 5 (10%), did not know, 2 (4%). Also, decision-making capacity was assessed separately for each issue and each treatment decision by 67% consultants, but 27% said this wasn't the case. Sixty per cent said that for at least half of patients being assessed for decision-making capacity, families and other professionals were consulted. Participants were asked, "What criteria do you use in assessing capacity?" Descriptive answers were coded into 10 categories: Understanding information (N = 47; 98%) Retaining information (N = 47; 98%) Weighing up information in the balance (N = 47; 98%) Communicating the decision (N = 45; 96%) Patient not subject to undue pressure in the assessment (N = 3; 7%) Assessment of decision-making capacity being time-specific (N = 5; 12%) Assessment of decision-making capacity being issue-specific (N = 7; 18%) Presence of mental impairment (N = 12; 25%) Dependent upon risk assessment (N = 3; 6%) The subject may need help in decision-making (N = 3;	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		6%). <u>Who conducts decision-making capacity assessments?</u> Over 60% of the consultants reported that more than half of the assessments of decision-making capacity were conducted by consultants, but over two-thirds reported that fewer than half ("some" and "nil") of the assessments of decision-making capacity were conducted by junior doctors (71%), nurses (67%), psychologists (75%), social workers (72%), occupational therapists (71%) and others (67%). <u>Training in the application of the Mental Capacity Act</u> – Less than 50% said it was mandatory, which could explain why only 60% said half or more of the staff had received Mental Capacity Act training. (p152). Training in the application of the Mental Capacity Act for health and social care professionals is not a statutory requirement.	

17. Walji I, Fletcher I, Weatherhead S (2014) Clinical psychologists' implementation of the Mental Capacity Act. Social Care and Neurodisability 5: 111–130

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To explore the experiences of clinical psychologists in implementing the Mental Capacity Act. This involves exploring their work with a range of client groups where they may have been involved in assessments of mental capacity, best interests decisions, deprivation of liberty safeguards, and general applications of the Mental Capacity Act	**Participants:** Professionals/practitioners – clinical psychologists. **Sample characteristics:** • Age – Not reported. • Gender – female n = 5; male n = 2. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Note that these are not the disabilities of respondents but they are the client groups with which the participants work – acquired/ traumatic brain injury; learning disabilities	NB. In line with the review question, only findings relating to participants' experiences of assessing decision-making capacity are extracted. <u>Competence and confidence</u> – Participants had attended Mental Capacity Act training but it was largely thought to be too basic. In terms of guidance, they relied on the Code of Practice and the 'easy read guide' (Mental Capacity Implementation Programme, 2007). Other guidance was not thought to be very accessible. Training was felt to be too general, not useful to their own client groups (for example, based on cases of people with learning disabilities when they tended to work with people with acquired brain injury) and too simplistic to be relevant	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
in different contexts. Other aims reported are to '… identify elements of best practice within the sample, provide accounts of comparable experiences for other clinical psychologists, and identify factors that improve competence and confidence when implementing the MCA.' (p115). **Methodology:** Qualitative – in-depth interviews with thematic analysis of transcripts. **Country:** United Kingdom. **Source of funding:** Not reported.	(n = 3) Neuropsychological presentations (n = 2) Older adults. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Professional role and years qualified – Clinical neuropsychologist 5–9; Consultant clinical psychologist 10–14; Clinical neuropsychologist 5–9; Clinical psychologist 10–14; Clinical psychologist 5-9; Principal clinical psychologist 10-14; Senior psychologist 20+. Participants were involved in the following aspects of the Mental Capacity Act – capacity, best interests and Deprivation of Liberty Safeguards. The capacity assessments had been conducted in the following contexts – capacity to request discharge from hospital, capacity to decide place of residence, capacity to give consent to treatment/ procedures, capacity for parenting, capacity for driving, capacity to conduct proceedings. **Sample size:** N = 7.	to the complexities of practice. The majority therefore learnt more through their own clinical practice: "I think it's kind of doing those assessments that focuses you, your attention, and means that you do the reading round and try and, you know, acquire the knowledge that you need. So it was probably through, you know, specific referrals for capacity assessments that kind of led me to getting most, you know, the best knowledge about it." (Participant, p118). This process and development of confidence was often facilitated through joint working with colleagues from other disciplines. When learning was shared, knowledge and skills were retained. Availability of appropriate supervision as well as support from peers was very important, especially in difficult cases. Understanding and uncertainty – Psychologists generally felt they had a good understanding of the Mental Capacity Act although some noted that the interface with Mental Health Act sometimes led to confusions, with some practitioners apparently not clear on the differences between the two. Colleagues, collaboration, conflicts and challenges – Joint working was highly valued and participants felt that the Mental Capacity Act facilitated greater collaboration between disciplines. Doing joint assessment was seen as a very positive means of developing competencies and a shared understanding. Incorporating different perspectives was considered best practice. In some teams it wasn't clear whose responsibility it was to take the lead on specific issues such as capacity assessment. In others, responsibility was shared: "I think the team has developed a really healthy attitude to	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		capacity in that there's no single person who can or can't assess capacity. The people who should be involved are those who perhaps are most relevant to the decision [...] there's a real sense of it's a team decision, and that more than one opinion is valuable in thinking about capacity. But equally, it doesn't have to be everyone. But anyone can do it.” (Participant, p121). Some participants described conflicts arising as a result of different interpretations of the Mental Capacity Act between different professionals, or rather, people in different teams. For example, "… the GP said [...] I can’t understand why you keep assessing his capacity, he hasn’t got capacity [...] I was really surprised because I thought a GP would’ve known time-specific, decision-specific, and he wasn’t aware of that …" (Participant, p121). Working within the law: processes and penalties – Participants emphasised the importance of working with the correct processes and within the law. They tried to keep abreast of ongoing case law to inform their work. Some had clearly adopted defensive practice: "You should be able to defend every single piece of work that you do, you should be able to defend it. And I think kind of engaging in MCA assessments, which I think need to be completely defensible..." (Participant, p121). As well as being aware of the legal consequences to their practice, some participants were concerned about the consequences for the individual: "It is that kind of difficult balance within the therapeutic relationship [...] you’re asked to provide a capacity assessment and the person doesn’t have capacity and that means that their money’s taken away from them, their children are taken away from them [...] you can think of drastic consequences …” (Participant, p122).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		<u>Other findings</u> – Participants emphasised the importance of not being too quick to judge capacity: "I've been involved with people that the local authority have been involved with [...] they look at the kind of 3 stage test and say, and just make very quick decisions, you know, about communication, about retention, about weighing up, about all those elements [...] seemed quite happy just to very quickly and crudely record that somebody doesn't meet those criteria …" (Participant, p123). They felt that in contrast, as psychologists they were well placed to treat people in a person-centred way and to conduct capacity assessments in line with the Mental Capacity Act: "I think we should have a clear role which we defend, given our skills in complex assessment, you know, holistic, complex, eclectic assessment …" (Participant, p122). Participants discussed the motivations of other professionals and said that on the one hand capacity was assumed to avoid implementing the Mental Capacity Act and on the other hand, for instance in learning disabilities and older people's services, incapacity was assumed so that the professional could make a 'better' decision for the individual.	

18. Williams V, Boyle G, Jepson M et al. (2014) Best interests decisions: professional practices in health and social care. Health and Social Care in the Community 22: 78–86

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To explore professional practice in relation to best interests decision-making. The study has been included for review question 3 as	**Participants:** • Service users and their families, partners and carers – The sample included family members or friends of service users; however, the nature of	NB. The authors report on issues related to assessment of capacity in relation to the best interests principle of the Mental Capacity Act. While findings related specifically to assessment of capacity are reported here, those relating to best interests decisions more generally will be extracted and presented as part of review question 4, which focuses	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
it also provides information on practice in relation to assessment of mental capacity. **Methodology:** Qualitative – interviews (telephone and face to face). **Country:** United Kingdom – England (no further details provided). **Source of funding:** Government – Department of Health.	their involvement is not clear and no details are provided on their socio-demographic background or the service user with whom they are connected. • Professionals/practitioners – Practitioners recruited from 1 of 4 areas in England. Participants were drawn from a range of sectors including the NHS, private and statutory organisations, and the voluntary sector. The roles of those participating are described as: allied health professional, ambulance staff, health clinician, Independent Mental Capacity Advocate, legal practitioner, mental health practitioner, psychologist, nurse, residential home staff, social care practitioners, staff in long-stay hospitals or care, and 'other'. **Sample characteristics:** • Age – Not reported. • Gender – Not reported. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** • Total sample size N = 112. • Telephone interviews were conducted with n = 68.	on best interests decisions. Best interests processes (and concerns regarding capacity) were usually prompted by an event or change in circumstance in which practitioners became aware of the risks that the service user faced (e.g. hospitalisation/discharge planning or rapid decline in health). The authors report that emergent findings on risk, safety and personal behaviour prompted them to ask interviewees how they 'took account' of the unwise decisions principle of the Mental Capacity Act. They report that responses '… revealed that risk was calibrated according to the possible severity of outcome for the person … and the length of time people had been living 'at risk'. Participants were often keen to portray their own professional actions as not being overly protective, and they justified their formal actions by showing how repeated prior attempts had been made to protect people from themselves.' (Authors, p81). The authors go on to note that when measures to reduce risk were seen as ineffective (e.g. support to budget money, or to protect someone from abuse by a third party) practitioners began to question the capacity of service users. They note that assessment of capacity '… proved to be the most difficult and sensitive aspect of the MCA.' (Authors, p81). Interviewees were asked about what had prompted them to decide that the service user they were discussing lacked capacity and the authors report that 'lack of insight' was regularly given as a reason. They cite discussion of a case by one practitioner as evidence of this: "We felt that she was unable to weigh up the information, so she didn't ... she wasn't able to demonstrate that she had any insight into her difficulties." (Practitioner, p82).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	- Face-to-face interviews were conducted with n = 44 (discussing 25 'cases').	The authors report that 'lack of insight' was usually framed as the inability by the service user to understand their condition and the support they needed (particularly when there had been a change in circumstance). Practitioners are reported to be unaware that an unwise decision is not in itself evidence of a lack of capacity and to use the term 'lack of insight' regularly as a proxy for lack of capacity. Participants were also reportedly reluctant to assess capacity, with a number stating that they preferred to do so by consulting with other practitioners to achieve a consensus or by asking a specialist to make an assessment. Interviewees also stated that they preferred to ask someone who knew the service user better to conduct the assessment. Interviewees were also asked about their understanding in relation to the concept of capacity and their experiences of capacity assessments. The authors report that 'in general', practitioners were concerned that capacity assessments were based on instinct, although some were reported to believe that the framework provided by the Mental Capacity Act was helpful. Practitioners were also reportedly supportive of the decision-specific focus of the Mental Capacity Act and '… gave very positive examples where a person was shown to be capable of some decisions, such as where to live, but not capable of others, such as financial matters.' (Authors, p82). The authors note capacity had been assessed by the person in charge of the best interests process in only a minority of cases under discussion. They go on to suggest that there was an identifiable '… concertina effect, in which practitioners moved between the best interests decision itself and the assessment of capacity, generally portraying both as an interaction with the person, conducted over time …' (Authors, p82). This was described as a 2-stage	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		process in which a risk was identified first (and possible solutions), followed by consideration of capacity. Building up an understanding with service users was reported to be identified by interviewees as a key part of this process. The authors go on to note that the concept of capacity was often ‘blurred’ in cases where a service user had been in receipt of social care support over a long period of time, and the concept was reportedly understood to be interchangeable with risk. A case in which a man with learning disabilities was thought to be engaging in ‘risky behaviour’ is cited by the authors as an example in which failures to support the individual to protect himself and cease engaging in ‘risky behaviour’ (i.e. associating with drug dealers) was seen as proof that the man did not have capacity. Strategies used to involve a service user in a best interests decision made for them (e.g. regular informal meetings in which trust was developed and practitioners were able to explain information in a more useful way to the service user) were reported by the authors to ‘feedback' into the assessment of capacity ‘… as, if and when they were able to understand and express an opinion, they could then show that they did have capacity after all.’ (Authors, p84).	

Research question 4. Best interests decision-making for those who have been assessed as lacking the mental capacity to make a specific decision:

- 4.1 – What interventions, tools, aids and approaches are effective and cost-effective in supporting best interests decision-making? No studies located.

- 4.2 – What are the views and experiences of people who may lack mental capacity, their families and carers and others interested in their welfare on the acceptability of interventions, tools and approaches to support best interests decision-making?

Effectiveness data

NB. No studies applicable to the UK context were located for question 4.1

Views and experiences

1. Dunn MC, Clare ICH, Holland AJ (2010) Living 'a life like ours': support workers' accounts of substitute decision-making in residential care homes for adults with intellectual disabilities. Journal of Intellectual Disability Research 54: 144–160

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors aimed to gain an understanding of the process of substitute decision-making in day-to-day residential support of people with intellectual disabilities; however, it should be noted that the authors do not specifically frame their findings in the context of best interests decisions (as defined by the Mental Capacity Act). **Methodology:** Qualitative – interviews and observation of practice. **Country:** United Kingdom – England – North Cambridgeshire and Kent. **Source of funding:** Not reported.	**Participants:** Professionals/practitioners – support workers of people with intellectual disabilities. The 3 homes at which these participants worked were selected because they operated on a non-statutory basis (including for profit services and charities). Residents of these homes were deemed to have high support needs and unable to live independently. The authors note that at the time of the study none of the participants had received training in relation to the Mental Capacity Act. **Sample characteristics:** • Age – Not reported. • Gender – Not clearly reported. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported.	NB. It should be noted that the authors do not discuss at all whether any of the people who were being supported had been determined to lack capacity in relation to these 'substitute decisions'. The authors report that support workers approaches to substitute decision-making were shaped by their hopes of providing 'a life like ours' to the people they supported. They state that this goal '… had 2 main elements. Support workers (1) described how their personal life routines provide the means to enhance the 'ordinary' everyday life experiences of residents, by breaking down some of the 'out of the ordinary' institutional features of residential care environments; and (2) outlined a perceived need to expose residents to new ways of living, reflecting their personal values about the constitutive elements of a valuable and meaningful life.' (Authors, pp149–150). <u>Enabling residents to have 'ordinary' life experiences</u> – The authors report that when discussing the decisions, which they made on behalf of the people who they supported, support workers provided a 'moral account' (authors, p150) in which they drew on their own experiences and beliefs to improve the lives of residents. This was reportedly a result of their belief that life in a care home can be repetitive and unfulfilling. The authors state that support workers believed that making substitute decisions on the	**Overall assessment of internal validity:** − **Overall assessment of external validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	Sample size: Total sample size for interview stage of study n = 21 (home A n = 9; home B n = 6; home C n = 6).	basis of care plans, despite the intention that these be person centred, could not mitigate against the uniformity of residential care and in some cases could even exacerbate this. They go on to suggest that support workers saw their role as a contrast to this regimentation and that by drawing on their own experiences they could 'transform' the lives of residents. The authors report that support workers suggested that thinking about their own lives and experiences was '… a defensible way of thinking about how to do the best thing …' (authors, p151), citing one worker who stated that they often needed to: "... stand back and think, 'what would I like to do? Would I really want to do that again when I did it the same time last week, the same time the week before?' 'Cause that's what it's all about you know, asking them kind of questions, thinking about what might be best, if they're ever going to live a life like ours." (Participant, p151). Support workers were also reportedly concerned regarding the limited number of opportunities and experiences that residents could expect to have and the authors suggest that this was a factor in the process of substitute decision-making, with interviewees commenting on how they tried to ensure that the life of the person they supported could become more 'ordinary' and similar to their own. The authors also report that support workers often put themselves in the place of the resident and made decisions on the basis of what they thought they would choose in a similar situation. <u>New experiences for residents</u> – The authors go on to report that support workers also described their attempts to enable the people they cared for to live in ways that the worker themselves thought to be meaningful. They suggest that these 'positive' attempts were usually contrasted with the 'negative' features of institutional life.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		A number of participants reportedly emphasised the '…the importance of making substitute decisions that were spontaneous, involved breaking free of established routines to try new activities and required risks to be taken.' (Authors, p152). The authors go on to suggest that support workers viewed risk-taking as a positive means of making a substitute decision. They cite one participant who they argue decided to take a spontaneous decision on something that they saw as an integral part of the day's activities even though it was not allowed and '… regardless of the fact that there was no attempt to imagine how the resident himself would recognise this experience in the same way as the support worker did.' (Authors, p152). The authors go on to report that similar ideas about risk and its centrality to everyday life were raised by a number of interviewees. They cite one support worker who commented that: "I think taking risks is normal, and I think everybody takes risks and that they should be encouraged to take risks. We shouldn't protect every little thing, it's an element of normalisation, isn't it, taking risks? And if that person is able to make a decision that involves taking risks then they should be supported to do that. It is normal, we all take risks, we all like to live dangerously." (Participant, p153). The authors state that interviewees felt that the substitute decisions they made were an opportunity to enrich the lives of residents and enable them to take part in 'extraordinary' experiences (usually an activity or a holiday). The authors argue that because these experiences were compatible with support workers own ideas about interesting activities they were valued by them and seen as the right decision despite 'limited evidence' that they were something that the service user themselves would have chosen to do.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		In their discussion section, the authors conclude that their findings show that there is a mismatch between the '… formalised, detached and procedural approach to the regulation of substitute decision-making under the MCA, and support workers' accounts of making substitute decisions that are embedded within the flexible and interdependent care practices that shape their support work.' (Authors, p155). The authors also go on to suggest that their data indicate that the substitute decisions that support workers were making were not preceded by concerns about the persons decision-making capacity and that these substitute decisions do '… not appear to be used in practice to solve the 'non-autonomy' problem highlighted by the MCA, but rather as a way of addressing a very different kind of problem: how to support residents to lead a good life.' (Authors, p155).	

2. Emmett C, Poole M, Bond J et al. (2014) A relative safeguard? The informal roles that families and carers play when patients with dementia are discharged from hospital into care in England and Wales. International Journal of Law, Policy and the Family 28: 302–320

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors aimed to explore the informal role of relatives of people with dementia in best interests decisions made regarding discharge from hospital and to determine whether they '… fulfil an effective safeguarding role when decisions are made to discharge older patients with dementia from hospital either back home or	**Participants:** • Service users and their families, partners and carers – people with dementia admitted to an elderly or orthogeriatric ward and their carers/relatives. Twenty out of 29 participants had been admitted to an acute setting, and 9 had been admitted to a rehabilitation setting. The average length of stay in hospital was 35 days for patients admitted to an acute setting (range 13–59 days); and 87 days for patients admitted to a rehabilitation ward (29– 157 days). NB. The	<u>The informal roles that the relatives of people with dementia take on during the discharge process</u> – The authors report that relatives often took on roles as advocates, caretakers, or information-gatherers, noting that they often facilitated communication between patients and practitioners, or advocated for relatives who were unable to convey their preferences as a result of their illness and/or confusion. The authors also highlight the role that relatives played in questioning practitioners and soliciting information. They suggest that this mirrors the 'inquisitorial' role which the participating Independent Mental Capacity Advocate took: '… my role is to, is to just investigate all the circumstances and try and find out as much as I can really, I call it 'have a dig around' …' (Independent Mental Capacity	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
into long-term care.' (p304). **Methodology:** Qualitative – interviews, focus groups and observation. **Country:** United Kingdom – England – north-east. No further details reported. **Source of funding:** Other – National Institute for Health Research.	authors only report on the 16 individuals who had been determined to lack the capacity to make a decision in relation to place of discharge in this paper. - Professionals/practitioners – Health and social care professionals including a care home manager, a chaplain, general practitioners, an Independent Mental Capacity Advocate, nursing staff (qualified, non-qualified, psychiatric liaison), occupational therapists, a physiotherapist, physicians and psychiatrists (junior and senior doctors), psychologists, social workers, and voluntary agency staff members. NB. No further details are provided regarding the characteristics of the participating practitioners. **Sample characteristics:** - Age – 83 years (average, range 69–92). - Gender – Female n = 16; male n = 13. - Ethnicity – White British n = 28; White European n = 1. - Religion/belief – Not reported. - Disability – Not reported. - Long-term health condition – Long-term health condition – No conditions other than dementia are reported. Twenty out of 29 patients participating in the study had a diagnosis of dementia; Mini-Mental State Examination scores ranged between 6 and 30.	Advocate, p309). The authors go on to highlight that some relatives appeared to find it difficult to ask for more information or challenge protocols or professional opinions, noting that the Independent Mental Capacity Advocate had a statutory right to access the health and social care records, something which relatives did not have. This inability resulted in their being sometimes unaware of relevant clinical information. <u>Potential barriers that can prevent relatives from effectively fulfilling a safeguarding role during the discharge process</u> – Although the authors report that some relatives did challenge professional opinion in certain cases, they suggest that there were a number of personal and professional issues hindering their attempts to do so: Provision of information and 'signposting' – The authors report that relatives were sometimes unaware of the purpose of discharge planning meetings and that in some cases had not been told that the meeting had any link to the discharge process whatsoever. The authors go on to note that a number of relatives felt that they had not been given enough information at the appropriate point to allow them to prepare, resulting in their feeling unable to make judgements about place of discharge or challenge practitioner views when necessary. Conflicts of interests – The authors go on to report that some relatives were unable to take on a safeguarding role as a result of a conflict between their own interests and those of their relative. They cite one case in which the daughter of a patient was reportedly having difficulties in doing so because the decision was likely to result in the loss of inheritance to pay for a private care home placement (through the sale of the family home). Power inequalities – The authors report that relatives who	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	- Sexual orientation – Not reported. - Socioeconomic position – Not reported. **Sample size:** Total sample size unclear; however, the study is based on the cases of 29 patients admitted to hospital and deemed to lack the capacity to make a decision regarding place of discharge. NB. The authors only report on the 16 individuals who had been determined to lack the capacity to make a decision in relation to place of discharge in this paper.	were older or less assertive could also find it difficult to play a safeguarding role despite their belief that this was needed. They suggest that many were 'ill-equipped' to take on the role as a result of their deference to professionals and hospital processes, or a tendency to cede to the views of more 'coercive' family members. They cite one case as an example of the tendency for some decisions to become 'medicalised' by practitioners as a result of their knowledge of clinical information that relatives are not always able to access. They suggest that this can result in the sudden exclusion of relatives from the decision-making process. They contrast these difficulties with the approach taken by the Independent Mental Capacity Advocate who described their role as the 'last line of defence', with a legal responsibility to question practitioners, regardless of professional hierarchies. Emotional challenges – The authors report that relatives were sometimes unable to effectively take on a safeguarding role due to the stress and emotional burdens resulting from their relative's admission to hospital and the impact that the decision regarding place of discharge was likely to have on their own life. Positive factors helping relatives to provide an effective safeguard during the discharge process – The authors cite the case of one individual who was able to be discharged to her own home (a preference which she had expressed despite her having been assessed as lacking capacity in this regard), noting that her families understanding of hospital processes (her daughter worked in the same hospital), and their '… tenacity and persistent questioning of hospital professionals … suggests the possibility (at least) that social class and education might play an important role in the degree to which relatives can offer effective support and advocate for older people.' (Authors, p314). Family dynamics and empathy – The researchers note that	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		in the majority of cases, relatives believed that people with dementia did not have the capacity to make any decisions; however, they cite one case in which the patient's family believed that there was capacity to make a decision regarding place of discharge. Their narrative implies that the authors attribute the family's determination to advocate for their relative to this belief regarding capacity. Resource availability and confidence – The authors also suggest that a close-knit and supportive family dynamic enabled this family to advocate for their relative in order to support discharge home. In contrast, they note that the majority of relatives lacked the confidence to do this (even when it was thought necessary), and that in some cases relatives were unlikely to advocate for a return home if they lacked the resources or were unwilling to support their relative at home.	

3. Harris D and Fineberg IC (2011) Multidisciplinary palliative care teams' understanding of Mental Capacity Act 2005 'best interest' determinations. International Journal of Palliative Nursing 17: 20–25

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To explore multidisciplinary palliative care teams' implementation of the concept of best interests as stated in the *Mental Capacity Act 2005*. **Methodology:** Qualitative – semi-structured interviews.	**Participants:** Professionals/practitioners – health and social-care professionals who provide palliative care services to terminally ill patients. **Sample characteristics:** • Age – Not reported. • Gender – Female n = 10; male n = 1. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported.	<u>Understanding of the Mental Capacity Act</u> – Participants' understanding of the Mental Capacity Act varied, with some demonstrating clarity, but almost half demonstrating a lack of clarity regarding the legislation, its best interests principle, and the best interests checklist. "The only things I would say I have picked up, I couldn't really tell you where from, is just that we should be making sure we go as far as we can in making sure we enable somebody to make their own choice before we look at other ways of getting things done. I couldn't really say I know much more than that." (Participant, p22).	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Country: United Kingdom – Northwest of England. **Source of funding:** Not reported.	• Long-term health condition – Not reported. • Sexual orientation – Not reported. Socioeconomic position – Not reported. **Sample size:** N = 11.	Perspective on best interests – Participants clearly attempted to establish patients' past and present wishes as far as possible despite the short time frame. Members of both teams recognised the importance of providing assessments, care, and treatments in the patients' best interests, although not specifically in relation to the Mental Capacity Act definition of best interests. "Best interests, very much you are looking to see what would be in their best interests. What do you do with patients who do not have capacity? It is very much a question of speaking to the family, speaking to the GP, speaking to whoever is involved in their care and what you can do for the best for them and that is not easy to decide always." (Participant, p22). Diagnosis and presumption of capacity – Patients with a diagnosis of Alzheimer's disease or another type of dementia were often automatically assumed to have lost capacity. "I think we manage it really well, it happens a lot, and that people do not have capacity especially when they have got end-stage dementia as well." (Participant, p23). Documented patient preferences – One experienced palliative care professional commented that most patients have not written down their preferences for the types of care or treatment that they may desire in the future: "Well, my understanding is that you have to take into account—well, you have to ask the person in the first place what they think their best interests are. Beyond that obviously from what they have done in the past, how they have been. You can get that either from them or from their family, so it is really about finding out how they would have wanted you to act even when they have not written it down." (Participant, p23).	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		"Well we haven't introduced this documentation yet because for the simple reason we need to do the training and communication skills training so that hasn't happened yet." (Participant, p23). Timing and consultation in decision-making – Teams appeared to be making best interests decisions in the patient's home rather than in formal multidisciplinary team meetings. "You can't leave it a week to get round and sit down and make a decision, particularly in the community. But someone in their own home you have to decide there and then. You can't fiddle about and wait for the GP and the family and whoever else to get together. So often it is done very informally." (Participant, p23). Conversely, participants working in the community hospital did describe a more collaborative and formal process: "This has to be a multidisciplinary decision involving family and carers and the team who are involved in the care. You have to work towards what is deemed to be in the best interests of the patient. There might be completely differing views from members of the team and it can be a difficult decision and if a decision is not reached then of course it will go to the court..." (Participant, p23).	

4. Manthorpe J, Samsi K, Rapaport J (2012) When the profession becomes personal: dementia care practitioners as family caregivers. International Psychogeriatrics 24: 902–910

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To present interview data from de-	**Participants:** Professionals/practitioners – specialist community nurses, care home managers and senior care staff,	Informing the professional role – Participants reported feeling greater empathy with carers, in which their own experiences of distress or feelings of helplessness, and in some	**Overall assessment of internal validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
mentia care professionals with family experiences of dementia and their reflections on decision-making frameworks. **Methodology:** Qualitative – interviews with dementia care practitioners regarding their role as family caregivers. **Country:** United Kingdom – England. **Source of funding:** Not reported.	care home workers, safe guarding adult co-ordinators, local Alzheimer's society staff, voluntary sector staff, social service staff. **Sample characteristics:** • Age – Total - range = 20–76 years; average = 46 years. • Gender – male = n = 20; female n = 95. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** Total sample N = 123 (n = 19 specialist community nurses, n = 28 care home managers and senior care staff, n = 17 care home workers, n = 17 safe guarding adult coordinators, n = 10 local Alzheimer's society staff, n = 22 voluntary sector staff, n = 10 social service staff).	cases bewilderment and uncertainty, shaped their interactions with carers. Two nurses and a social worker explained that they sometimes 'crossed' professional boundaries and shared their experiences with carers if they thought this would help the carer to understand aspects of the Mental Capacity Act (such as the benefits of making arrangements in advance of the loss of financial decision-making capacity). Participants confessed 'bewilderment' when arranging care for their relative with dementia and expressed that lay people would be even more likely to find the system baffling. "I don't know what it's like for carers who don't know the system . . . it was a nightmare." (Participant, p905). <ins>Insight into services</ins> – Participants considered that their experiences helped them in their work and gave them a better understanding of services, and allowed them to be more confident. Reflecting on the provisions of the Mental Capacity Act, they felt that these would have enabled them to more assertive about their relatives' care: "Both my parents had advanced dementia, my mother was in residential care, and looking back, if I knew what I know now and there had been an Act in place, then I would certainly have dealt with some issues that she encountered in residential care differently, very much so." (Participant, p905). Some professionals chose to work in dementia care as a result of their experiences as a carer and they were motivated to improve care for other people with dementia: "I know I can't change the whole thing but I'd like to make someone have a better quality of life than they had in a home. [Grandparent] was strapped to a chair . . . covered in mess . . . sat in a room. Told to sit there and stay there." (Participant, p906).	**Overall assessment of external validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		Professional influences on caring – Several participants viewed the Mental Capacity Act as something they would have wanted to be in place when they were carers negotiating or communicating with professionals involved in their relative's care. "It ... certainly informed my job and my job informed how I coped with it, it’s circular really. I’m sure because I was a social worker I was in a good position to argue to get him [relative] some personal care that took into account his background and personal choices to stay at home for as long as possible until he became a bit muddled and he went into a home." (Participant, p906). Bridging the personal and professional worlds – Some participants reported that they were often consulted by anxious members of their own family and found that they became ‘a bridge’ between the family and professionals because of their knowledge of dementia care. Participants provided a number of examples in which the Mental Capacity Act had convinced a relative of the importance of respecting the seemingly ‘unwise’ decisions of a person near the end of life, or had been used to challenge medical opinion. "The doctors go on at him to stop drinking (alcohol) but he said, I'm 77 years old, I've drunk all my life. If it's going to kill me it's going to kill me. . . . He smokes about ten cigarettes a day . . . at the end of the day he's 77. Why should he stop because they tell him to stop?” (Participant, p906). Planning – There were few differences between participants regarding planning in advance for a lack of capacity and profession did not seem to have an impact on this. Few had made any arrangements (such as registering a Lasting Power of Attorney), but most reported that they planned to, either for older relatives and/or themselves, usually as a result of their combined professional and personal experiences and, for some, their Mental Capacity Act	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		training. "Yes, I'm thinking I will probably move next year. . . .And my mother has no intention whatsoever of giving any of us Lasting Power of Attorney … it's impossible … it's going nowhere." (Participant, p907). Several care home staff mentioned that a prime objective of their own plan was (or would be) to avoid being a burden on their children, if and when they developed dementia or another similar disease; however, these concerns did not feature elsewhere. "Yes, as a matter of fact I said to my kids I am going to do my own care plan . . .and then one day if ever they need it they can have it." (Participant, p907). Several participants had relatives who had drawn up Lasting Powers of Attorneys. However, family resistance due to emotional and sometimes cultural issues had hampered progress (i.e. registration of the Lasting Power of Attorney). <u>No apparent effect of the Mental Capacity Act</u> – A small number of participants, despite their personal experiences, reported that the Mental Capacity Act had made no impression on their professional work.	

5. Ramasubramanian L, Ranasinghe N, Ellison J (2011) Evaluation of a structured assessment framework to enable adherence to the requirements of Mental Capacity Act 2005. British Journal of Learning Disabilities 39: 314–320

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To '… explore the quality, thoroughness and practice of how mental capacity and	**Participants:** Service users and their families, partners and carers – patients admitted to a specialist inpatient unit for people with learning disabilities. NB. No	<u>'If no capacity, least restrictive options explored' (target of 100% adherence)</u> – Before introduction of the checklist, the least restrictive options were explored in 16% (1/6) of those cases examined; after introduction of the checklist,	**Overall assessment of internal validity:** − **Overall assessment of**

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
issues around consent, best interests and final care plan decisions were assessed and documented in a specialist learning disabilities unit and to develop and evaluate a structured assessment framework to act as a guideline to help adhere to the requirements of the Mental Capacity Act.' (Authors, p316). **Methodology:** Audit – review of minutes from Best Interests Group meetings and patient notes. **Country:** United Kingdom – England – Liverpool. **Source of funding:** Not reported.	details are provided in relation to the practitioners involved in the case of each patient. **Sample characteristics:** • Age – Range = 21–55 years (mean = 36 years). • Gender – Female n = 7 (35%); male n = 13 (65%). • Ethnicity – Black and ethnic minorities n = 4 (20%); white n = 16 (80%). • Religion/belief – Not reported. • Disability – All patients had an intellectual/learning disability – these are categorised as 'mild' n = 12 (60%); 'moderate' n = 7 (35%); 'severe' n = 1 (5%). • Long-term health condition – Three participants (15%) were reported to have an identified genetic disorder. The majority also had an additional ICD-10 diagnosis. These were – organic mental disorder (F0-9); psychosis (F20-29); affective disorder (F30-39); anxiety disorder (F40-48); autistic spectrum disorder (F84); epilepsy (G40). • Sexual orientation – Not reported. • Socioeconomic position – Not clear; however, the authors report the living situation of participants – living with partner/wife n = 4 (20%); living alone n = 3 (15%); living with parent n = 3 (15%); supported accommodation n = 10 (50%). **Sample size:** Total sample size N = 20.	this was the case in 71% (10/14) of those cases examined. This result was not significant (*p* = 0.180). 'Exploring whether the person could have capacity at a different time' (target of 100% adherence) – Before introduction of the checklist, 33% (2/6) of those cases examined included exploration of the possibility that the person may have capacity to make the decision at a different time; after introduction of the checklist, this was the case in 100% (14/14) of those cases examined. This result was significant (*p* <0.001). 'Exploring whether the decision/act wait until that time' (target of 100% adherence) – Before introduction of the checklist, 33% (2/6) of those cases examined explored whether the decision could wait until a point at which the person may have capacity; after introduction of the checklist, this was the case in 100% (14/14) of those cases examined. This result was significant (*p* < 0.001). 'Advance statement/directive/Previous wishes, LPA, Court appointed deputy-checked' (target of 100% adherence) – Before introduction of the checklist, practitioners checked whether the person had an advance statement, Lasting Power of Attorney, court-appointed deputy, etc. in 0% (0/6) of those cases examined; after introduction of the checklist, this was the case in 86% (12/14) of those cases examined. This result was significant (*p* < 0.05). 'Involving family, carers and relevant parties in decision-making' (target of 100% adherence) – Before introduction of the checklist, families, carers and other relevant parties were involved in 67% (4/6) of those cases examined; after introduction of the checklist, this was the case in 100% (14/14) of those cases examined. This result was significant (*p* < 0.001).	**external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	The audit was conducted before and after the introduction of a checklist – 6 cases were examined before introduction of the checklist, and 14 were examined after introduction of the checklist. NB. Only those standards relating to review question 4 are reported here. **Outcomes measured:** Service user related outcomes – the audit measured against 14 standards, the target for each was 100% adherence.	‘If none present, consider consulting an IMCA’ (target of 100% adherence) – Before introduction of the checklist, 33% (2/6) of those cases examined showed that involvement of an Independent Mental Capacity Advocate was considered; after introduction of the checklist, this was the case in 86% (12/14) of those cases examined. This result was not significant (*p* = 0.180). ‘Documentation of final care plan’ (target of 100% adherence) – Before introduction of the checklist, 33% (2/6) of those cases examined had documented a finalised care plan; after introduction of the checklist, this was the case in 100% (14/14) of those cases examined. This result was significant (*p* < 0.001). NB. Only those findings relating specifically to question 4 have been included in the narrative summary for this study.	

6. Redley M, Clare ICH, Luke L et al. (2009) Mental Capacity Act (England and Wales) 2005: The emergent Independent Mental Capacity Advocate (IMCA) service. British Journal of Social Work 40: 1812–1828

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The aim of the evaluation was to ascertain whether an Independent Mental Capacity Advocate service could protect the interests of adults who lack capacity and are without family or friends, and are faced with a potentially life-changing decision. In addition, the authors sought	**Participants:** • Service users and their families, partners and carers – Clients of Independent Mental Capacity Advocate. • Professionals/practitioners – Managers of Independent Mental Capacity Advocate provider organisations, Independent Mental Capacity Advocate caseworkers, staff from each advocacy provider organisation, health and social-care decision-makers and	Number of referrals for each type of decision (n = 249): Serious medical treatment n = 37 (15%); change of accommodation – prior to discharge from hospital n = 98 (39%); other change of accommodation n 114 (46%). Consultation with family and friends – Almost two-thirds (63%) of the 231 clients had family or friends who could, in principle, have been consulted, but this step was judged by decision-makers not to be practical or appropriate. Practical barriers to consultation with family and friends – practical:	**Overall assessment of internal validity:** ++ **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
to identify and understand any practical difficulties that Independent Mental Capacity Advocates might face following the introduction of the statutory service. **Methodology:** Mixed methods – quantitative data describing the number and types of referrals to the pilot Independent Mental Capacity Act service, and qualitative interview data capturing key stakeholders' experiences and perceptions of Independent Mental Capacity Advocate casework. **Country:** United Kingdom – England. **Source of funding:** Government – Department of Health.	practitioners. **Sample characteristics:** • Age – Not reported. • Gender – Not reported. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Among the 231 clients, the 2 largest groups were men and women whose compromised capacity resulted from learning disabilities (40%) or dementia (33%). The remainder were a heterogeneous group comprising adults with acquired brain injury, mental health problems, or a combination of these and other conditions. • Long-term health condition – Among the 231 clients, the 2 largest groups were men and women whose compromised capacity resulted from learning disabilities (40%) or dementia (33%). The remainder were a heterogeneous group comprising adults with acquired brain injury, mental health problems, or a combination of these and other conditions. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** Two hundred and thirty-one clients with compromised capacity; 7 managers of Independent Mental Capacity Advocate provider organisations; 7 Independent Mental Capacity Advocate	• Family or friends had not been in contact for a long time (30%) • Mentally or physically too frail (16%) • Lived far away or were reluctant to be involved (8% for both). Reasons why it was considered inappropriate to involve family and friends: • Conflicts of interest where it was felt they stood to gain or lose some material benefit as a result of a particular outcome (17%) • Suspicions that they had abused the person lacking capacity (11%) • Disagreements among different family members (3%) • Disputes with the decision-maker (3%). Other findings: • Men and women referred for a change of accommodation prior to discharge from hospital were significantly older than those referred for the 2 other decisions. • The majority (60%) of referrals for decisions of this kind related to people with a diagnosis of dementia. • Among the older group, two-thirds (67%) were moving from one residential placement to another. • The majority (60%) of referrals relating to serious medical treatment were for people with a diagnosis of a learning disability. Communication: • Three-quarters (74%) of the 231 clients used English or another spoken language. • One in 5 (17%) used an alternative means of communication (sign language, pictures or non-standard vocalisations). • Only 6% were described as having no obvious means of expressing themselves to others. • Importantly, it was reported by the Independent Mental	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	case workers; 8 staff from advocacy provider organisation; 16 decision-makers in health and social care; 35 healthcare practitioners.	Capacity Advocates that more than half (54%) of the 109 clients whose referrals were completed at the end of the evaluation were able to communicate some indication of their wishes that could be passed on to a decision-maker. Dealing with referrals: • Overall, Independent Mental Capacity Advocates spent just over 9 hours on each referral. Independent Mental Capacity Advocates revealed considerable uncertainty around the ending of their involvement with clients, particularly in relation to change of accommodation decisions. • There was a consensus among the Independent Mental Capacity Advocates that their involvement should end only when a decision had been made and implemented fully. Independent Mental Capacity Advocates reported that they often felt ‘out of the loop’ and that it was rare for them to receive any response to, or even acknowledgement of, their written reports. • In 16 (15%) of 149 referrals, the Independent Mental Capacity Advocate challenged the decision that had been made. Challenges were made related to judgements of incapacity, substitute decisions about change of accommodation. The Independent Mental Capacity Advocate role: • Over the course of the pilot, there were changes in the views of both those Independent Mental Capacity Advocates who were strongly committed to a person-centred approach and those Independent Mental Capacity Advocates who were more comfortable with decision-specific advocacy. • Decision-makers in both health and social care expressed positive views of involving advocates in substitute decisions about changes in accommodation. • The decision-makers in social care were impressed	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		with the Independent Mental Capacity Advocates knowledge, feeling that they shared a common language. - The 7 healthcare decision-makers who had worked with Independent Mental Capacity Advocates in changes of accommodation decisions for in-patients reported that they had been impressed with the service they had received, though some concern was expressed over the possibility that advocates had contributed to slight delays in the process of discharging a patient from hospital. Two of the healthcare decision-makers working with Independent Mental Capacity Advocates reported that their initial scepticism had been challenged by the experience and that statutory advocacy had made a useful contribution to the decision-making process. - Healthcare decision-makers who had not worked with an Independent Mental Capacity Advocate, expressed 4 main concerns: first, doubts about the contribution that could be made by anyone without medical training; second, scepticism about the professional ability of advocates to represent clients' views; third, that advocacy was unnecessary, since, as healthcare practitioners, they themselves already acted in the best interests of their patients; and, finally, that a service available only within office hours was unhelpful. - In striking contrast, the same respondents were enthusiastic about the involvement of an Independent Mental Capacity Advocate in changes in accommodation decisions arising in the context of patients being discharged from hospital. These decisions were not seen as entirely medical and, therefore, the involvement of an advocate, offering a lay person's perspective, was considered to be both appropriate and possibly of considerable value. - It was apparent, however, from our interviews with these healthcare decision-makers that many of them	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		did not fully understand the decision-specific approach to capacity outlined in the *Mental Capacity Act 2005*.	

7. Samsi K and Manthorpe J (2013) Everyday decision-making in dementia: findings from a longitudinal interview study of people with dementia and family carers. International Psychogeriatrics 25: 949–961

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: To explore the experiences of people with dementia and their family carers regarding everyday decision-making, how decisions are negotiated, and how experiences changed over time. **Methodology:** Qualitative – face-to-face interviews conducted every 3 to 4 months over a 1-year period. **Country:** United Kingdom – England – London. **Source of funding:** Other – National Institute for Health Research.	**Participants:** Service users and their families, partners and carers – people with dementia and their family carers. Participants were recruited via day/community centres and local branches of the Alzheimer's Society. Snowball sampling was also used to recruit friends and relatives of these participants. The authors describe the participants as having 'mild to moderate dementia' on the basis that they had been diagnosed 3 to 11 months before the first stage of the study. NB. People with dementia who were unable to consent to interview at the first stage of the study were excluded. **Sample characteristics:** • Age – People with dementia – range = 72–92 years; family relative range = 49–88 years. • Gender – People with dementia – female n = 6, male n = 6; family relative – female n = 8, male n = 4. • Ethnicity – White/British n = 11 dyads; Asian/Indian n = 1 dyad. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – The authors do not report on any conditions	The authors report that when family carers made decisions on behalf of their relative, they prioritised the person's best interests and wellbeing (the authors suggest that while this was not stated by the carers themselves this emerged during the course of the interviews). The authors conceptualise these 'best interests decisions' as the 'substitute decision-making' end of a continuum beginning at 'supported decision-making'. Citing the case of 2 dyads, the authors report that even though carers tried to involve the person with dementia in decision-making, the final decisions often reflected the carers' preferences because the person with dementia had begun to have difficulties in making decisions. They go on to state that carers were committed to involving the person they cared for in decisions and report that they used a range of strategies to do so, such as providing a more limited range of options, asking for the person's opinion at the 'right' time to ensure that they could be engaged. One carer reportedly expressed concerns regarding the role of substitute decision-maker, expressing concern at the level of responsibility this could imply. Another carer was reported to have been required to take on more responsibility in relation to medical care: "No, I mean I have to give him (husband with dementia) his tablets and now when he goes he, has had quite a few illnesses, a few operations, but now if he doesn't feel well or anything it is up to me to take him to the doctors and I have to go in wherever he goes now for anything medical – I have to go in with him now and just, you know, and speak for him really."	**Overall assessment of internal validity:** + **Overall assessment of external validity:** +

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	other than dementia. No further details on this condition are provided with the exception of time since diagnosis – range 3 months to 11 months. - Sexual orientation – Not reported. - Socioeconomic position – characteristics of dyads – married couples n = 7, friends n = 1, mother-child/step-child n = 3, uncle/niece n = 1, housing situation - owner-occupied n = 10, privately rented n = 1. **Sample size:** - Total sample size n = 30 (15 people with dementia and 15 family relatives). - Time 1 (month 0 –1) – n = 30 (15 people with dementia and 15 family relatives). - Time 2 (months 4–5) – n = 21 (10 people with dementia and 11 family relatives). - Time 3 (months 8–9) – n = 23 (11 people with dementia and 12 family relatives). - Time 4 (months 12–13) – n = 23 (11 people with dementia and 12 family relatives).	(Participant, p956). The authors also report that carers also employed other strategies to try to '… continue their relative or friend's involvement in general or domestic decisions … For instance, carers talked of reducing decision-making opportunities for their relatives by making smaller everyday decisions on their behalves. This management, carers felt, thereby enabled them to "save" their relative's decision-making capacities for bigger and more significant decisions …' (Authors, p956) The authors report that later interviews revealed that carers increasingly had to make decisions on behalf of the person with dementia. They state that while most had generally accepted this, some found the extra responsibility to be frustrating and a strain. Spousal carers reportedly used their in-depth knowledge of the person to 'retrospectively' think about their beliefs and preferences in order to come to a decision about what they 'would have wanted'. The authors also state that the carers who were supporting a parent were more likely to recall earlier conversations with their parent when doing this (for example, in relation to moving if their parents' health deteriorated significantly). The authors go on to report that 'many' carers reportedly found that being relied upon to make decisions could be a burden and lead to feelings of guilt. The authors report that the concept of 'best interests' underpinned many carers intentions when making decisions with or on behalf of the person they supported; however, they note that many carers found it difficult to 'weigh up' best interests as they had a tendency to connect their own best interests with those of the person they supported.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
		The authors report that common examples of these decisions included decisions about respite care and whether to continue driving. The authors state that only ‘a few’ carers reported receiving support regarding decision-making, citing the case of one carer who reported feeling isolated when making decisions on behalf of her husband, noting that while she had had some support from the local carers’ centre, decision-making tends to be seen as a private matter. The authors state that most carers felt that they would benefit from support with decision-making; however, this was felt to be not widely available. In their discussion section, the authors suggest that there was a tendency for carers to prioritise the autonomy of the person they cared for by using a range of strategies to involve them in decisions, even when the person with dementia did not want to be involved in these decisions. NB. Only those findings that are clearly relevant to NCCSC review question 4 have been extracted.	

8. Sorinmade O, Strathdee G, Wilson C et al. (2011) Audit of fidelity of clinicians to the Mental Capacity Act in the process of capacity assessment and arriving at best interests decisions. Quality in Ageing and Older Adults 12: 174–179

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The authors aimed to ‘... evaluate health professionals’ fidelity to the Mental Capacity Act (MCA) principles on determining mental capacity and arriving at best interests decisions in the care of individuals found to lack the relevant decision-making	**Participants:** Service users and their families, partners and carers – the authors analysed the records of patients who had been found to lack capacity to make a decision. Records were provided by Community Mental Health Teams/ psychiatrists (working age psychiatry, older adults’ psychiatry, and learning disability psychiatry) for patients who were over the age of 18 and had (in the last 2 years) been determined to lack capacity	Enquiries made regarding Lasting Power of Attorney: Enquiries regarding Lasting Power of Attorneys were made in 25% of case records (n = 17). Only 2 of these patients had made a Lasting Power of Attorney. Enquiries made regarding existence of a court appointed deputy: Enquiries regarding the existence of a court appointed deputy with powers relating to the issue for which capacity had been questioned were made in 9% of cases. The authors report that ‘… in none of those cases was the existence of a court appointed deputy ascertained.’ (p176).	**Overall assessment of internal validity:** − **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
capacity.' (p174). **Methodology:** Audit – review of patient records provided by Community Mental Health Teams/ psychiatrists and geriatricians working at a local hospital. **Country:** United Kingdom – England – South-east London. **Source of funding:** Not reported.	to make a decision regarding their place of residence, their finances, or their treatment. The authors also requested records from geriatricians working at a local hospital; however, it is not clear for which type of decisions these patients had been found to lack capacity. NB. No further details on the individuals to whom the case notes relate or the practitioners who had created them are reported. **Sample characteristics:** • Age – Not reported. • Gender – Not reported. • Ethnicity – Not reported. • Religion/belief – Not reported. • Disability – Not reported. • Long-term health condition – Not reported. • Sexual orientation – Not reported. • Socioeconomic position – Not reported. **Sample size:** N = 68 (older adults n = 52; working age adults n = 11; people supported by the learning disability team n = 5). **Outcomes measured:** Service outcomes – the audit tool developed by the authors aimed to support the collection of data relating to – • The reason for the capacity assessment. • The legal tests used to assess capacity. • The best interests process followed	Consultation with families and friends in the best interests process: The authors report narratively that '… the majority of clinicians …' consulted with the family and friends of patients when making a best interests decision. Involvement of an Independent Mental Capacity Advocate – The authors report narratively that in '… only a very small proportion of the entire sample …' did records indicate that an Independent Mental Capacity Advocate had been involved. NB. Only those findings relevant to review question 4 are presented here.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
	after it had been determined that the patient lacked capacity (i.e. was the process outlined in the Mental Capacity Act followed?). - Demographics. - ICD 10 diagnosis. - How well issues relating to capacity assessments were documented (was this 'easy'?). - How were assessment processes documented?		

9. Williams V, Boyle G, Jepson M et al. (2012) Making Best Interests Decisions: People and processes. London: Mental Health Foundation

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Study aim: The main aim of the study was to provide a picture of practice according to the main contexts and types of decisions being made (healthcare, personal welfare and property and affairs), and relating to different groups of individuals. Within this overall research goal, several questions were addressed – - In which contexts are best interests decisions formulated, and for what groups of individuals?	**Participants:** Professionals/practitioners – health, social care and legal professionals. **Sample characteristics:** - Age – Stage 1 – online survey – 385 valid responses, total response was 392. The age of the respondents ranged from 20–69 with mean age – 44 years. The most frequently reported age of the respondents was 40-49, with over a third (37%) of respondents in this age group. Stage 2 – telephone survey – 68 participants Age 18–29 – 3 (4%) Age 30–39 – 8 (12%) Age 40– 49 – 29 (43%) Age 50–59 –17 (25%) Age 60 and over – 9 (13%) Stage 3 – face-to-face interviews – 25 participants. - Gender – Stage 1 – online survey – 385 valid responses, total response	Findings from the online survey – The two largest client groups represented in this survey were people with dementia (154; 40%), followed by those with a learning disability (131; 34%). Others includes mental illness –107 (28%); neurodisability 75 (19.5%). Respondents were drawn from four areas of England – Bradford (34%), Surrey (26%), Dorset (21%), and Sandwell (19%). Combined findings (online survey, telephone interviews and face-face interviews) – When and why are best interests decisions made? Of the 385 valid responses to the survey, almost half (48%) of all decisions were made regarding healthcare. A quarter (24%) were about personal welfare or social matters, and a slightly smaller percentage (20%) were about more than one matter; 78 (20%), property and finance – 28 (7%). One hundred and eighty-four people needed a decision	**Overall assessment of internal validity:** + **Overall assessment of external validity:** ++

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
- What is the range of current practice models for making best interests decisions, and is there any association between any of these models and particular contexts? - How is capacity being assessed, and what prompts such assessments? - How is extant decision-making by the person lacking capacity being facilitated? - What factors are taken into account by those who make best interests decisions, and how are these factors considered? - How are the personal views and beliefs of the person lacking capacity examined? - How are the views of relatives and carers, professionals and panel members weighted against the objective factors involved in weighing up outcomes of decisions?	was 392. Almost three-quarters (283; 72%) of the respondents were female, with 107 (27%) being male. Two respondents did not report their gender. Stage 2 – telephone survey – 68 participants. The majority of telephone interviewees were female (64%) Stage 3 – face-to-face interviews – 25 participants. - Ethnicity – Stage 1 – online survey – 385 valid responses, total response was 392. The majority of respondents were of White British ethnicity (85%), with no other ethnic group comprising more than 6% of respondents. Stage 2 – telephone survey – 68 participants. The majority of telephone interviewees were white British (91%). Stage 3 – face to face interviews - 25 participants - Religion/belief – Not reported. - Sexual orientation – Not reported. - Socioeconomic position - Stage 1 – online survey – 385 valid responses, total response was 392 Over half of the respondents (238; 60.5%) worked within the NHS, the largest proportion working within a mental health/ learning disabilities Trust (134; 34%). Those describing 'other' employers included those who had retired, were self-employed, or worked for non-specific employers such as a 'care home'. Stage 2 – telephone survey – 68 participants. They were health and social-care professionals, family	made regarding a health matter. Forty per cent of the decisions were regarding consent to serious physical healthcare treatment and a further 33% were regarding other physical healthcare treatment. People with mental illness were more likely to have mental healthcare decisions made for them compared to those without mental illness (*p* <.001). People with learning disabilities were more likely than those without learning disabilities to have physical healthcare decisions made (*p* <.05). There was no statistically significant difference between people who were intoxicated with alcohol or drugs and those who were not, and people who were unconscious and those who were not, despite initial impressions. The role of respondents in making the best interests decisions: Almost half (170; 43%) of respondents were part of a multi-disciplinary team that made the best interests decision. A third (126, 32%) were joint decision-makers, and a small number (26; 7%) said that they were the sole decision-maker. The role of respondents and the type of decision being made: Respondents involved in healthcare decisions were almost exclusively health care professionals (87.5%). The number of respondents describing themselves as joint decision-makers was 46, and most (87%) were healthcare professionals. 99 respondents were part of a multidisciplinary team, and again almost all of these (91%) were healthcare professionals. The role of respondents and the impairment of the person: Respondents supporting people with learning disabilities more frequently reported being part of multi-disciplinary teams making best interests decisions (59%) and were significantly different from respondents of people without learning disabilities in the role that they played in the decision-making process (*p* <.001)	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
- What influence, if any, do resource allocation mechanisms have on the eventual outcome? - What challenges do professionals face when making best interests decisions? **Methodology:** Mixed methods – Multi-stage, mixed-methods project. - Stage 1 – online survey (reported in analytical report 1). The researchers aimed to recruit 400 people to participate in an online survey, and achieved 385. Stage 2 – telephone survey (reported in analytical report 2). The target was 70–100 – 68 people took part. - Stage 3 – face-to-face interviews (reported in analytical report 3) We sought to recruit 20–25 'cases' to follow-up in more detail using face-to-face interviews, and achieved 25 cases.	member Stage 3 – face-to-face interviews – 25 participants. **Sample size:** Stage 1 – online survey – 385 valid responses, total response was 392 Stage 2 – telephone survey – 68 participants Stage 3 – face-to-face interviews – 25 participants.	Findings in detail – telephone and face-to-face interviews - Physical healthcare: Serious deterioration in physical health was often cited as the start of a best interests process. The typical pattern was that the person in question was resisting treatment, or that the risks of the treatment had to be balanced against the psychological wellbeing or quality of life of the individual. Discharge from hospital and change of accommodation was the second largest context for making a best interests decision. Personal welfare or social matters – 93 people needed a decision made regarding a personal welfare or social matter. The majority (41%) involved a change in the person's accommodation involving a move into or out of a care home. People with dementia were more likely than others to have decisions made for them regarding a change in their accommodation involving a move into or out of a care home than were people without dementia ($p < .01$). Safeguarding triggers and Deprivation of Liberty Safeguards: Risk was a very common trigger for a best interests process, and best interests decisions were taken to protect people from harm. Fifteen (16% of the social care decisions in the online survey) were reported to be about adult safeguarding (p43). Ten (15%) of the 68 telephone interviewees described a situation in which there was a safeguarding concern, and an additional 2 where the concern was about safeguarding financial interests. Safeguarding was of course also a concern in those cases that had involved an application for Deprivation Of Liberty Safeguards, of which 4 were mentioned in telephone interviews.	

Research aims.	PICO (population, intervention, comparison, outcomes).	Findings.	Validity ratings.
Country: United Kingdom – England. **Source of funding:** Government – Department of Health.		Matters primarily triggered by social-care needs: A specific change in social-care needs could also give rise to a best interests decision. For instance, that accounted for 35 of the 93 (38%) social-care cases in the online survey. Most typical in this group were those cases where a breakdown of existing care arrangements was foreseen: “The difficulty arose was because her husband really didn't think he could cope. He didn't think she had capacity to weigh up the implications of her going home; she couldn't manage stairs, and the house had steps up to it.” (Participant, p13). It was interesting, however, that many of these ‘breakdown of care’ situations arose particularly at the point when the person lacking capacity had had a health intervention or a stay in hospital. Several of those instances involved a person who was living in a supported situation, but was refusing to accept care or support in particular ways. Property (including a person’s tenancy) or financial affairs matters: Twenty-nine people (7%) had a best interest’s decision made regarding property (including a person’s tenancy) or financial affairs matters. Two-thirds (68%) of decisions were regarding the person’s financial affairs. Concerns about financial capacity, or about possible financial abuse, also led to best interests decisions in a few cases in this research. ‘A 39-year-old man with moderate learning disabilities was living in a group home, with support for a few hours during the day provided by an agency. He had long been considered vulnerable, since he had formed relationships with people who were selling him drugs, and he tended to go out at night to meet with those friends, despite the attempts of staff to instil in him a sense of his own safety. He had a long period of counselling with a psychologist, and was then the subject of formal safeguarding meetings, where it was considered that it would be in his best interests to live in a more protected environment. As he did not want to do this, however, his capacity was assessed in relation to his understanding of safe drug use,	

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		and also in relation to the proposed move. It was agreed that he did not have a full understanding of the risks he was facing, and so it was decided that he would have to be persuaded to move into a home with 24-hour support.' (Authors, report 3, p44). About 1 in 5 best interest's decisions were made for more than 1 reason. What precipitates best interests decisions? Medical practitioners tended to identify only the medical need itself, while care home staff then had the task of considering the issues and effectively bringing a medical decision into the arena of 'best interests'. Decisions precipitated by pressure from a third party – Finally, there were a few cases that appeared to have been precipitated not just by the person's own escalating needs, but by a particular crisis that was initiated by another party. These cases particularly highlighted the need for joint working. Decision-making because the person was making a decision thought to be unwise – 23 (6%) respondents stated that the main reason for deciding what was in the person's best interests was because the person was making a decision thought to be unwise. Eight of the 23 decisions (35%) made because the person was making a decision thought to be unwise were made with respect to healthcare decisions. Nine of the 23 decisions (39%) made because the person was making a decision thought to be unwise were made with respect to personal welfare or social matters. Decision-making because of the person's age, their appearance or their behaviour – 13 (3%) respondents stated that the main reason for deciding what was in the person's best interests was because of the person's age, their appearance or their behaviour. Six of these decisions were	

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		made with respect to personal welfare or social-care matters; 4 were made regarding a healthcare matter and 1 was made regarding a property or financial affairs matter. The time taken to assess the person's best interests before the decision had to be made or action taken – Over a third (126; 32.5%) of assessments were made within 24 hours of the decision having to be made. Almost a third (118; 30.5%) of assessments were made up to a couple of weeks before action had to be taken, and just over a third (141; 37%) were made over several weeks. It seems that decisions regarding healthcare and personal welfare or social matters were more likely to be made within 24 hours, whereas decisions about property or financial affairs matters were more likely to be made over the course of several weeks. However, there is no statistically significant difference when considering time in which it took to make the decision and the type of decision ($\chi^2 = 6.83$; $p = .337$). Delays in best interests decision-making – For almost half of the cases (167; 43.5%) it was not thought possible to delay the best interests decision. A greater proportion of healthcare decisions (47%), and personal welfare or social decisions (45%) were thought not able to be delayed. A quarter of property or financial affairs decisions (25%), or those involving more than one issue (23%) were delayed so that the person could regain capacity or be helped to make the decision. (p60). The process of best interests decision-making – Although not statistically significant, it seems that urgent decisions were more likely to fall into the healthcare category (38% up to 24 hours), and lengthier decisions were more likely to be about property and affairs (50%, several weeks), or about more than one matter. Further analysis showed that urgent decisions were most likely to be associated with people who were unconscious or who were under the influence of drink or drugs. From this sample of interviews, the	

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		most urgent decisions involved ambulance crews deciding to transport someone to hospital in their best interest: none of the best interests cases involving ambulance crews took more than 2 hours to complete. Quick decision-making processes are more likely to be associated with healthcare. Most participants in this research favoured joint or consensus decision-making. The online survey revealed that almost half of respondents were part of a multi-disciplinary team making a best interests decision, and a third were joint decision-makers; only a small proportion (7%: 26) claimed to be the sole decision-maker. The greatest trend towards multi-disciplinary decision-making appeared to be reported by nurses, of whom 56% were part of a multi-disciplinary team and by professions allied to medicine, of whom 61% were part of a team. (p 63). "All the ones I've been involved with are very much a team effort. It's not one person making a decision." (T 31) (Participant, p64). A mental health service manager described a decision about financial appointeeship for someone with dementia, who was giving away his money without full understanding of others' motives. "…it's not a single person's decision. I think what makes it easier is because we look at it from a totally multi-disciplinary angle." (Participant, p27). There was a distinction between leading a best interests process and actually being the decision-maker. On occasions different people carried out these 2 functions. Those in multi-disciplinary teams often held regular meetings, where best interests decisions were incorporated as part of the standing agenda. Best interests were also considered in some cases as part of other processes, such as safeguarding. Over half of the respondents in the online survey identified that they were part of a multi-disciplinary team making a decision. There was a highly significant difference regarding the process of decision-making when	

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		considering the types of decisions made ($\chi^2 = 33.92$; $p < .001$). A special best interests meeting for a patient or client could take many different shapes. In some cases, an 'executive' meeting fed into a larger more formal meeting; at other times a single best interests meeting pulled together relevant parties, and the outcome was then fed into a regular multi-disciplinary process. However, approximately one in ten of the decisions did not involve the person lacking capacity. "There was a build up of getting to the point where we were going to the consultant with everybody having built up information about pros and cons and everything. And then when we got to that final one with everybody together, it was sort of, right, on this date a decision will be made, with the consultant having the overriding, 'we'll do it, or we won't'." (Participant, p74). Over half of all decisions regarding personal welfare or social matters, property or financial matters, and more than one matter, involved a series of meetings between the decision-maker, the person and usually others who knew the person. However, this was the case for only 31% of healthcare decisions. Healthcare decisions were more frequently made than other types of decisions made at a single meeting, or at meeting(s) that did not involve the person lacking capacity. Disagreement about the person's best interests – As noted in the telephone survey, conflicts could be between professionals, as well as between family members and professionals. The real frustrations in conflicting situations were expressed by those professionals who felt that they were disempowered to speak up for the client or patient they knew. That was so, for instance, with the appointees , where they felt they knew the client better than the social	

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		worker who overturned their decision to protect a young woman from a potentially harmful decision to purchase a car, where her money would be likely to run out and she would also put herself at risk on the roads. There was also a strong sense of disempowerment among the care home staff dealing with general practitioners decisions in end-of-life cases. Further, there seemed to be almost a professional antagonism between solicitors and social services: “I haven't spoken to anybody from social services about this, but I get the impression that if a client comes to you and instructs a solicitor, they're immediately on their guard, and they feel as if you're criticising them.” (Participant, p34). Best interests decisions were not always made via meetings; sometimes they were made through informal processes, such as conversations around a bedside. Although most people said they had taken into account the wishes and values of the person lacking capacity, there were only a few clear examples where wishes and values were influential in the best interests decision, or where past values had been explored. Communication with a person lacking capacity was sometimes more successfully accomplished outside meetings, and with accessible information strategies or real-life experiences, or observation: ‘A man with autism and some complex communication and learning disabilities had been living in an NHS residential facility that was due to close as a result of local policy. He had been assessed as not needing continuing healthcare, and so was due to move into a flat on a ‘supported living’ basis. However, the interviewee felt that time needed to be taken to consider the man’s needs carefully, before he moved. He therefore raised this matter with the social worker, and fought hard to get things in place so that the	

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		man would have a well-managed move into a situation where his needs could best be met. An accessible information picture book was made with the man, who was taken to see the new house which was proposed. Photos were taken, and the interviewee had continued conversations with the man about the place.' (Authors, p85). Involving the person lacking capacity and those close to him/her – 47% of people lacking capacity were involved in best interests meetings with multiple participants. People with learning disabilities were significantly less likely to be invited to a formal meeting, and those with dementia were more likely. The online survey results showed that best interests processes were most likely to involve the person lacking capacity, either in a series of meetings (36%: 140 cases) or in a single meeting (21%: 80 cases). Only 12% of cases (46) definitely did not involve the person lacking capacity in any meetings, while a further 9.5% (37) respondents were unsure or marked as 'other'. Best interests decision-making meetings that did not involve the person at any meetings – There were 46 cases for which best interests decision-making meetings did not involve them. Seventy per cent (n = 32) of these cases involved a healthcare decision, 15% (n = 7) involved a personal welfare or social matter; one involved a property or financial affairs matter; and 13% (n = 6) involved more than one type of decision. Over half of the 46 cases (27; 59%) had learning disabilities. Others had dementia (12; 26%), mental illness (10; 22%), neuro-disability (9; 20%) or were unconscious (3; 6.5%). Although they may not have been involved in the best interests meetings, over half of the cases (27; 59%) were thought to have been as fully involved as possible in the decision-making process, and over three-quarters (37; 80%) were said to have had their past and present wishes and feelings taken into account. Eighty-eight per cent of respondents in the online survey	

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		felt that people close to the person lacking capacity had been consulted, and 86% felt that their views had been taken into account. The majority of the 68 telephone interviews concerned a decision which could be discussed in relatively informal and repeated ways with the person lacking capacity, particularly if there were people who knew the person well. In many cases, the interviewee was one such person: in at least 24 cases, the interviewee had already known the person who lacked capacity, as a care home manager, or a member of the nursing staff in a long-stay facility. Where there were suspicions of abuse, family members were excluded from the best interests process and informed afterwards about the outcome. Although the majority of respondents in the online survey reported that there had been no disagreement, nevertheless 65 reported some type of conflict. Independent Mental Capacity Advocates – Independent Mental Capacity Advocates were involved in 47 (25.5%) of the 184 best interests decisions regarding personal welfare or social matters, and with 22 (24%) of the 74 best interest decisions regarding serious medical treatment. Statistically, there were no significant differences between those in a particular impairment group and others when considering whether or not an Independent Mental Capacity Advocate was involved. One of the themes that emerged in the telephone survey was that there was a mixed level of awareness of the Independent Mental Capacity Advocate role among professionals. This finding was echoed in the face-to-face interviews with Independent Mental Capacity Advocates themselves. In a positive example from a medical setting, an Independent Mental Capacity Advocate was invited to attend a multi-disciplinary team meeting to discuss a proposed intervention for a man with dementia, the meeting chair was a cardiologist, and he clearly described the role of the Independent Mental Capacity Advocate: “He explained that I was there to support the gentleman and speak up for him, and also, from the Mental Capacity Act	

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		point of view, making sure that we were making good best interest decisions for this gentleman. He had a really good understanding.” (Participant, p43). Where an Independent Mental Capacity Advocate was instructed, they were generally involved in best interests meetings, and 4 of the 7 who filled in the online survey said they were involved in making the decision. There was often a tension in cases where Independent Mental Capacity Advocates were instructed, between the need to delay processes against the clinical need for immediate action. A consultant involved in making a decision about a move from a hospital setting appeared to appreciate this role of the Independent Mental Capacity Advocate in seeking out information: “And then if you're still not sure about whether you've got all the information ... then think about who else could be usefully involved in helping you make that decision. So I mean using the Independent Mental Capacity Advocate was useful.” (Participant, p45). Independent Mental Capacity Advocates were sometimes appointed when there was a conflict with family members or suspicion about their motives. Their commitment to the person lacking capacity, however, sometimes reinforced disputes. There was a greater proportion of disagreement in cases involving Independent Mental Capacity Advocates. While it is hard to tell why that is, Independent Mental Capacity Advocates said that they would challenge bad practice under the Mental Capacity Act, which could have led to constructive criticism from Independent Mental Capacity Advocates. Although there is a general lack of awareness of the finer aspects of the Independent Mental Capacity Advocate role, nevertheless both Independent Mental Capacity Advocates and professionals leading best interests decisions	

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		agreed that swiftness in appointment of an Independent Mental Capacity Advocate is important. Recording of best interests decisions and assessment of capacity – Most best interests processes were recorded formally, with about one-third of the online respondents using formal note-keeping (35.5%) and a further third using standardised pro forma (34%, more common among social care practitioners). Decisions about healthcare matters were more frequently recorded in a detailed note about the process and outcome, whereas decisions regarding property or financial affairs, or about personal welfare or social matters were more frequently recorded on standardised forms or pro forma. These differences were statistically significant ($\chi^2 = 18.68$; $p = .005$). People often felt frustrated by how inadequately records were shared, even though their concerns sometimes hinged on a lack of understanding of the confidentiality of an Independent Mental Capacity Advocate report. In some of the more complex and time-consuming cases described, minutes and notes were clearly shared among the many professionals involved. Best interests decisions for everyday matters were sometimes recorded informally using daily staff logs, or as 'balance sheets' attached to a care plan. Twenty-one interviewees reported that best interests decisions were noted down in 'case notes'; again, these could be either social-care notes within a care home, or medical notes in hospitals. Two interviewees mentioned a computerised record system, one in a day hospital, and the other in a community psychology service. The basis of the decision – Both medical and social-care decisions were often based on an assessment of risk. In	

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		social-care decisions, protection and safety were key drivers, but respondents did sometimes mention having considered less restrictive options. A strong guide in making a best interests decision was a consideration of what a person did actually want, or would have wanted, if they had capacity to decide for themselves. Less restrictive options – The majority of the cases discussed involved someone who could not manage without support and practices that would protect them, and therefore, the decision involved them losing independence and freedom in their own life. Best interests decisions often had to balance the needs of one person against another. There were dilemmas for staff that were driven primarily by the need to respect autonomy in clients or patients, and felt concerned about overriding that autonomy. Person centred practice – In some cases, this entailed going beyond the obvious 'clinical' decision, as a nurse explained, in relation to an older patient being discharged into a nursing home: "I think everybody has to understand it can't be a clinical decision. Because it's an emotional one, and clinical makes it too easy. And I think if you're trying to do what's right – like this gentleman – the clinical, easy decision was to put him into a nursing home, but it wasn't what he wanted, or what his wife wanted. And I think these decisions shouldn't just be clinical." (Participant, p47). The success of a best interests decision could only be known if there was a system for keeping in touch, or reviewing, how things were for the person lacking capacity. Family members, for instance, were well aware of the detail in their relative's life. The Mental Capacity Act was felt to have given greater	

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		clarity to a confused area of practice, and was welcomed by most of our participants. "I think it's made a huge difference. It's provided a clear structure. And it has a good balance between opposing situations. So that you get less neglect, but you also get the person's voice heard, but you also get the system's voice heard where there's a difference of opinion. I think it is good. I've certainly found that I think that services are much more contained and less impulsive as a result of the act -learning disability psychologist." (Participant, p112). Barriers to a good outcome relating to the process of best interests decision – These were barriers relating to poor communication, lack of information sharing, and hostilities between professions. There were also sometimes delays caused, for instance while waiting for an Independent Mental Capacity Advocate report. Medical decisions – Successful decisions about medical interventions were sometimes made through a multi-stage process, where consultation was carried out with those who knew the person, and the result was passed up to the senior medical practitioner, who had to take the final decision. In some of the successful practices, the social and personal interests of the patient were weighed up well. Strictly medical best interests did not always predominate, although they always did play a role in reaching the end decision. Outcomes in health-related decisions – Medical decisions were nearly always driven by a desire to preserve life. Social-care matters – Despite possible research sampling effects, it would seem that the Mental Capacity Act was most often being used in social care in relation to change of accommodation and safeguarding in a broad sense. By contrast, it appeared to be under-used in relation to care reviews, direct payments and care planning, and also in	

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		everyday, routine best interests decisions. Best interests decisions in social care were most frequently carried out through a series of multi-disciplinary team meetings. Pro forma for recording best interests decisions were more often used, and found to be useful, in social-care cases. However, in everyday decisions it was more difficult to find appropriate ways to keep accurate records. Property and affairs decisions – A much smaller proportion (9; 13%) of cases cited in the 68 telephone interviews concerned a decision relating to property and affairs. One of these was with a solicitor, but others were with people who had been involved in best interests decisions, and included a community psychiatric nurse who had referred a client to appointees in the local council. These corporate deputies (or appointees) were also involved in making best interests decisions. People with dementia and best interests decisions – People with dementia accounted for 40% (154) of the cases discussed in the online survey. Most of the social-care decisions about people with dementia related to a change of accommodation and only a minority related to safeguarding. They were less likely to have health or medical treatment decisions made for them. People with learning disabilities and best interests decisions – People with learning disabilities accounted for 131 (34%) in the online survey. Healthcare decisions were common, and the pattern emerged where a health deterioration or sudden need for treatment could reveal a raft of other issues, primarily relating to social care and/or accommodation. People with learning disabilities were less likely than other groups to be invited to best interests meetings, but they often had their views taken into account in other ways, including through: a) one-one communication; b)	

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		real-life experiences and observation; c) accessible information. Family members and others were more likely to be consulted in decisions made in the best interests of people with learning disabilities, than for other groups. People with mental health problems and best interests decisions – People with mental health problems accounted for 107 (28%) in the online survey. Typically, their best interests were considered in relation to their mental health needs, rather than in relation to physical healthcare needs. Successful processes for best interests decisions for people with mental health problems were often characterised by informality, quiet or calm contexts, and by the involvement of trusted and familiar people. People with neuro-disabilities and best interests decisions – People with neuro-disability and those with brain injuries were under-represented in our research (75 or 19.5% in the online survey). Best interests decisions and the issues involved in capacity are likely to be distinct for the 2 groups, those with neuro-disability and those with brain injury. Family members were regularly involved, and had strong and important roles to play in best interests processes. Models of best interests decision-making – Urgent decisions – Some decisions simply have to be actioned almost immediately, and in those cases, the assessment of capacity was indistinguishable from the actual decision, and then the action. Multi-disciplinary meetings – A typical model for many of the decisions, both health and social care, was the best interests meeting, preceded by a series of more informal discussions and fact-finding with those concerned with the case. Regular meetings – Some of the decisions described took place in the course of routine staff meetings, which teams would have on a weekly or monthly basis, to discuss patients in a hospital or residents in a home. Where a best interests matter came up, this	

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		would then just be a part of the meeting. Informal meetings – Informal meetings often led into a more formal best interests meeting. However, in other cases, the best interests decision was made entirely through a series of informal meetings between professionals, the person lacking capacity and others who may have information. Good information and preparation to inform a decision – From the different variations to the best interests process identified above, it is clear that a 'best interests process' is not a homogenous entity. However, there is a sense that all those coming to the meeting needed to be well informed, and to have already been in prior discussion about some of the most complex cases. Leading a best interests decision – Interviewees were sometimes reluctant to call themselves a 'best interests decision-maker'. That lack of clarity was re-iterated in the interviews, for instance, where it was unclear whether the home manager, doctor or care staff were leading the decision about taking over personal care for a man with learning disabilities. However, it is clearly important that someone takes on the responsibility of both leading the process, and ensuring that a decision is made.	