National Institute for Health and Care Excellence

FINAL

Shared decision making

[E] Evidence review for effective approaches and activities to normalise shared decision making in the healthcare system

NICE guideline NG197

Evidence reviews underpinning recommendations 1.1.1 to 1.1.10 and research recommendations in the NICE guideline

June 2021

Final

These evidence reviews were developed by the NICE Guideline Updates Team

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

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Contents

Effective approaches and activities to normalise shared decision making in the healthcare system

Review question

What are the most effective approaches and activities to normalise shared decision making in the healthcare system?

Introduction

Shared decision making is a collaborative process that involves the person using the service working with the healthcare professional to reach a joint decision about their care, now or in the future (for example, through advance care planning). It involves healthcare professionals working together with people who use services and their families and carers to choose tests, treatments, management or support packages, based on evidence and informed personal preferences, health beliefs, and values. This involves making sure the person has a good understanding of the risks, benefits and possible consequences of different options through discussion and information sharing.

Although the benefits of shared decision making are increasingly being recognised it is not yet routinely practised in every setting, and definitions of what constitutes shared decision making can vary. National surveys have shown that many inpatients want to be more involved in decisions about their care (45% and over 30% of primary care patients [CQC inpatient survey 2019]. The GP survey 2020 suggests 93% of patients in primary care are as involved as they want to be in their care, but there are still opportunities for more evidence around the best ways to perform and implement SDM.

A landmark ruling was made in 2015 by the UK Supreme Court following the Montgomery v Lanarkshire case. A new legal standard set out that adults 'of sound mind' are entitled to make informed decisions when giving or withholding consent to treatment or diagnosis. Consent 'must be obtained before treatment interfering with bodily integrity is undertaken', and it should only be gained when healthcare users have shared a decision informed by what is known about the risks, benefits and consequences of all reasonable NHS treatment options. It is the healthcare professional's duty to 'take reasonable care to ensure that the healthcare user is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.'

The aim of this review is to explore the most effective approaches and activities to support the normalisation of shared decision making (by making it standard or routine practice) at the level of healthcare systems.

PICO table

Table 1: PICO table for Identifying the most effective approaches and activities to normalise shared decision making in the healthcare system

Type of review	Effectiveness review

Population	Healthcare settings
Intervention	Interventions to normalise or embed SDM
Comparators	No intervention No comparator (before and after/ITS)
Outcomes	• engagement in shared decision making by healthcare providers and people who use healthcare services and their families, carers and advocates • wellbeing and quality of life (including physical health, mental health and social wellbeing) • changes in knowledge, intentions, culture, norms, ability and confidence in relation to undertaking shared decision making among healthcare providers and people who use healthcare services and their families, carers and advocates • satisfaction with shared decision making of people who use healthcare services (including perceptions of how satisfied they are from their family members, carers and advocates) • unintended consequences
Study types	• RCT's • SRs of RCTs • Non-randomised controlled studies • Before and after studies • ITS

Methods and process

This evidence review update was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in appendix A

For further details of the methods used see appendix B.

The search strategies used in this review are detailed in appendix C.

Declarations of interest were recorded according to NICE's 2018 conflicts of interest policy.

Clinical evidence

Included studies

A systematic search was carried out to identify randomised controlled trials (RCTs), systematic reviews of RCTs, non-randomised controlled studies, before and after studies and interrupted time series. The original search (up to 4th October 2019) and the reruns search (up to 19th august 2020) found 7,679 references (see appendix C for the literature search strategy).

In total, 26 references were identified for screening at title and abstract level with 22 excluded at this level. Four studies reported results for normalising or embedding SDM in healthcare systems and were included in this review. The studies were all cluster RCTs.

References for included studies can be found in appendix J.

Excluded studies

Details of studies excluded at full text, with reasons for exclusion, is given in appendix I.

Expert testimony

Due to the lack of evidence found in the published literature, the committee agreed to ask experts in the field to contribute to the evidence base to allow the committee to make recommendations in this area. The evidence presented by the experts is in appendix H.

Summary of clinical studies included in the evidence review

Study characteristics are presented in Table 2.

Table 2: Summary of characteristics of included studies

Author	Study type	Country	N	Intervention	Setting
Goossens 2020	Cluster RCT	Belgium	311	We decide optimised	Nursing homes
Koerner 2014	Cluster RCT	Germany	532	Train-the-trainer programme 'Fit for Shared decision making'	In-patient medical rehabilitation clinics
Koerner 2012	Cluster RCT	Germany	542	Train-the-trainer programme 'Fit for Shared decision making'	In-patient medical rehabilitation clinics
O'Leary 2015	Cluster RCT	USA	236	Patient-centred bedside rounds	Nonteaching hospitalist service units in a large urban hospital

See appendix E for full evidence tables.

Koerner 2012 and 2014

Although not clearly described in either paper, an overlap of the population in these studies was considered to be extremely likely due to similarities in the data, for example the number of trainers trained (74 in both), date range, region and medical centre type

- 2012 study looked at 12 rehabilitation clinics in Southwest Germany
  - First survey May – September 2009, second survey July to November 2010
  - 532 staff questionnaires
- 2014 study looked at 11 rehabilitation clinics in Southwest Germany
  - Study period April 2009 to November 2011
  - 662 staff questionnaires and 1419 patient questionnaires

As a result, NICE has made the decision to present only the 2014 data for outcomes that had data in both studies.

Summary grade table

Table 3: Interventions targeting patients compared to usual care

Name	Sample size	Final Effect Estimate	MID +/	Quality	Interpretation of effect
Goossens 2020: OPTION 12 – 3 months	**85**	**MD 28.85 (23.13, 34.58)**	**+/- 4.61**	**Moderate**	**Effect (Favours intervention)**
Goossens 2020: OPTION 12 – 6 months	**62**	**MD 34.13 (27.64, 40.62)**	**+/- 4.66**	**Moderate**	**Effect (Favours intervention)**
Koerner 2014: External participation – Patient SDM-Q-9 – post intervention	463	MD -2.00 (-6.71, 2.71)	+/- 12.6	Low	No meaningful difference
Koerner 2014: External participation – Patient SDM-Q-9 – 6 months	461	MD -0.80 (-5.90, 4.30)	+/- 13.85	Low	No meaningful difference
Koerner 2014: External participation – Staff SDM-Q-9 – post intervention	167	MD 5.60 (-0.52, 11.72)	+/- 11.25	Very Low	Could not differentiate
Koerner 2014: Internal participation – Patient – post intervention	387	MD -3.90 (-6.93, -0.87)	+/- 7.4	Low	No meaningful difference
Koerner 2014: Internal participation – Patient – 6 months	399	MD 1.60 (-1.80, 5.00)	+/- 8.8	Low	No meaningful difference
Koerner 2014: Internal participation – Staff – post intervention	158	MD 0.00 (-5.19, 5.19)	+/-7.9	Low	No meaningful difference
O'Leary 2015: Concordance between experienced and preferred role of decision making	236	MD -8.00 (-30.71, 14.71)	+/- 44.65	Low	No meaningful difference
O'Leary 2015: Patient activation	236	MD 0.69 (-2.82, 4.20)	+/- 6.87*	Very Low	No meaningful difference
O'Leary 2015: Patient satisfaction	236	OR 0.93 (0.61, 1.43)	NA	Very Low	Could not differentiate
O'Leary 2015: Decision control	236	RR 0.93 (0.61, 1.43)	0.8, 1.25	Very Low	Could not differentiate

*MID calculated from ½ SD of control arm, control arm SD back calculated from MD so equal in intervention and control arms

Quality assessment of clinical studies included in the evidence review

Individual RCTs and cluster RCTs were quality assessed using the Cochrane Risk of Bias v.2.0 Tool. Each individual study was classified into one of the following three groups:

- Low risk of bias – The true effect size for the study is likely to be close to the estimated effect size.
- Moderate risk of bias – There is a possibility the true effect size for the study is substantially different to the estimated effect size.
- High risk of bias – It is likely the true effect size for the study is substantially different to the estimated effect size.

Each individual study was also classified into one of three groups for directness, based on whether there were concerns about the population, intervention, comparator and/or outcomes in the study and how directly these variables could address the specified review question. Studies were rated as follows:

- Direct – No important deviations from the protocol in population, intervention, comparator and/or outcomes.
- Partially indirect – Important deviations from the protocol in one of the population, intervention, comparator and/or outcomes.
- Indirect – Important deviations from the protocol in at least two of the following areas: population, intervention, comparator and/or outcomes

See appendix E for appraisal of individual studies.

Recommendations supported by this evidence review

This evidence review supports recommendations 1.1.1 to 1.1.10 and the research recommendation on normalising shared decision making. Other evidence supporting these recommendations can be found in the evidence reviews on interventions to increase SDM at organisational level (review 1.1/1.2).

The committee's discussion of the evidence

Outcomes that matter most

The committee understood that NICE have already agreed, as part of their social value judgements, that shared decision making (SDM) is a vital aspect of healthcare. It focused on finding the most effective way to encourage the use of SDM in healthcare situations. The committee's aim is that this guideline will aid in the implementation of SDM for those who are not sure of the best way to practice it. This section of the guideline seeks to inform people using and providing healthcare services about system level interventions that could help normalise SDM as a process.

The committee agreed that one of the primary outcomes identified in the quantitative evidence (engagement in SDM by healthcare providers and people who use healthcare services) was the most important. The other outcome of "concordance between experienced and preferred role of decision making" did not match the committees understanding of concordance as an SDM outcome (agreement between the healthcare user and healthcare professional, reached after negotiation that respects the beliefs and wishes of the healthcare user in determining whether, when and how their treatment is undertaken). The evidence alone was not sufficient to make recommendations, therefore the committee invited testimony from expert witnesses to assist them in making recommendations.

Quality of the evidence

The committee acknowledged that Goossens 2020 presented the only non-low quality evidence of an objective outcome measuring SDM itself (OPTION), and that this was shown to have an effect favouring SDM, which fit with their experience in practice and was supported by expert witness testimony.

When discussing the study by O'Leary 2015, the committee noted that only 50% of healthcare users in the intervention arm of the study received the intervention, and remarked that this is quite informative of how difficult and complex it can be to implement SDM at a system level, even in a trial setting where the motivation to implement is at its greatest. It also noted that the overall lack of evidence identified for this research question may be another indicator of the difficulties in implementing or embedding SDM processes. The committee noted that these factors highlighted the need for organisational leadership to implement SDM policies from the top down by advocating for SDM, and ensuring it exists and is fostered within the organisation's values and behaviours. The committee agreed it was important to include this in the recommendations.

The committee acknowledged that based on the quantitative evidence in this review, the "train-the-trainer" intervention was not effective. However, there were several concerns around the quality of the study that reported the train-the-trainer evidence because five of twenty-two clinics dropped out during the study and there were low survey return rates. The control group also had twice as many participants as the intervention group. to the committee agreed that this limited the generalisability of the results of this study.

Despite the lack of effectiveness shown in the published evidence for train-the-trainer programmes the committee were convinced by the positive experiences of the expert

witnesses (particularly the Centre for Shared decision making and “Making choices together”, who reported positive progress with these methods in real-world practice) was more in agreement with their own experience and expertise. The committee noted that train-the-trainer programmes were difficult to evaluate in randomised trials and, in their experience, were likely to be the best method for delivering SDM training.

The committee noted that there was a gap in both the evidence and the expert testimony regarding SDM interventions in black and minority ethnic groups, older people and other groups who may face challenges accessing services And agreed to highlight this in the equality impact assessment for this guideline.

Benefits and harms

The committee felt that the structure of the recommendations needed to reflect the “Three pillars” of support for SDM, which are reflected in the review questions. The three pillars in question were “the organisation”, “the healthcare practitioner” and “the person using the service”. The committee noted that when it referred to an ‘organisation’, it was speaking broadly about any healthcare organisation and that as well as hospital, services or practices, it could also include networks of practices or integrated care systems.

The committee commented that a good way to help address institutional continuity would be a process to track shared decisions that had been made, to ensure that a healthcare user’s decision can be followed across different organisations, systems and staff and agreed this was reflected in their recommendation about sharing information across services. This was reinforced by expert testimony from places where SDM had been successfully rolled out. The committee received expert testimony from the SDM leader from a network of Danish hospitals where SDM has been successfully implemented, and from representatives from UK settings that adopted similar models.

Having a key leader in the organisation (with the power to influence policy decisions) willing to support the policy was a common factor across the expert testimony in ensuring SDM support,

On the basis of this testimony, alongside their own experience, the committee agreed that giving a senior board member responsibility for the roll-out of SDM can help implement SDM at the organisational level, as there will be a specific individual or individuals to oversee this process. This role can include taking responsibility for a range of SDM related activities from ensuring training takes place through to ensuring materials to help healthcare users understand SDM are distributed and used correctly. Alongside this board level leadership, one or more clinicians should be appointed as SDM champions. The committee expressed the importance of ensuring SDM is advocated for from both a board and clinician level, and across the wider healthcare system, as opposed to one specific area of the organisation, stating the organisation should create an environment where every team feels involved in implementing SDM. The committee discussed the preferred seniority of healthcare professionals in terms of which healthcare professionals would be appointed the organisation-wide ‘champion’. In the Danish model the champions were senior clinicians who were well known and respected and who junior staff would follow. However the committee were more convinced by the idea of a balance between having more senior staff who are more likely to be able to enact or lead change and more junior staff who are able to use this to grow into a role as an expert in SDM and bring the culture of the organisation with them. The committee was concerned that limiting this role to senior healthcare professionals limits the ability of practitioners to participate and reinforces a hierarchy that the committee felt was unhelpful. People don’t start as senior but can move into it through this work. As a result, when the committee recommended organisation wide champions, it did not specify any level of seniority.

The recommendation to consider appointing a “patient director” was added based on expert witness testimony that suggested ensuring service users were involved in promoting SDM at the highest levels of the organisation was vital to implementing a culture of SDM. This was also true in regard to appointing “patient champions”. The committee stated recommendations should empower both people using services and healthcare professionals to support SDM. It also agreed that people should have access to available support and training to ensure they have an equal footing to practitioners. The committee was unable to make recommendations directly to people who use services but agreed to direct organisations to promote SDM to the people who used their services, and to provide resources for them.

Based on the expert evidence they received, the committee agreed that SDM should be centered in a suite of “Care for the 21st century” that also includes self-management, advanced care planning and agenda setting (often called person-centered or patient-centered care). The committee noted that there is often a perception that “performing SDM” is an arbitrary target that healthcare professionals have to meet. However, in their experience SDM can be a solution to challenges around delivering healthcare with the greatest value within fixed budgets

When discussing planning for SDM, the committee agreed that it had got a sense from expert evidence and their own experience that a narrative has to be fashioned in the organisation that instills the culture of SDM, as opposed to one-off training sessions. This would be done through developing an organisation-wide implementation initiated within senior leadership teams and cascaded down through middle management to frontline staff. The committee emphasised the importance of finding people who are well respected and to whom others look to set the agenda for how healthcare is practiced in that institution, who are able to consistently enforce the ethos of SDM. These people would be the best individuals to be trained in how to provide the training to other members of staff in the institution, as they are invested and believe in the outcomes of the training.

The committee agreed there are challenges with implementing a train-the-trainer process, as identified by expert witnesses from both North-East England and Wales. Identifying people who have the time, resources and permission to do the cascade training can be difficult. The committee agreed that these challenges can be met by using SDM champions and by ensuring that the departments where SDM is implemented first are the ones where enthusiasm for its practice is high and many of the SDM processes are already in place. . These are places where SDM training has been higher on the agenda and may have been implemented and begun to be practiced. If not, the enthusiasm for training might be higher in these settings. The committee also noted that, based on the committee members experience, the willingness and acceptance for SDM in primary care was greater than in many areas of secondary care. It therefore added detail about selecting departments where SDM was easier to implement to the recommendation about planning for SDM.

The committee stated that monitoring and evaluation of SDM processes was also key to implementation succeeding and that the evidence from experts where SDM had been implemented successfully clearly demonstrated this. This could involve methods such as patient and clinician surveys and observation of staff. The committee expressed their concern that “measuring” consultations in the sense of a single measurement (such as OPTION or COLLABORATE) would not capture the sense of whether SDM was truly being implemented, in terms of occurring from preparation before consultations, to a series of consultations, with often complex and revisited clinical decisions. It pointed to the “Hello my name is” campaign that began in cancer care and was expanded to other settings as an example that would be hard to quantify the effect of despite reported success. It suggested that ‘assessing’ consultations through observation would be more useful but acknowledged this would be costly due to time commitment of either video or in person observation. As a result, the committee made a recommendation to monitor and evaluate SDM but did not specify a method for doing this.

The committee highlighted that, in their experience, there should be more opportunity to assess healthcare staff's readiness to engage in SDM processes when they are being interviewed for employment, and if this is not possible to seek to encourage these behaviours once healthcare practitioners are in post and the SDM implementation plan recommended in this guideline is in use.

The committee noted that there were implementation starter kits available for organisations to build their own processes upon, such as NHS England's implementation assessment checklist.

The committee agreed with evidence from experts that it was key to have SDM advisory boards or steering groups with patient leads. These could be recruited from a general patient and relatives board. The committee stated these people should be provided classes or patient leadership programs to inform them on SDM matters and give them the skills to participate, meaning they are not just participating in SDM in appointments but also reviewing what happens in hospital and able to see patient experience measures. The committee was clear that patient involvement at both the leadership level as well as in everyday healthcare settings is vital to the successful roll-out of SDM.

The committee noted that it can be difficult to implement SDM due to lack of resources in primary care networks and some other settings, but reflect that in places where senior leadership pressure exists, SDM is being implemented, which further highlights the importance of this desire for SDM implementation starting at the top level, and not just with clinicians. The committee noted that in the hospital in Denmark where one expert witness works they've put 3,000 people through SDM training from all levels of the hospital staff, meaning that when healthcare users ask anybody in the organisation questions the staff can respond in a patient-centered manner. The committee state that while having enough financial resource is important, it is only one aspect, and passionate leadership is also required.

The committee used system-level themes from the qualitative chapter of this guideline (chapter 1.2) to inform its recommendations concerning 'space for SDM', 'Continuity of, and access to, care', 'practitioner development', 'clinicians attitude and skills', 'patient empowerment', 'trust', and 'family, carer and other healthcare advocate engagement'.

The committee noted that in their experience some healthcare users are not informed of the idea of a shared agenda. Clinicians then do not realise that they and the healthcare user are not on the same page. The committee noted a person can be more focused on being amiable during a consultation and as a result be unwilling to engage in decision-making conversations, and that this leads to an unequal conversation that must be rebalanced. A shared understanding between the practitioner and healthcare user that SDM processes are part of modern healthcare and should be done in every meeting is key to implementation. The committee noted a key factor that influences the success of this: welcoming new healthcare users and introducing SDM as a concept when they visit, empowering healthcare users from the very beginning. The committee therefore made a recommendation that organisations should advertise and promote their approach to SDM.

The committee commented on how difficult it can be to change practitioner's behaviour. Most clinicians work in quite routine ways. It was the committee's experience that practitioners develop a certain style early in their career that requires conscious change and willingness to potentially make mistakes as new skills and methods are learned.

The committee acknowledge that many places are already practicing some form of SDM, and believe training should be designed to build on where each practice is and what aspects they are already doing well

Appendices

Appendix A – Review protocols

Review protocol for assessing the most effective approaches and activities to normalise shared decision making in the healthcare system.

ID	Field	Content
0.	PROSPERO registration number	153085
1.	Review title	Identifying the most effective approaches and activities to normalise shared decision making in the healthcare system.
2.	Review question	What are the most effective approaches and activities to normalise shared decision making in the healthcare system?
3.	Objective	To identify the most effective approaches and activities to normalise shared decision making in the healthcare system
4.	Searches	The following databases will be searched: • Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE

		Searches will be restricted by: • English language • 1990 onwards The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion. The full search strategies for MEDLINE database will be published in the final review.
5.	Condition or domain being studied	Shared decision making is a collaborative process through which a healthcare professional supports a person to reach a decision about their care, now or in the future (for example, through advance care planning).
6.	Population	Healthcare settings
7.	Intervention/Exposure/Test	• Interventions to normalise or embed shared decision making
8.	Comparator/Reference standard/Confounding factors	• No intervention • No comparator (before and after)

		• Other included SDM intervention
9.	Types of study to be included	• RCTs • Systematic reviews of RCTs • Comparative cohort studies • Before and after studies • Interrupted time series

10.	Other exclusion criteria	• Non-English language papers
		• Theses, dissertations and conference abstracts
		• Editorials, opinion pieces and letters
		• Surveys
		• Non-OECD countries (OECD countries are
		  ○ Australia
		  ○ Austria
		  ○ Belgium
		  ○ Canada
		  ○ Chile
		  ○ Czech Republic
		  ○ Denmark
		  ○ Estonia
		  ○ Finland
		  ○ France
		  ○ Germany
		  ○ Greece
		  ○ Hungary
		  ○ Iceland
		  ○ Ireland

		○ Israël ○ Italy ○ Japan ○ Korea ○ Latvia ○ Lithuania ○ Luxembourg ○ Mexico ○ Netherlands ○ New Zealand ○ Norway ○ Poland ○ Portugal ○ Slovak Republic ○ Slovenia ○ Spain ○ Sweden ○ Switzerland ○ Turkey ○ United Kingdom ○ United States) • Papers prior to 1990
11.	Context	This review is for part of a new NICE guideline for shared decision making.

12.	Primary outcomes (critical outcomes)	Over the follow up time reported in included studies: • Attitudes to SDM • Implementation of SDM • engagement in shared decision making by healthcare providers and people who use healthcare services and their families, carers and advocates • wellbeing and quality of life (including physical health, mental health and social wellbeing) • unintended consequences (for example, changes in waiting lists, changes in resource use) • The summaries of qualitative findings from RQ1.2 are likely to be also relevant to these questions and the SoQF table will be provided to the committee alongside the evidence review. Links will be made where possible to illuminate the effectiveness findings with existing qualitative evidence.
13.	Secondary outcomes (important outcomes)	Over the follow up time reported in included studies: • changes in knowledge, intentions, culture, norms, ability and confidence in relation to undertaking shared decision making among healthcare providers and people who use healthcare services and their families, carers and advocates • satisfaction with shared decision making of people who use healthcare services (including perceptions of how satisfied they are from their family members, carers and advocates) The summaries of qualitative findings from RQ1.2 are likely to be also relevant to these questions and the SoQF table will be provided to the committee alongside the evidence review. Links will be made where possible to illuminate the effectiveness findings with qualitative evidence.

14.	Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. Data will be extracted from the included studies for assessment of study quality and evidence synthesis. Extracted information will include: study setting; study population and participant demographics and baseline characteristics; details of the intervention and control conditions; study methodology; recruitment and study completion rates; outcomes and times of measurement and information for assessment of the risk of bias. Study investigators may be contacted for missing data where time and resources allow.
15.	Risk of bias (quality) assessment	Risk of bias for RCTs will be assessed using the Cochrane RoB (2.0) checklist as described in Developing NICE guidelines: the manual. For systematic reviews the ROBIS tool will be used. For ITS and before and after studies, the EPOC tool will be used.
16.	Strategy for data synthesis	Meta-analyses of interventional data will be conducted with reference to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al. 2011). Fixed- and random-effects models (der Simonian and Laird) will be fitted for all syntheses, with the presented analysis dependent on the degree of heterogeneity in the assembled evidence. Fixed-effects models will be the preferred choice to report, but in situations where the assumption of a shared mean for fixed-effects model is clearly not met, even after appropriate pre-specified subgroup analyses is conducted, random-

		effects results are presented. Fixed-effects models are deemed to be inappropriate if one or both of the following conditions was met: • Significant between study heterogeneity in methodology, population, intervention or comparator was identified by the reviewer in advance of data analysis. • The presence of significant statistical heterogeneity in the meta-analysis, defined as I2≥50%. Meta-analyses will be performed in Cochrane Review Manager V5.3 Confidence in each outcome will be assessed using GRADE or modified GRADE and reported in the review.
17.	Analysis of sub-groups	If there is heterogeneity in the meta-analysis, and where data allow disambiguation, subgroup analysis will explored to explain the heterogeneity. Possible sub-groups are: • Age band • Gender • Healthcare setting • Healthcare practitioner
18.	Type and method of review	☒ Intervention ☐ Diagnostic ☐ Prognostic

		☐ Qualitative ☐ Epidemiologic ☐ Service Delivery ☐ Other (please specify)		
19.	Language	English		
20.	Country	England		
21.	Anticipated or actual start date	1st October 2019		
22.	Anticipated completion date	[Give the date by which the guideline is expected to be published. This field may be edited at any time. All edits will appear in the record audit trail. A brief explanation of the reason for changes should be given in the Revision Notes facility.]		
23.	Stage of review at time of this submission	**Review stage**	**Started**	**Completed**
		Preliminary searches	☐	☐

		Piloting of the study selection process	☐	☐
		Formal screening of search results against eligibility criteria	☐	☐
		Data extraction	☐	☐
		Risk of bias (quality) assessment	☐	☐
		Data analysis	☐	☐
24.	Named contact	**5a. Named contact** Guidelines Updates Team **5b Named contact e-mail** SDMguideline@nice.org.uk **5e Organisational affiliation of the review**		

		National Institute for Health and Care Excellence (NICE)
25.	Review team members	From the Guideline Updates Team: • Mr. Chris Carmona • Mr. Joseph Crutwell • Ms. Amy Finnegan • Mr. Gabriel Rogers
26.	Funding sources/sponsor	This systematic review is being completed by the Guideline Updates Team, which is part of NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/

29.	Other registration details	None.
30.	Reference/URL for published protocol	None.
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
32.	Keywords	Shared decision making, patient engagement, patient activation
33.	Details of existing review of same topic by same authors	None
34.	Current review status	☒ Ongoing ☐ Completed but not published ☐ Completed and published

		☐ Completed, published and being updated ☐ Discontinued
35..	Additional information	None.
36.	Details of final publication	www.nice.org.uk

Appendix B- Methods

Methods for combining intervention evidence

No pooling of data was possible for this review.

Minimal clinically important differences (MIDs)

No MIDs were identified for this review, and thus the committee agreed to use the default MIDs as outlined below.

For continuous outcomes expressed as a mean difference where no other MID was available, an MID of 0.5 of the median standard deviations of the comparison group arms was used (Norman et al. 2003). For continuous outcomes expressed as a standardised mean difference where no other MID was available, an MID of 0.5 was used. For relative risks where no other MID was available, a default MID interval for dichotomous outcomes of 0.8 to 1.25 was used.

When decisions were made in situations where MIDs were not available, 'the committee's discussion of the evidence' section of that review makes explicit the committee's view of the expected clinical importance and relevance of the findings. In particular, this includes consideration of whether the whole effect of a treatment (which may be felt across multiple independent outcome domains) would be likely to be clinically meaningful, rather than simply whether each individual sub outcome might be meaningful in isolation.

GRADE for pairwise meta-analyses of interventional evidence

GRADE was used to assess the quality of evidence for the selected outcomes as specified in 'Developing NICE guidelines: the manual (2014)'. Data from all randomised controlled trials was initially rated as high quality and data from observations studies were originally rated as low quality. The quality of the evidence for each outcome was downgraded or not from this initial point, based on the criteria given in **Table 4**.

Table 4: Rationale for downgrading quality of evidence for intervention studies

GRADE criteria	Reasons for downgrading quality
Risk of bias	Not serious: If less than 33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias, the overall outcome was not downgraded. Serious: If greater than 33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias, the outcome was downgraded one level. Very serious: If greater than 33.3% of the weight in a meta-analysis came from studies at high risk of bias, the outcome was downgraded two levels. Outcomes meeting the criteria for downgrading above were not downgraded if there was evidence the effect size was not meaningfully different between studies at high and low risk of bias.
Indirectness	Not serious: If less than 33.3% of the weight in a meta-analysis came from partially indirect or indirect studies, the overall outcome was not downgraded.

GRADE criteria	Reasons for downgrading quality
	Serious: If greater than 33.3% of the weight in a meta-analysis came from partially indirect or indirect studies, the outcome was downgraded one level. Very serious: If greater than 33.3% of the weight in a meta-analysis came from indirect studies, the outcome was downgraded two levels. Outcomes meeting the criteria for downgrading above were not downgraded if there was evidence the effect size was not meaningfully different between direct and indirect studies.
Inconsistency	Concerns about inconsistency of effects across studies, occurring when there is unexplained variability in the treatment effect demonstrated across studies (heterogeneity), after appropriate pre-specified subgroup analyses have been conducted. This was assessed using the I^2 statistic. N/A: Inconsistency was marked as not applicable if data on the outcome was only available from one study. Not serious: If the I^2 was less than 33.3%, the outcome was not downgraded. Serious: If the I^2 was between 33.3% and 66.7%, the outcome was downgraded one level. Very serious: If the I^2 was greater than 66.7%, the outcome was downgraded two levels. Outcomes meeting the criteria for downgrading above were not downgraded if there was evidence the effect size was not meaningfully different between studies with the smallest and largest effect sizes.
Imprecision	If an MID other than the line of no effect was defined for the outcome, the outcome was downgraded once if the 95% confidence interval for the effect size crossed one line of the MID, and twice if it crosses both lines of the MID. If the line of no effect was defined as an MID for the outcome, it was downgraded once if the 95% confidence interval for the effect size crossed the line of no effect (i.e. the outcome was not statistically significant), and twice if the sample size of the study was sufficiently small that it is not plausible any realistic effect size could have been detected. Outcomes meeting the criteria for downgrading above were not downgraded if the confidence interval was sufficiently narrow that the upper and lower bounds would correspond to clinically equivalent scenarios.

The quality of evidence for each outcome was upgraded if any of the following three conditions were met:

- Data from non-randomised studies showing an effect size sufficiently large that it cannot be explained by confounding alone.
- Data showing a dose-response gradient.
- Data where all plausible residual confounding is likely to increase our confidence in the effect estimate.

Publication bias

Publication bias was assessed in two ways. First, if evidence of conducted but unpublished studies was identified during the review (e.g. conference abstracts, trial protocols or trial records without accompanying published data), available information on these unpublished studies was reported as part of the review. Secondly, where 10 or more studies were included as part of a single meta-analysis, a funnel plot was produced to graphically assess the potential for publication bias.

Evidence statements

Evidence statements for pairwise intervention data are classified in to one of four categories:

- Situations where the data are only consistent, at a 95% confidence level, with an effect in one direction (i.e. one that is 'statistically significant'), and the magnitude of that effect is most likely to meet or exceed the MID (i.e. the point estimate is not in the zone of equivalence). In such cases, we state that the evidence showed that there is an effect.
- Situations where the data are only consistent, at a 95% confidence level, with an effect in one direction (i.e. one that is 'statistically significant'), but the magnitude of that effect is most likely to be less than the MID (i.e. the point estimate is in the zone of equivalence). In such cases, we state that the evidence could not demonstrate a meaningful difference.
- Situations where the confidence limits are smaller than the MIDs in both directions. In such cases, we state that the evidence demonstrates that there is no meaningful difference.
- In all other cases, we state that the evidence could not differentiate between the comparators.

For outcomes without a defined MID or where the MID is set as the line of no effect (for example, in the case of mortality), evidence statements are divided into 2 groups as follows:

- We state that the evidence showed that there is an effect if the 95% CI does not cross the line of no effect.
- The evidence could not differentiate between comparators if the 95% CI crosses the line of no effect.

1 Appendix C – Literature search strategies

2

3 **Search strategies**

4

Database: Medline
Strategy used: 1 decision making/ (90736) 2 decision support systems, clinical/ (7418) 3 decision support techniques/ (19317) 4 ("shared decision making" or SDM).ti,ab. (6060) 5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).ti. (28945) 6 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).ab. /freq=2 (36459) 7 or/1-6 (137565) 8 (normal* or embed* or imbed* or integrat* or implement* or universal* or generalis* or generaliz* or standardise* or standardize* or incoporat* or ingrain* or install* or assimilat*).tw. (2818813) 9 ((routine* or standard or common) adj1 (practice* or protocol*)).tw. (24022) 10 8 or 9 (2837141) 11 7 and 10 (24651) 12 animals/ not humans/ (4589000) 13 11 not 12 (23917) 14 limit 13 to english language (22970) 15 limit 14 to ed=19900101-20191231 (22358) 16 limit 15 to (letter or historical article or comment or editorial or news or case reports) (604) 17 15 not 16 (21754) 18 randomized controlled trial.pt. (490385) 19 randomi?ed.mp. (758693) 20 placebo.mp. (188081) 21 or/18-20 (809138)

22 17 and 21 (1560)

23 (MEDLINE or pubmed).tw. (146555)

24 systematic review.tw. (105429)

25 systematic review.pt. (112720)

26 meta-analysis.pt. (105138)

27 intervention$.ti. (115362)

28 or/23-27 (345973)

29 17 and 28 (1530)

30 Controlled Before-After Studies/ (428)

31 (Control* adj Before adj After adj Stud*).tw. (194)

32 Interrupted Time Series Analysis/ (669)

33 "Interrupted Time Series Analys*".tw. (844)

34 Comparative Study.pt. (1841011)

35 (comparat* adj stud*).tw. (87353)

36 (follow up adj (study or studies)).tw. (43765)

37 or/30-36 (1917118)

38 17 and 37 (1393)

39 22 or 29 or 38 (3885)

40 Developing Countries/ (72963)

41 afghanistan/ or exp africa/ or albania/ or andorra/ or antarctic regions/ or arctic regions/ or argentina/ or exp asia, central/ or exp asia, northern/ or exp asia, southeastern/ or exp atlantic islands/ or bahrain/ or balkan peninsula/ or bangladesh/ or Bhutan/ or bolivia/ or borneo/ or "bosnia and Herzegovina"/ or brazil/ or bulgaria/ or exp caribbean region/ or exp central america/ or exp china/ or colombia/ or "Commonwealth of Independent States"/ or croatia/ or "Democratic People's Republic of Korea"/ or ecuador/ or french guiana/ or gibraltar/ or greenland/ or guyana/ or Holy Roman Empire/ or exp india/ or exp Indian Ocean Islands/ or indonesia/ or iran/ or iraq/ or jordan/ or kosovo/ or kuwait/ or lebanon/ or liechtenstein/ or macau/ or "macedonia (republic)"/ or exp melanesia/ or exp micronesia/ or moldova/ or monaco/ or mongolia/ or montenegro/ or Netherlands Antilles/ or New Guinea/ or nepal/ or oman/ or pakistan/ or paraguay/ or peru/ or philippines/ or exp polynesia/ or qatar/ or "republic of Belarus"/ or romania/ or exp russia/ or san marino/ or saudi arabia/ or serbia/ or sri lanka/ or suriname/ or syria/ or taiwan/ or exp transcaucasia/ or ukraine/ or uruguay/ or united arab emirates/ or exp ussr/ or venezuela/ or yemen/ (1085219)

42 40 or 41 (1118893)

43 Developed Countries/ (20263)

44 australasia/ or exp australia/ or austria/ or exp Baltic States/ or belgium/ or exp canada/ or chile/ or czech republic/ or europe/ or exp france/ or exp germany/ or greece/ or hungary/ or ireland/ or Israel/ or exp italy/ or exp japan/ or korea/ or luxembourg/ or mexico/ or netherlands/ or

	new zealand/ or north america/ or poland/ or portugal/ or exp "republic of korea"/ or exp "Scandinavian and Nordic Countries"/ or slovakia/ or slovenia/ or spain/ or switzerland/ or turkey/ or exp united kingdom/ or exp united states/ or vatican city/ (3042429)
45	43 or 44 (3048312)
46	42 not 45 (1012094)
47	39 not 46 (3721)
48	Economics/ (27079)
49	exp "Costs and Cost Analysis"/ (228631)
50	Economics, Dental/ (1907)
51	exp Economics, Hospital/ (23901)
52	exp Economics, Medical/ (14124)
53	Economics, Nursing/ (3994)
54	Economics, Pharmaceutical/ (2890)
55	Budgets/ (11175)
56	exp Models, Economic/ (14407)
57	Markov Chains/ (13682)
58	Monte Carlo Method/ (27213)
59	Decision Trees/ (10701)
60	econom$.tw. (224676)
61	cba.tw. (9616)
62	cea.tw. (19868)
63	cua.tw. (951)
64	markov$.tw. (16995)
65	(monte adj carlo).tw. (28623)
66	(decision adj3 (tree$ or analys$)).tw. (12385)
67	(cost or costs or costing$ or costly or costed).tw. (435210)
68	(price$ or pricing$).tw. (31780)
69	budget$.tw. (22715)
70	expenditure$.tw. (46932)
71	(value adj3 (money or monetary)).tw. (1973)
72	(pharmacoeconomic$ or (pharmaco adj economic$)).tw. (3392)
73	or/48-72 (881578)

74 "Quality of Life"/ (182018)

75 quality of life.tw. (214255)

76 "Value of Life"/ (5660)

77 Quality-Adjusted Life Years/ (11432)

78 quality adjusted life.tw. (10007)

79 (qaly$ or qald$ or qale$ or qtime$).tw. (8223)

80 disability adjusted life.tw. (2446)

81 daly$.tw. (2240)

82 Health Status Indicators/ (23012)

83 (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).tw. (21405)

84 (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).tw. (1277)

85 (sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).tw. (4546)

86 (sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).tw. (28)

87 (sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).tw. (373)

88 (euroqol or euro qol or eq5d or eq 5d).tw. (8021)

89 (qol or hql or hqol or hrqol).tw. (40799)

90 (hye or hyes).tw. (58)

91 health$ year$ equivalent$.tw. (38)

92 utilit$.tw. (161449)

93 (hui or hui1 or hui2 or hui3).tw. (1227)

94 disutili$.tw. (359)

95 rosser.tw. (89)

96 quality of wellbeing.tw. (12)

97 quality of well-being.tw. (368)

98 qwb.tw. (186)

99 willingness to pay.tw. (4059)

100 standard gamble$.tw. (769)

101 time trade off.tw. (995)

102 time tradeoff.tw. (224)

103 tto.tw. (862)

104 or/74-103 (463808)

105 73 or 104 (1281155)

106 47 not 105 (2560)

1

Database: Medline in process

Strategy used:

1 decision making/ (0)

2 decision support systems, clinical/ (0)

3 decision support techniques/ (0)

4 ("shared decision making" or SDM).ti,ab. (1599)

5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).ti. (4728)

6 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).ab. /freq=2 (7005)

7 or/1-6 (9837)

8 (normal* or embed* or imbed* or integrat* or implement* or universal* or generalis* or generaliz* or standardise* or standardize* or incoporat* or ingrain* or install* or assimilat*).tw. (403344)

9 ((routine* or standard or common) adj1 (practice* or protocol*)).tw. (4022)

10 8 or 9 (406355)

11 7 and 10 (2736)

12 animals/ not humans/ (0)

13 11 not 12 (2736)

14 limit 13 to english language (2715)

15 limit 14 to dt=19900101-20191231 (2714)

16 limit 15 to (letter or historical article or comment or editorial or news or case reports) (34)

17 15 not 16 (2680)

18 randomized controlled trial.pt. (276)

19 randomi?ed.mp. (67371)

20 placebo.mp. (16446)

21 or/18-20 (73237)

22 17 and 21 (185)

23 (MEDLINE or pubmed).tw. (31044)

24 systematic review.tw. (25612)

25 systematic review.pt. (412)

26 meta-analysis.pt. (38)

27 intervention$.ti. (18947)

28 or/23-27 (60052)

29 17 and 28 (232)

30 Controlled Before-After Studies/ (0)

31 (Control* adj Before adj After adj Stud*).tw. (20)

32 Interrupted Time Series Analysis/ (0)

33 "Interrupted Time Series Analys*".tw. (217)

34 Comparative Study.pt. (45)

35 (comparat* adj stud*).tw. (11418)

36 (follow up adj (study or studies)).tw. (3187)

37 or/30-36 (14870)

38 17 and 37 (10)

39 22 or 29 or 38 (373)

40 Developing Countries/ (0)

41 afghanistan/ or exp africa/ or albania/ or andorra/ or antarctic regions/ or arctic regions/ or argentina/ or exp asia, central/ or exp asia, northern/ or exp asia, southeastern/ or exp atlantic islands/ or bahrain/ or balkan peninsula/ or bangladesh/ or Bhutan/ or bolivia/ or borneo/ or "bosnia and Herzegovina"/ or brazil/ or bulgaria/ or exp caribbean region/ or exp central america/ or exp china/ or colombia/ or "Commonwealth of Independent States"/ or croatia/ or "Democratic People's Republic of Korea"/ or ecuador/ or french guiana/ or gibraltar/ or greenland/ or guyana/ or Holy Roman Empire/ or exp india/ or exp Indian Ocean Islands/ or indonesia/ or iran/ or iraq/ or jordan/ or kosovo/ or kuwait/ or lebanon/ or liechtenstein/ or macau/ or "macedonia (republic)"/ or exp melanesia/ or exp micronesia/ or moldova/ or monaco/ or mongolia/ or montenegro/ or Netherlands Antilles/ or New Guinea/ or nepal/ or oman/ or pakistan/ or paraguay/ or peru/ or philippines/ or exp polynesia/ or qatar/ or "republic of Belarus"/ or romania/ or exp russia/ or san marino/ or saudi arabia/ or serbia/ or sri lanka/ or suriname/ or syria/ or taiwan/ or exp transcaucasia/ or ukraine/ or uruguay/ or united arab emirates/ or exp ussr/ or venezuela/ or yemen/ (0)

42 40 or 41 (0)

43 Developed Countries/ (0)

44 australasia/ or exp australia/ or austria/ or exp Baltic States/ or belgium/ or exp canada/ or chile/ or czech republic/ or europe/ or exp france/ or exp germany/ or greece/ or hungary/ or ireland/ or Israel/ or exp italy/ or exp japan/ or korea/ or luxembourg/ or mexico/ or netherlands/ or new zealand/ or north america/ or poland/ or portugal/ or exp "republic of korea"/ or exp "Scandinavian and Nordic Countries"/ or slovakia/ or slovenia/ or spain/ or switzerland/ or turkey/ or exp united kingdom/ or exp united states/ or vatican city/ (2)

45 43 or 44 (2)

46 42 not 45 (0)

47 39 not 46 (373)

48 Economics/ (0)

49 exp "Costs and Cost Analysis"/ (0)

50 Economics, Dental/ (0)

51 exp Economics, Hospital/ (0)

52 exp Economics, Medical/ (0)

53 Economics, Nursing/ (0)

54 Economics, Pharmaceutical/ (0)

55 Budgets/ (0)

56 exp Models, Economic/ (0)

57 Markov Chains/ (0)

58 Monte Carlo Method/ (0)

59 Decision Trees/ (0)

60 econom$.tw. (40365)

61 cba.tw. (389)

62 cea.tw. (1707)

63 cua.tw. (186)

64 markov$.tw. (5226)

65 (monte adj carlo).tw. (16058)

66 (decision adj3 (tree$ or analys$)).tw. (2120)

67 (cost or costs or costing$ or costly or costed).tw. (87198)

68 (price$ or pricing$).tw. (5343)

69 budget$.tw. (4615)

70 expenditure$.tw. (6001)

71 (value adj3 (money or monetary)).tw. (341)

72 (pharmacoeconomic$ or (pharmaco adj economic$)).tw. (512)

73 or/48-72 (151459)

74 "Quality of Life"/ (0)

75 quality of life.tw. (35306)

76 "Value of Life"/ (0)

77 Quality-Adjusted Life Years/ (0)

78 quality adjusted life.tw. (1516)

79 (qaly$ or qald$ or qale$ or qtime$).tw. (1286)

80 disability adjusted life.tw. (454)

81 daly$.tw. (418)

82 Health Status Indicators/ (0)

83 (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).tw. (2490)

84 (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).tw. (703)

85 (sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).tw. (692)

86 (sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).tw. (4)

87 (sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).tw. (17)

88 (euroqol or euro qol or eq5d or eq 5d).tw. (1544)

89 (qol or hql or hqol or hrqol).tw. (6715)

90 (hye or hyes).tw. (7)

91 health$ year$ equivalent$.tw. (2)

92 utilit$.tw. (28315)

93 (hui or hui1 or hui2 or hui3).tw. (164)

94 disutili$.tw. (65)

95 rosser.tw. (6)

96 quality of wellbeing.tw. (7)

97 quality of well-being.tw. (28)

98 qwb.tw. (9)

99 willingness to pay.tw. (840)

100 standard gamble$.tw. (53)

101 time trade off.tw. (115)

102 time tradeoff.tw. (16)

103 tto.tw. (113)

104 or/74-103 (65843)

105 73 or 104 (208681)

106 47 not 105 (276)

1

2

Database: MEP

Strategy used:

1 decision making/ (0)

2 decision support systems, clinical/ (0)

3 decision support techniques/ (0)

4 ("shared decision making" or SDM).ti,ab. (380)

5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).ti. (933)

6 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).ab. /freq=2 (1569)

7 or/1-6 (2036)

8 (normal* or embed* or imbed* or integrat* or implement* or universal* or generalis* or generaliz* or standardise* or standardize* or incoporat* or ingrain* or install* or assimilat*).tw. (55087)

9 ((routine* or standard or common) adj1 (practice* or protocol*)).tw. (640)

10 8 or 9 (55536)

11 7 and 10 (530)

12 animals/ not humans/ (0)

13 11 not 12 (530)

14 limit 13 to english language (526)

15 limit 14 to dt=19900101-20191231 (526)

16 limit 15 to (letter or historical article or comment or editorial or news or case reports) (0)

17 15 not 16 (526)

18 randomized controlled trial.pt. (1)

19 randomi?ed.mp. (12640)

20 placebo.mp. (3019)

21 or/18-20 (13711)

22 17 and 21 (54)

23 (MEDLINE or pubmed).tw. (6450)

24 systematic review.tw. (6123)

25 systematic review.pt. (25)

26 meta-analysis.pt. (14)

27 intervention$.ti. (3787)

28 or/23-27 (12701)

29 17 and 28 (63)

30 Controlled Before-After Studies/ (0)

31 (Control* adj Before adj After adj Stud*).tw. (10)

32 Interrupted Time Series Analysis/ (0)

33 "Interrupted Time Series Analys*".tw. (51)

34 Comparative Study.pt. (0)

35 (comparat* adj stud*).tw. (1270)

36 (follow up adj (study or studies)).tw. (617)

37 or/30-36 (1947)

38 17 and 37 (4)

39 22 or 29 or 38 (105)

40 Developing Countries/ (0)

41 afghanistan/ or exp africa/ or albania/ or andorra/ or antarctic regions/ or arctic regions/ or argentina/ or exp asia, central/ or exp asia, northern/ or exp asia, southeastern/ or exp atlantic islands/ or bahrain/ or balkan peninsula/ or bangladesh/ or Bhutan/ or bolivia/ or borneo/ or "bosnia and Herzegovina"/ or brazil/ or bulgaria/ or exp caribbean region/ or exp central america/ or exp china/ or colombia/ or "Commonwealth of Independent States"/ or croatia/ or "Democratic People's Republic of Korea"/ or ecuador/ or french guiana/ or gibraltar/ or greenland/ or guyana/ or Holy Roman Empire/ or exp india/ or exp Indian Ocean Islands/ or indonesia/ or iran/ or iraq/ or jordan/ or kosovo/ or kuwait/ or lebanon/ or liechtenstein/ or macau/ or "macedonia (republic)"/ or exp

melanesia/ or exp micronesia/ or moldova/ or monaco/ or mongolia/ or montenegro/ or Netherlands Antilles/ or New Guinea/ or nepal/ or oman/ or pakistan/ or paraguay/ or peru/ or philippines/ or exp polynesia/ or qatar/ or "republic of Belarus"/ or romania/ or exp russia/ or san marino/ or saudi arabia/ or serbia/ or sri lanka/ or suriname/ or syria/ or taiwan/ or exp transcaucasia/ or ukraine/ or uruguay/ or united arab emirates/ or exp ussr/ or venezuela/ or yemen/ (0)

42 40 or 41 (0)

43 Developed Countries/ (0)

44 australasia/ or exp australia/ or austria/ or exp Baltic States/ or belgium/ or exp canada/ or chile/ or czech republic/ or europe/ or exp france/ or exp germany/ or greece/ or hungary/ or ireland/ or Israel/ or exp italy/ or exp japan/ or korea/ or luxembourg/ or mexico/ or netherlands/ or new zealand/ or north america/ or poland/ or portugal/ or exp "republic of korea"/ or exp "Scandinavian and Nordic Countries"/ or slovakia/ or slovenia/ or spain/ or switzerland/ or turkey/ or exp united kingdom/ or exp united states/ or vatican city/ (0)

45 43 or 44 (0)

46 42 not 45 (0)

47 39 not 46 (105)

48 Economics/ (0)

49 exp "Costs and Cost Analysis"/ (0)

50 Economics, Dental/ (0)

51 exp Economics, Hospital/ (0)

52 exp Economics, Medical/ (0)

53 Economics, Nursing/ (0)

54 Economics, Pharmaceutical/ (0)

55 Budgets/ (0)

56 exp Models, Economic/ (0)

57 Markov Chains/ (0)

58 Monte Carlo Method/ (0)

59 Decision Trees/ (0)

60 econom$.tw. (6041)

61 cba.tw. (60)

62 cea.tw. (310)

63 cua.tw. (23)

64 markov$.tw. (693)

65 (monte adj carlo).tw. (1192)

66 (decision adj3 (tree$ or analys$)).tw. (395)

67 (cost or costs or costing$ or costly or costed).tw. (12301)

68 (price$ or pricing$).tw. (879)

69 budget$.tw. (548)

70 expenditure$.tw. (1161)

71 (value adj3 (money or monetary)).tw. (63)

72 (pharmacoeconomic$ or (pharmaco adj economic$)).tw. (51)

73 or/48-72 (20270)

74 "Quality of Life"/ (0)

75 quality of life.tw. (6611)

76 "Value of Life"/ (0)

77 Quality-Adjusted Life Years/ (0)

78 quality adjusted life.tw. (369)

79 (qaly$ or qald$ or qale$ or qtime$).tw. (320)

80 disability adjusted life.tw. (91)

81 daly$.tw. (79)

82 Health Status Indicators/ (0)

83 (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).tw. (443)

84 (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).tw. (50)

85 (sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).tw. (147)

86 (sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).tw. (1)

87 (sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).tw. (5)

88 (euroqol or euro qol or eq5d or eq 5d).tw. (348)

89 (qol or hql or hqol or hrqol).tw. (1298)

90 (hye or hyes).tw. (2)

91 health$ year$ equivalent$.tw. (0)

92 utilit$.tw. (4758)

93 (hui or hui1 or hui2 or hui3).tw. (26)

94 disutili$.tw. (16)

95 rosser.tw. (0)

96 quality of wellbeing.tw. (1)

97 quality of well-being.tw. (6)

98 qwb.tw. (4)

99 willingness to pay.tw. (156)

100 standard gamble$.tw. (9)

101 time trade off.tw. (20)

102 time tradeoff.tw. (6)

103 tto.tw. (19)

104 or/74-103 (11650)

105 73 or 104 (30189)

106 47 not 105 (74)

1

2

Database: Embase

Strategy used:

1 shared decision making/ (5356)

2 decision support system/ (21135)

3 clinical decision support system/ (2572)

4 ("shared decision making" or SDM).ti,ab. (11056)

5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).ti. (42317)

6 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).ab. /freq=2 (60078)

7 or/1-6 (100958)

8 (normal* or embed* or imbed* or integrat* or implement* or universal* or generalis* or generaliz* or standardise* or standardize* or incoporat* or ingrain* or install* or assimilat*).tw. (4234394)

9 ((routine* or standard or common) adj1 (practice* or protocol*)).tw. (47218)

10 or/8-9 (4269483)

11	7 and 10 (26868)
12	random:.tw. (1463616)
13	placebo:.mp. (443181)
14	double-blind:.tw. (203543)
15	or/12-14 (1714854)
16	11 and 15 (2578)
17	(MEDLINE or pubmed).tw. (233932)
18	exp systematic review/ or systematic review.tw. (266088)
19	meta-analysis/ (172445)
20	intervention$.ti. (186639)
21	or/17-20 (602308)
22	11 and 21 (2190)
23	Clinical study/ (154799)
24	Case control study/ (146776)
25	Family study/ (26141)
26	Longitudinal study/ (131272)
27	Retrospective study/ (832024)
28	comparative study/ (822357)
29	Prospective study/ (554874)
30	Randomized controlled trials/ (169604)
31	29 not 30 (549068)
32	Epidemiology/ (205263)
33	(Control* adj Before adj After adj Stud*).tw. (256)
34	"Interrupted Time Series Analys*".tw. (1442)
35	comparative study/ (822357)
36	(comparat* adj stud*).tw. (115523)
37	(follow up adj (study or studies)).tw. (61194)
38	or/23-28,31-37 (2762819)
39	11 and 38 (2606)
40	16 or 22 or 39 (6368)
41	nonhuman/ not human/ (4494386)

42	40 not 41 (6308)
43	limit 42 to (conference abstract or conference paper or "conference review") (2013)
44	42 not 43 (4295)
45	limit 44 to english language (4166)
46	limit 45 to dc=19900101-20191231 (4151)
47	exp Health Economics/ (816504)
48	exp "Health Care Cost"/ (282505)
49	exp Pharmacoeconomics/ (196933)
50	Monte Carlo Method/ (37461)
51	Decision Tree/ (11670)
52	econom$.tw. (344332)
53	cba.tw. (12473)
54	cea.tw. (33162)
55	cua.tw. (1406)
56	markov$.tw. (28118)
57	(monte adj carlo).tw. (44772)
58	(decision adj3 (tree$ or analys$)).tw. (21500)
59	(cost or costs or costing$ or costly or costed).tw. (720674)
60	(price$ or pricing$).tw. (53865)
61	budget$.tw. (36463)
62	expenditure$.tw. (71042)
63	(value adj3 (money or monetary)).tw. (3263)
64	(pharmacoeconomic$ or (pharmaco adj economic$)).tw. (8370)
65	or/47-64 (1664436)
66	"Quality of Life"/ (442640)
67	Quality Adjusted Life Year/ (24794)
68	Quality of Life Index/ (2693)
69	Short Form 36/ (27102)
70	Health Status/ (122581)
71	quality of life.tw. (409078)
72	quality adjusted life.tw. (18230)

73 (qaly$ or qald$ or qale$ or qtime$).tw. (18616)

74 disability adjusted life.tw. (3690)

75 daly$.tw. (3656)

76 (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).tw. (39774)

77 (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).tw. (2248)

78 (sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).tw. (8910)

79 (sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).tw. (55)

80 (sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).tw. (438)

81 (euroqol or euro qol or eq5d or eq 5d).tw. (18765)

82 (qol or hql or hqol or hrqol).tw. (90017)

83 (hye or hyes).tw. (127)

84 health$ year$ equivalent$.tw. (41)

85 utilit$.tw. (271106)

86 (hui or hui1 or hui2 or hui3).tw. (2140)

87 disutili$.tw. (861)

88 rosser.tw. (121)

89 quality of wellbeing.tw. (41)

90 quality of well-being.tw. (474)

91 qwb.tw. (239)

92 willingness to pay.tw. (7966)

93 standard gamble$.tw. (1075)

94 time trade off.tw. (1644)

95 time tradeoff.tw. (283)

96 tto.tw. (1580)

97 or/66-96 (930241)

98 65 or 97 (2447056)

99 46 not 98 (2784)

100 elsevier.cr. (25042061)

101 99 and 100 (1818)

102 46 and 100 (2767)

Database: Cochrane CDSR and CENTRAL

Strategy used:

#1 MeSH descriptor: [Decision Making] this term only 2129

#2 MeSH descriptor: [Decision Support Systems, Clinical] this term only 342

#3 MeSH descriptor: [Decision Support Techniques] this term only 767

#4 ("shared decision making" or SDM):ti,ab 1148

#5 (decision* or decide* or deciding* or decisive* or choice* or goal* or judgment* or judgement*) NEAR/1 (share* or sharing* or inform* or making* or make* or support* or behaviour* or behavior* or conflict* or collab* or aid*):ti,ab 13116

#6 {or #1-#5} 14410

#7 (normal* or embed* or imbed* or integrat* or implement* or universal* or generalis* or generaliz* or standardise* or standardize* or incoporat* or ingrain* or install* or assimilat*):ti,ab 209262

#8 ((routine* or standard or common) near/1 (practice* or protocol*)) 6043

#9 #7 or #8 213546

#10 #6 and #9 4263

#11 "clinicaltrials.gov":so 147057

#12 "www.who.int":so 126192

#13 "conference":pt162733

#14 #11 or #12 or #13 435982

#15 #10 NOT #14 with Publication Year from 1990 to 2019, in Trials 2264

#16 #10 NOT #14 with Cochrane Library publication date Between Jan 1990 and Oct 2019, in Cochrane Reviews 167

#17 #16 NOT "conference":pt 167

1

Database: PsycInfo
Strategy used: 1 exp Decision Making/ (115174) 2 exp Decision Support Systems/ (3132) 3 ("shared decision making" or SDM).ti,ab. (2515) 4 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).ti. (25508) 5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).ab. /freq=2 (33336) 6 or/1-5 (127817) 7 (normal* or embed* or imbed* or integrat* or implement* or universal* or generalis* or generaliz* or standardise* or standardize* or incoporat* or ingrain* or install* or assimilat*).tw. (776603) 8 ((routine* or standard or common) adj1 (practice* or protocol*)).tw. (4731) 9 or/7-8 (779939) 10 6 and 9 (23629) 11 animals/ not (animals/ and humans/) (7192) 12 10 not 11 (23600) 13 limit 12 to english language (22605) 14 (199* or 200* or 201*).up. (3708377) 15 13 and 14 (21548) 16 limit 15 to conference proceedings (17) 17 15 not 16 (21531) 18 randomized controlled trial.pt. (0) 19 randomi?ed.mp. (78861) 20 placebo.mp. (39267) 21 or/18-20 (103358) 22 (MEDLINE or pubmed).tw. (20837) 23 systematic review.tw. (24850) 24 systematic review.pt. (0)

25	meta-analysis.pt. (0)
26	intervention$.ti. (67158)
27	or/22-26 (100537)
28	Controlled Before-After Studies/ (0)
29	(Control* adj Before adj After adj Stud*).tw. (17)
30	Interrupted Time Series Analysis/ (0)
31	"Interrupted Time Series Analys*".tw. (270)
32	Comparative Study.pt. (0)
33	(comparat* adj stud*).tw. (14728)
34	(follow up adj (study or studies)).tw. (12676)
35	or/28-34 (27650)
36	21 or 27 or 35 (213759)
37	17 and 36 (1195)

1

2

Database: DARE

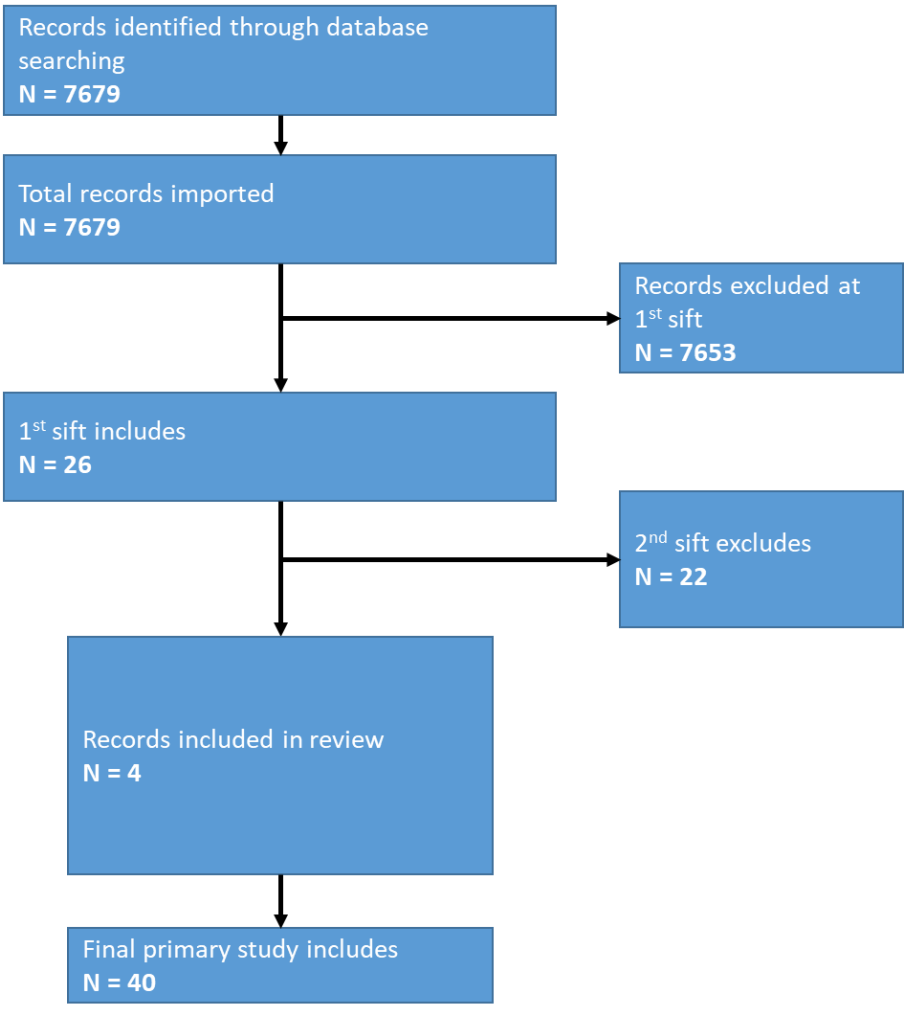
Strategy used:

	Line	Search	Hits
☐	1	MeSH DESCRIPTOR decision making	359
☐	2	MeSH DESCRIPTOR decision support systems, clinical	101
☐	3	MeSH DESCRIPTOR decision support techniques	1352
☐	4	("shared decision making" or SDM)	44
☐	5	(((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)))	3368
☐	6	#1 OR #2 OR #3 OR #4 OR #5	3369
☐	7	((normal* or embed* or imbed* or integrat* or implement* or universal* or generalis* or generaliz* or standardise* or standardize* or incoporat* or ingrain* or install* or assimilat*))	16605
☐	8	(((routine* or standard or common) adj1 (practice* or protocol*)))	1028
☐	9	#7 OR #8	16926
☐	10	#6 AND #9	1603
☐	11	(#10) IN DARE WHERE LPD FROM 01/01/1990 TO 07/10/2019	262
☐	12	(#10) IN DARE FROM 1990 TO 2019	262
☐	13	#11 OR #12	262

1

2

Appendix D – Clinical evidence study selection



1 Appendix E - Clinical evidence tables

Goossens, 2020

Bibliographic Reference	Goossens, B.; Sevenants, A.; Declercq, A.; Van Audenhove, C.; Improving shared decision-making in advance care planning: Implementation of a cluster randomized staff intervention in dementia care; Patient Education and Counseling; 2020; vol. 103 (no. 4); 839-847

2

3 **Study details**

Study type	Cluster randomised controlled trial Cluster RCT
Study location	Belgium
Study setting	Nursing homes
Study dates	NR
Duration of follow-up	6 months
Sources of funding	This study is part of the Flemish Initiative for Networks for Dementia Research (VIND), a collaboration between KU Leuven and the University of Antwerp. The Flemish government agency for Innovation by Science and Technology supported the study with a grant [SBO IWT nr. 135043]. The King Baudouin Foundation supported the information campaign of the study [Malou Malou Fund np. ZKD0097]. The IWT and the King Baudouin Foundation exerted no influence on the design, execution, analysis and interpretation of the data.
Inclusion criteria	Criteria 1 The ward unit must be focused on persons with dementia, or at least have a mixed population.

	Criteria 2 A minimum of 4 to a maximum of 6 ward staff members can participate. Criteria 3 At least one of these members must stem from either middle or executive management. This person must be directly involved with the participating ward (e.g. work there or coordinate tasks) and delegate all information and assessment requirements to the other members. These other participants can be either care or non-care professionals as long as they interact with the residents and their families on a regular basis. Enlisting wards enroll in both the training as well as the research module. The nursing home has not participated in 'We DECide', and will not participate in other ACP research for the duration of the training.
Exclusion criteria	Criteria 1 NR
Sample size	311
Loss to follow-up	Int: 6 - High turnover of participants Ctrl: 7 - High turnover of participants
% Female	Int: 87,5% Ctrl: 87.4%
Mean age (SD)	Staff: Ctrl: 40.12 (11.68) Int: 42.06 (10.60)
Outcome measures	Outcome 1 OBOM SDM: IFC-SDM OPTION

	OBOM SDM: OPTION-12

Study arms

We DECiDE optimized (N = 34) Provides three steps to SDM: creating insight into the availability of multiple options (Choice Talk), providing information on these options (Option Talk) and discussing preferences while working towards a decision (Decision Talk). The intervention consisted of 2 workshops of 4 hours each, in which 3 modules were introduced, and was followed by implementation support. The two workshops were separated by one month. The modules were: (1) theoretical information on ACP and SDM, (2) role play exercises and (3) reviewing the internal ACP policy. A homework assignment between sessions let the participants practice the three-talk model during daily conversations with residents with dementia and their family members.
Control (N = 31) No training

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
1b. Bias arising from the timing of identification and recruitment of	Risk of bias judgement for the timing of identification and recruitment of	Low

Section	Question	Answer
individual participants in relation to timing of randomisation	individual participants in relation to timing of randomisation	
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Low
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low *(Some missing recordings and reasons not clarified between the two arms. However, reasons for not recording conversations were 1) not receiving informed consent from the resident with dementia or family members, (2) absence of opportunity to discuss ACP due to no new admissions or crises, and (3) difficulties with recording the conversation. It was felt these reasons were not clearly linked to intervention and thus paper was scored low.)*
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	Low
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Low
	Overall Directness	Directly applicable

1

2

Koerner, 2014

1

Bibliographic Reference	Koerner, Mirjam; Wirtz, Markus; Michaelis, Martina; Ehrhardt, Heike; Steger, Anne-Kathrin; Zerpies, Eva; Bengel, Jurgen; A multicentre cluster-randomized controlled study to evaluate a train-the-trainer programme for implementing internal and external participation in medical rehabilitation.; Clinical rehabilitation; 2014; vol. 28 (no. 1); 20-35

2 **Study details**

Study type	Cluster-RCT
Study location	Freiburg region, Germany
Study setting	Rehabilitation clinics: Of the 11 clinics that had participated in both surveys over the whole study period, eight treated mainly somatic diseases (orthopaedics, metabolism, neurology, cardiology and oncology) (four clinics in the intervention and four in the control group) and three specialized in psychosomatic diseases, especially addiction (one clinic in the intervention and two in the control group).
Study dates	April 2009 - November 2011
Duration of follow-up	each data collection period covered approximately four to six months.
Sources of funding	The study (01GX720) is part of the German grant programme ‘Chronic illness and patient orientation’ and is supported by the German Federal Ministry of Research and Education and the German statutory pension insurance scheme.
Inclusion criteria	Criteria 1 Sufficient german language ability Criteria 2 no cognitive impairments >= 18 years informed consent signed Staff inclusion criteria working within a treatment team in the inpatient rehabilitation clinics and direct participation in patient treatment.
Sample size	17 clinics
Split between study groups	Intervention: (n = 5 clinics)

	Patient: p1 n=158 p2: n=199 p3: n=168 Staff: p1: n=82 p2: n=58 Controlled: Patient: p1: n=244 p2: n=264 p3: n=293 Staff: p1: n=113 p2: n=110
Loss to follow-up	NR

% Female	Int pre: 63 (40.6%) Int post: 82 (41.6%) Int 6 mo: 79 (47.0%) Control pre: 80 (33.1%) Control post: 86 (33.0%) Control 6 mo: 113 (38.6%)
Mean age (SD)	Int pre: 57.1 (13.8) Int post: 56.7 (13) Int 6 mo: 61.5 (13.2) Control pre: 53.6 (12.7) Control post: 57.5 (13.7) Control 6 mo: 55.3 (13.9)
Outcome measures	SDM-Q-9 for patients AND for physicians The instruments were modified to assess the implementation of shared decision making from the wider healthcare professional perspective, rather than purely from the physicians' perspective as in the original versions. Self-compiled scale self compiled six-item Internal Participation Scale (IPS)

1

2 **Study arms**

Intervention "Train the trainer" fit for SDM programme (N = 5)

University project team trained the providers in executive positions in the clinics as trainers, who then in step 2 trained their staff in the health care team.

Control (N = 6)

Offered training after the data collection had been completed in all clinics.

1

2 **Cochrane risk of bias for cluster RCTs (v2.0)**

Bias arising from the randomisation process

Some concerns
(Not independent randomisation and baseline imbalances not reported and may be large)

Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation

Low

Bias due to deviations from intended interventions

Some concerns
(unblinded but not really a topic area that can be blinded)

Bias due to missing outcome data

High
(Large amounts of missing data)

Bias in measurement of the outcome

High
(Not objective SDM outcomes)

Bias in selection of the reported result Low
Risk of bias judgement High **Overall directness** Directly applicable

Koerner, 2012

Bibliographic Reference	Keorner, Mirjam; Ehrhardt, Heike; Steger, Anne-Kathrin; Bengel, Jurgen; Interprofessional SDM train-the-trainer program "Fit for SDM": provider satisfaction and impact on participation.; Patient education and counseling; 2012; vol. 89 (no. 1); 122-8

Study details

Study type	Cluster-RCT
Study location	Germany
Study setting	in-patient medical rehabilitation clinics
Study dates	First data collection period: May to September 2009 Second staff survey: July to November 2010 Exec providers trained as trainers: November 2009 to July 2010
Duration of follow-up	NR
Sources of funding	The study is part of the German grant program ‘‘Chronic illness and patient orientation’’ and is supported by the German Federal

	Ministry of Research and Education and the German statutory pension insurance scheme (Grant number: 01GX0720).
Inclusion criteria	None none reported
Exclusion criteria	None none reported
Sample size	Executives trained: 6 clinics (74 participants module 1, 68 participants module 2)
Loss to follow-up	NR
% Female	Module 1: 41% female, 59% male Module 2: 40% female, 55% male, 6% missing
Mean age (SD)	Overall: Part 1: 17-25: 11 (5.4%), 26-35: 34 (16.7%), 36-45: 55 (27%), 46-55: 70 (34.4%), 56-65: 27 (13.2%), 66 or older: 1 (0.5%), missing: 6 (2.9%) Part 2: 17-25: 11 (6.1%), 26-35: 21 (11.7%), 36-45: 44 (24.6%), 46-55: 59 (33%), 56-65: 36 (20.1%), 66 or older: 0 (0%), missing: 8 (4.5%)
Outcome measures	Outcome 1 One scale measured self-evaluation of SDM competences. There were nine items for the evaluation of this aspect at the end of Module 1 (e.g. I am familiar with the concept of shared decision making (SDM), I am familiar with the effects of SDM), and seven items at the end of Module 2 (e.g. I consider I am capable of training Table 1 Comparison of the original SDM model with the adapted SDM model for the interprofessional context. SDM model Adapted SDM model Focus of decisions Medical aspects Treatment (medical, psychological) aspects, organizational and team aspects Setting Patient–physician dyad Patient–physician dyad Interprofessional team Levels of participation Micro (patient–provider interaction) Micro (patient–provider interaction) Meso (team) Macro (clinic) Participation form External participation External and internal participation M. Ko¨rner et al. / Patient Education and Counselling 89 (2012) 122–128 123 Supplied by the British Library 24 Oct 2019, 08:05 (BST) my staff in SDM, I think it is important that all providers learn about the concept of SDM, I find the internal participation of the different providers just as important as the external participation). Outcome 2 Another six items summed up general training assessment (e.g. Overall I liked the training, Overall the training was well organized). SDM-Q-9 External SDM participation Self-compiled scale

	Six item team scale for internal participation. 1. Overall there is a friendly climate in the clinic 2. The providers work hand-in-hand 3. Coordination between the providers is efficient 4. The different types of treatment are well synchronized 5. Communication in the team is efficient 6. The providers respect each other. Scale ranges form 1 to 4. Satisfaction Step 1: satisfaction with content (six items, e.g. The training content contributed to gaining more insight and knowledge, The training content was new for me) & satisfaction with the trainers (five items, e.g. The trainers were well prepared and organized, The trainers were keen for participants to succeed) Outcome 3 train-the-trainer approach was evaluated by means of three self-compiled items (1) I find the train-the-trainer approach useful, (2) I find the train-the-trainer approach practicable, (3) I feel better prepared for my role as trainer through the training program than I did before training). All items were evaluated on a Likert-scale from 1 = does not apply at all to 6 = fully applies. Scale reliability was moderate throughout (Cronbach's Alpha from .74 to .89).

1

2 **Study arms**

Intervention group. (N = 225) University project team trained the providers in executive positions in the clinics as trainers, who then in step 2 trained their staff in the health care team.
Control group (N = 307) The clinics in the control group could choose between actual training and receiving the training slides/manual after the implementation and evaluation process.

3

4 **Cochrane risk of bias for cluster RCTs (v2.0)**

Bias arising from the randomisation process High *(Large lack of info around Randomization.)* **Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation** Some concerns *(Lack of reporting.)* **Bias due to deviations from intended interventions**

High
(Return rate of outcomes and larger n in intervention group is imbalanced.)

Bias due to missing outcome data

High
(Large amounts of missing data)

Bias in measurement of the outcome

High
(Not objective SDM outcomes)

Bias in selection of the reported result

Low

Risk of bias judgement
High

Overall directness
Directly applicable

O'Leary, 2016

Bibliographic Reference	O'Leary, Kevin J; Killarney, Audrey; Hansen, Luke O; Jones, Sasha; Malladi, Megan; Marks, Kelly; M Shah, Hiren; Effect of patient-centred bedside rounds on hospitalised patients' decision control, activation and satisfaction with care.; BMJ quality & safety; 2016; vol. 25 (no. 12); 921-928

Study details

Study type	Cluster-RCT

Study location	Illinois, USA
Study setting	Four similar nonteaching hospitalist service units in a large urban hospital.
Study dates	12 May 2014 through 31 January 2015
Duration of follow-up	NR
Sources of funding	The Globe Foundation.
Inclusion criteria	None
Exclusion criteria	Criteria 1 Disorientation Criteria 2 preferred language was not English
Sample size	493
Loss to follow-up	NR
% Female	Intervention: 124 (56.6%) Control: 148 (54.0%)
Mean age (SD)	Post discharge patient satisfaction survey respondents: Control: 65.3 (15.8%) Intervention: 63.4 (16.7%)
Outcome measures	Outcome 1 Patient activation measure Outcome 2 nurses', physicians' and advanced practice providers' (APP) perceptions of PCBR using a survey developed for this study Satisfaction

	postdischarge patient satisfaction survey items related to teamwork, involvement in decisions and overall care. Outcome 3 declined to participate Control Preferences Scale Degner Control Preferences Scale,18 a two-item tool used in prior research to characterise discordance in decision-making Outcome 4 withdrew from the study

1

2 **Study arms**

Implement patient-centred bedside round (N = 219) daily, interprofessional rounds conducted at the bedside, designed with input from patients, family members and frontline professionals.
Control (N = 274)

3

4 **Cochrane risk of bias for cluster RCTs (v2.0)**

Bias arising from the randomisation process Low **Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation** Some concerns *(No reporting on randomization order.)* **Bias due to deviations from intended interventions** High *(Over half of patients in intervention arm did not have PCBR)* **Bias due to missing outcome data**

Low **Bias in measurement of the outcome** High *(High but with caveat of study type making blinding very difficult)* **Bias in selection of the reported result** Low
Risk of bias judgement High **Overall directness** Directly applicable

1

1

2 Appendix F – Forest plots

3 Due to all outcomes featuring only a single study, no meta-analysis was possible and thus no forest plots are included here.

Appendix G – Grade tables

Table 5: Interventions aimed at embedding SDM in the healthcare system

No. of studies	Study design	Sample size	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Inconsistency	Indirectness	Imprecision	Quality
OPTION 12 – 3 months										
1 (Goossens 2020)	Cluster RCT	85	MD 28.85 (23.13, 34.58)	-	-	Serious[1]	NA[3]	Not serious	Not serious	Moderate
OPTION 12 – 6 months										
1 (Goossens 2020)	Cluster RCT	62	MD 34.13 (27.64, 40.62)	-	-	Serious[1]	NA[3]	Not serious	Not serious	Moderate
External participation – Patient SDM-Q-9										
1 (Koerner 2014)	Cluster RCT	463	MD -2.00 (-6.71, 2.71)	-	-	Very serious[2]	NA[3]	Not serious	Not serious	Low
External participation – Patient SDM-Q-9 – 6 months										
1 (Koerner 2014)	Cluster RCT	461	MD -0.80 (-5.90, 4.30)	-	-	Very serious[2]	NA[3]	Not serious	Not serious	Low
External participation – Staff SDM-Q-9										

1 (Koerner 2014)	Cluster RCT	167	MD 5.60 (-0.52, 11.72)	-	-	Very serious[2]	NA[3]	Not serious	Serious[4]	Very Low
Internal participation – Patient										
1 (Koerner 2014)	Cluster RCT	387	MD -3.90 (-6.93, -0.87)	-	-	Very serious[2]	NA[3]	Not serious	Not serious	Low
Internal participation – Patient – 6 months										
1 (Koerner 2014)	Cluster RCT	399	MD 1.60 (-1.80, 5.00)	-	-	Very serious[2]	NA[3]	Not serious	Not serious	Low
Internal participation - Staff										
1 (Koerner 2014)	Cluster RCT	158	MD 0.00 (-5.19, 5.19)	-	-	Very serious[2]	Not serious	Not serious	Not serious	Low
Concordance between experienced and preferred role of decision making										
1 (O'Leary 2015)	Cluster RCT	236	MD -8.00 (-30.71, 14.71)	-	-	Very serious[2]	NA[3]	Not serious	Not serious	Low
Patient activation										
1 (O'Leary 2015)	Cluster RCT	236	MD 0.69 (-2.82, 4.20)	-	-	Very serious[2]	NA[3]	Not serious	Serious[4]	Very Low
Patient satisfaction										
1 (O'Leary 2015)	Cluster RCT	236	OR 1.15 (0.77, 1.72)	-	-	Very serious[2]	NA[3]	Not serious	Serious[4]	Very Low

Decision control										
1 (O'Leary 2015)	Cluster RCT	236	RR 0.93 (0.61, 1.43)	-	-	Very serious[2]	NA[3]	Not serious	Very serious[5]	Very Low

1. >33.3% of studies at Moderate risk of bias
2. >33.3% of studies at High risk of bias
3. Only one study so inconsistency non-calculable
4. Confidence intervals cross line of no effect
5. Confidence intervals cross both ends of defined MIDs (0.8, 1.25)

1 Appendix H – Expert witness testimony

2 Testimony 1: Dave Tomson

3

Credentials and influences

- GP and typical generalist – 'Jack of all, master of none'
- Career long interest in systems change, QI, education, communication skills
- 10 years working with Prof Richard Thomson on SDM (MAGIC and SDM MAGIC North)
- Exec partner CHC and currently Clinical Director NS LWL PCN

For this presentation:

- MAGIC implementation experience – trained nearly 2000 health professionals, and QI from individual practice to whole health system
- Veile hospital system Denmark – consultant to their programme
- Angela Coulter's work

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You asked me:

Effective approaches/ activities to normalise SDM in the health care system?

Using a 9 component framework developed by Angela Coulter to organise our thinking.

Will focus more on those parts of the overall framework that the GDG is more able to influence and adding one or two areas of relevance

Signpost to other components, so that any recommendations from the GDG are embedded within an understanding of what needs to happen elsewhere in the 'system'

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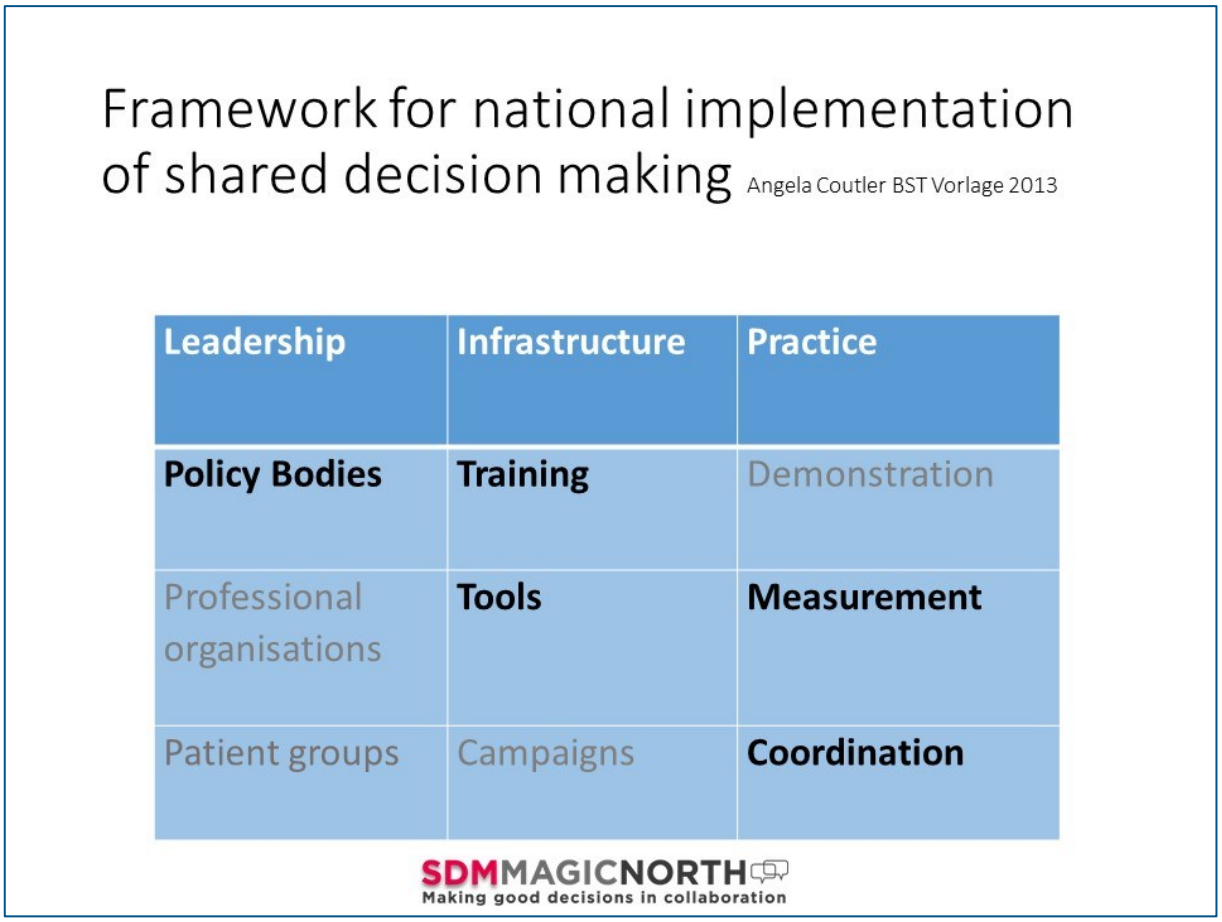
Framework for national implementation of shared decision making
Angela Coutler BST Vorlage 2013
Leadership
Infrastructure
Practice
Policy Bodies
Training
Demonstration
Professional organisations
Tools
Measurement
Patient groups
Campaigns
Coordination
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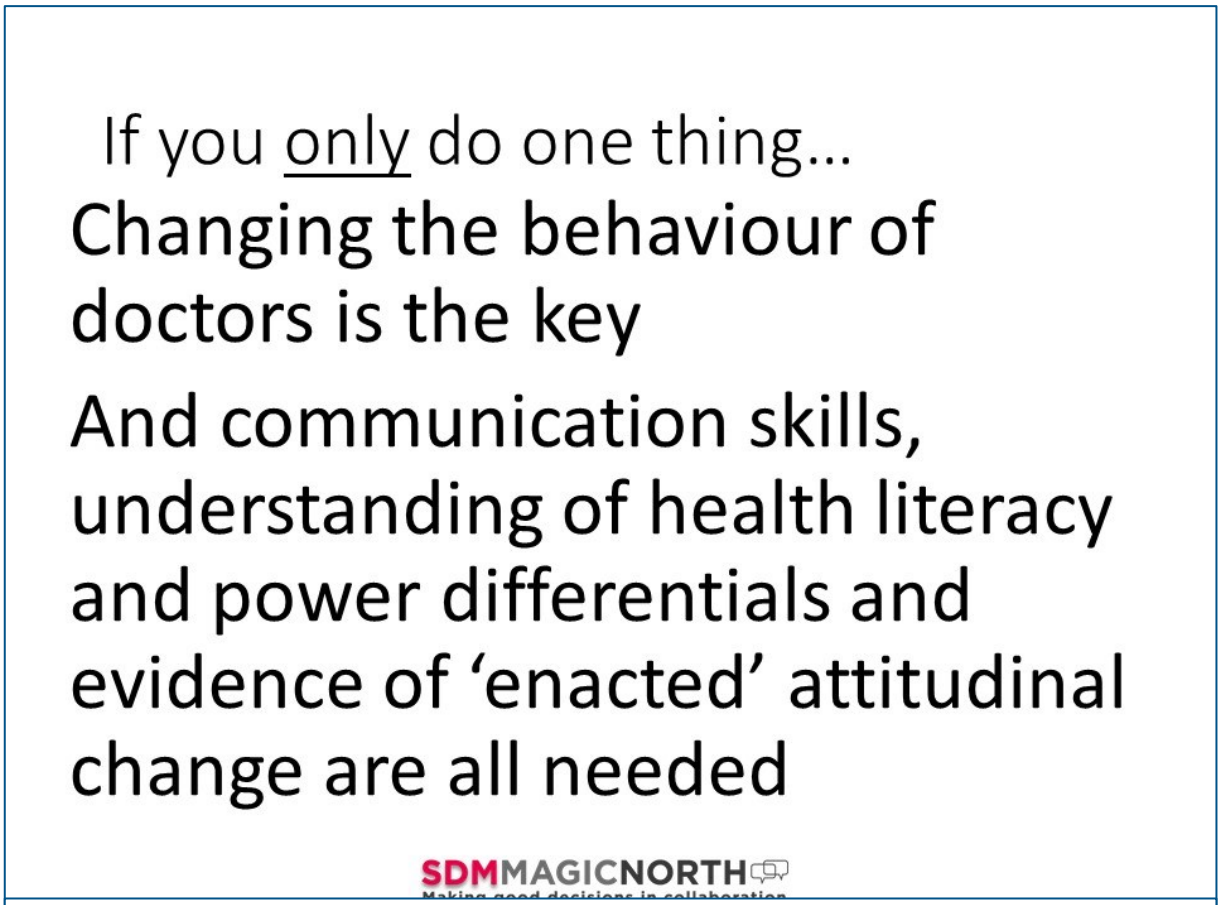
If you only do one thing…
Changing the behaviour of doctors is the key
And communication skills, understanding of health literacy and power differentials and evidence of 'enacted' attitudinal change are all needed
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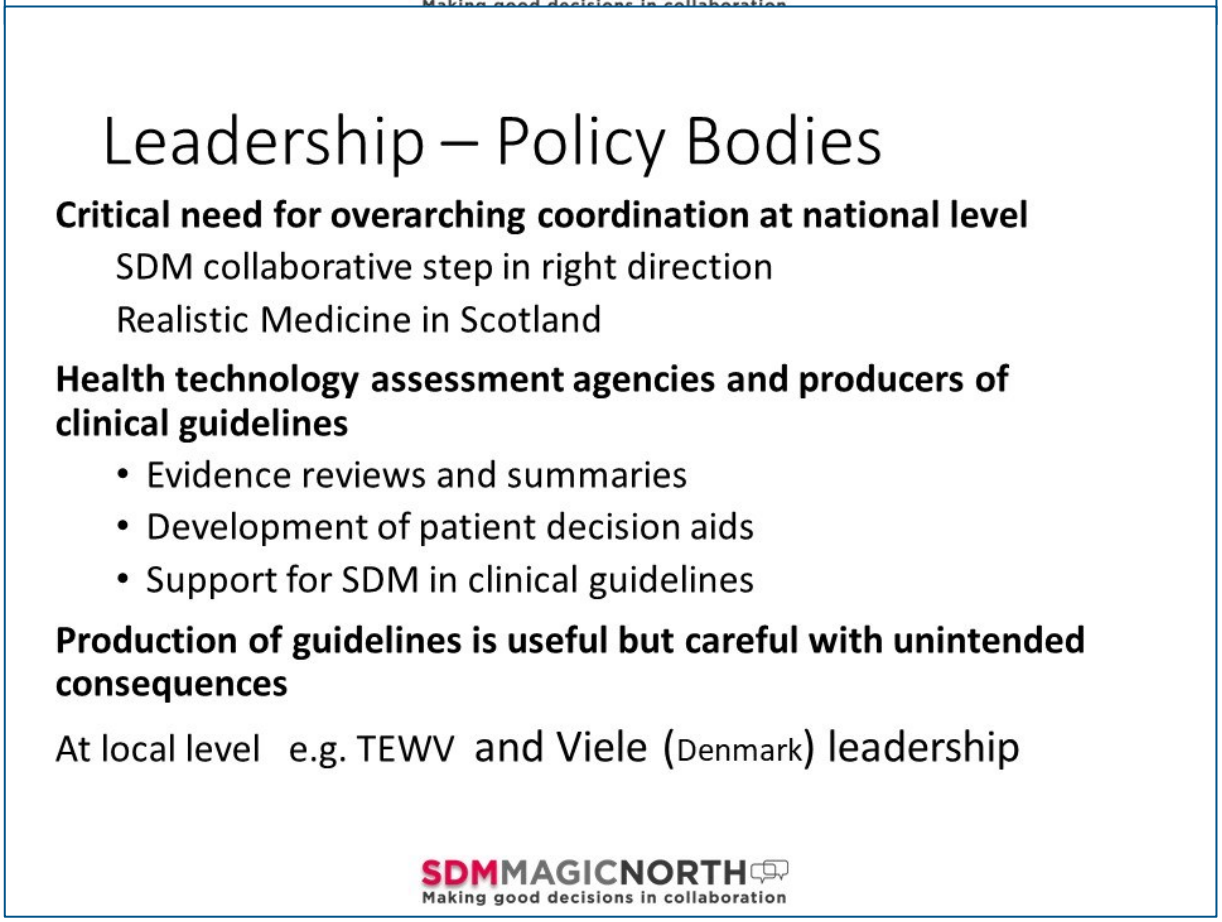
Leadership – Policy Bodies
Critical need for overarching coordination at national level
SDM collaborative step in right direction
Realistic Medicine in Scotland
Health technology assessment agencies and producers of clinical guidelines
• Evidence reviews and summaries
• Development of patient decision aids
• Support for SDM in clinical guidelines
Production of guidelines is useful but careful with unintended consequences
At local level e.g. TEWV and Viele (Denmark) leadership
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Recommendations Leadership – Policy Bodies

NICE Collaborative statement: To support this (*implementation of SDM*), a single organisation should be identified to promote and support all elements of shared decision making, and to track progress.

- Many agencies and organisations are involved but I think we need a national coordinating body (but with a wider remit than SDM alone – I would suggest combining this with a wider patient centred focus)
- Dedicated funding for research into person centred approaches?

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Recommendations Leadership – Policy Bodies

- Guidance to leadership in Trusts and PCNs – but careful with blunt tools and over engineered or monitored requirements
- Realistic Medicine or Choosing Wisely adopted more widely
  - Building a Personalised approach to Care;
  - Changing our style to Shared Decision Making;
  - Reducing harm and waste;
  - Reducing unwarranted variation in practice and outcomes;
  - Managing risk better;
  - Become Improvers and Innovators;

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Leadership - Professional

Professional regulators	Codes of conduct Training standards
Medical colleges and specialty societies	Curriculum design Clinical guidelines Collaboration with patient organisations Campaigns, e.g. Choosing Wisely Ambassadors and change agents

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Recommendations Leadership - professional

- Make training and evaluation of SDM or possibly elements of Patient centred practice mandatory before CTT (Neil Maskery) – could consider how health care organisations could make this part of CPD and PG training

- More coordinated approach to a campaign such as the Realistic medicine approach that Scotland has started – encouraging hospitals and CCGs to adopt a realistic medicine approach

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Leadership - Patient

Actors	Activities
General patient/consumer organisations and 'umbrella' groups	Advocacy campaigns Designing and advising on implementation projects Evidence summaries Collaborative projects Surveys
Disease-focused patient organisations	Helping to design PDAs and other materials Involvement in research and evaluation Information and publicity

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Recommendations Leadership - Patient

- Critically important for patient groups to hold Professional and Policy to account and their activities need to be supported
- Individual disease specific groups can be powerful influence on individual medical Specialities

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Infrastructure - Training

Training levels	learning objectives
Pre-registration Post-registration Continuing professional development E-learning	Relational competencies Risk communication competencies

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Recommendations

Infrastructure - Training

- Need to find ways of making training mandatory in PG and CPD for all patient facing clinicians – Trusts have a role here
- Training must include rehearsal of skills – real time or video feedback is the most effective (but hardest to deliver)
- Balance training on SDM skills with broader training on patient centred practice and include over time '**skills for 21st century practice**'– including but not exclusively:
  - Self care management support
  - Care planning skills
  - End of Life consulting skills
  - Motivational / coaching skills

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Infrastructure - Tools

Types	examples
Question prompts	Just Ask
Information sources	Numerous leaflets/ web resources
Designed decision aids	Within consultation tools External paper External on line

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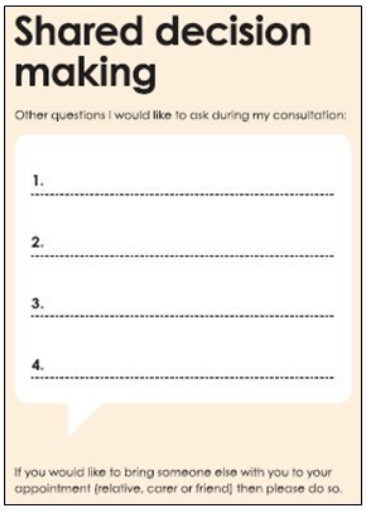
Ask 3 Questions



A6 flyer for use in appointment letters, waiting areas, consulting rooms.

Posters for use in waiting areas and consulting rooms.

Short film to encourage patient Involvement: 'So Just Ask'

Acknowledgement to Shepherd et al, School of Public Health, University of Sydney

2

Recommendations and comments

Tools help but don't just concentrate on highly engineered tools and don't think that use of a tool constitutes successful SDM

NICE should lead on the coordination of all continually updated, readily available, appropriate, PDAs

Concerted effort to get the Clinical system IT providers (EMIS Systemone etc) to embed prompt tools linked to diagnosis or real time consultation (EMR)

We need to get much more creative about methods of information transfer and think more about Health Literacy

Patient focussed tools - such as Just Ask or the Taiwanese approach are worth pursuing – Incorporated into Long term condition reviews, or in referral letters - *What matters to me?*

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Infrastructure - Campaigns

Social marketing

For clinicians and the health and social care providers	**Choosing Wisely Realistic medicine**
For patients	Just ask Taiwanese example

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Recommendations and comments

Campaigns focussed on patients – the main issue is the power differential

Learning from MAGIC – e.g. Just ask campaign at New York surgery.

- must be part of a combined approach to change clinician behaviour at the same time

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Practice - Demonstration

Health foundation 10 questions

Convincing people that there is a problem	Tribalism and lack of staff engagement
Convincing people that the solution chosen is the right on	Leadership
Getting data collection and monitoring systems right	Balancing carrots and sticks– harnessing commitment through incentives and potential sanctions
Excess ambitions and 'projectness	Securing sustainability
The organizational context, culture and capabilities	Considering the side-effects of change

2

So why aren't we doing it?

Main challenges

- "We're doing it already"
- "We don't have the right tools"
- "Patients don't want SDM"
- "How can we measure it?"
- "We have too many other demands and priorities"

Lack of implementation strategy

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The Health Foundation
Inspiring Improvement

MAGIC
Making good decisions in collaboration

thebmj

BMJ 2017;357:j1744 doi: 10.1136/bmj.j1744 (Published 2017 April 18)

ANALYSIS

Check for updates

Implementing shared decision making in the NHS: lessons from the MAGIC programme

OPEN ACCESS

Shared decision making requires a shift in attitudes at all levels but can become part of routine practice with the right support, say **Natalie Joseph-Williams and colleagues**

Natalie Joseph-Williams *lecturer*[1], Amy Lloyd *research fellow*[2], Adrian Edwards *professor*[1], Lynne Stobbart *senior research associate*[3], David Tomson *executive partner and freelance consultant in patient centred care*[4,4], Sheila Macphail *consultant in obstetrics and fetal medicine and assistant medical director*[5], Carole Dodd *director*[6], Kate Brain *reader*[1], Glyn Elwyn *professor*[6], Richard Thomson *professor*[3]

2

Implementation bundle

- Interactive shared decision making skills development
- Access to decision support including brief SDM tools
- Patient activation and preparation
- Measurement
- Organisation buy-in/senior level support
- Collaborative and facilitated approach
- Structural considerations – wider context

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Recommendations - Demonstration continued

Denmark Viele

- V clear leadership
- Research funding
- Strong education across whole organisation
- Re design of pathways
- Patients involved at every level
- PDA development involving front line staff
- Strategic and embedded not a project

2

Practice - Measurement

Specific measures that patients fills in post consult or at later date
Observer measures
General patient surveys

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Recommendations and comments

- Immediate post consultation measures have limited value and very hard to collect in routine practice but can be useful for intensive behaviour change work and can be used intermittently
- There is a need for the development of a more useful measure that could be adopted at a system level
- General patient surveys measures DO provide policy incentives but are relatively non specific
- Tools to measure impact of SDM and Person centred care at systems level would be useful

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Practice - Coordination

Strategy development	Convening stakeholder meetings to agree priorities and develop an implementation plan, liaising with politicians, policy organisations and funding bodies.
Education and training	Core competencies for SDM, mapping training opportunities, encouraging the development of new training courses, shaping curricula, designing assessments, promoting shared learning.
Tools	**Coordinating the development of PDAs, a central register, quality assuring PDAs, hosting these on a national portal, linking them to clinical guidelines, ensuring they are kept up-to-date, establishing a certification scheme, liaising with suppliers to build PDAs and SDM prompts into electronic medical record systems**

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Practice - Coordination

Campaigns	Organising conferences, designing social marketing campaigns, developing and distributing materials, liaising with patient and professional organisations
Demonstrations	Mapping, supporting and evaluating demonstration projects, summarising and disseminating the learning from these, encouraging replication
Measurement	Developing or selecting appropriate measurement instruments, monitoring the state of SDM nationally, providing feedback and publishing regular reports.

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Recommendations and comments

Coordination of the educational offer and the policy around this – probably more role of SDM Collaborative but GDG may be able to comment on this

Urgent need to coordinate around TOOLS – there is a role for NICE

Need to find an effective measurement tool

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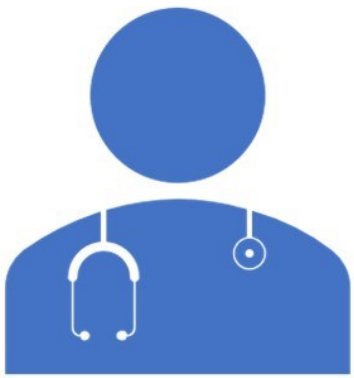

Measurement - patient questionnaires
(e.g. SDM Process 4 © MGH, Boston USA)

- How much did you and your health care providers talk about the reasons you might want to have [test/intervention]?
- How much did you and your health care providers talk about the reasons you might **not** want to have [test/intervention]?
- Did any of your healthcare providers talk about [alternatives] as something you should seriously consider?
- Did any of your health care providers ask if you wanted to have [test/intervention]?

2

Unintended consequences

- Guidelines treated as mandatory by (junior) clinicians
- Wait time targets leading to reluctance to change pathways
- Criterion based referral management models
- PDAs being used as scripts with no shift in relationship
- Seeing SDM as a technical issue and not a cultural shift
- Turf wars between SDM and related skill sets (SSM or Care planning)
- New NHSE Specification for PCNs insisting on use of PDA in MSK but without all the other components of QI programme

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Implementation - My 'Takehomes'

In addition to recommendations above:

- There is no RCT evidence or single magic bullet
- Shift the curve and don't just work with the converted
- The more of Coulter's 9 components you incorporate into implementation programmes the better BUT also be opportunistic and align incentives
- Understand and plan for, of the barriers AND the unintended consequences

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Implementation - My 'Takehomes'

All programmes must include intensive (face to face, small group, with rehearsal) - training for all clinicians who make important decisions with patients

NICE SDM Collaborative to explore with Royal Colleges and others whether communication skills assessment can be part of CPD – in particular the skill of finding out **what matters to the patient**.

Locate SDM in a wider framework of patient centred practice – including Care planning/ supporting self management/EoL care/ MI

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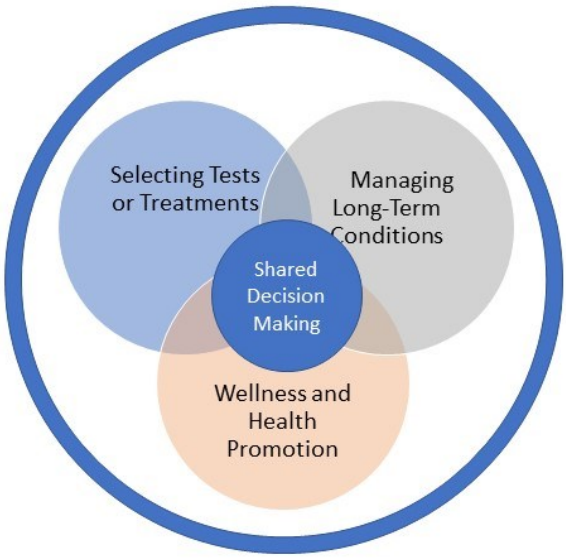
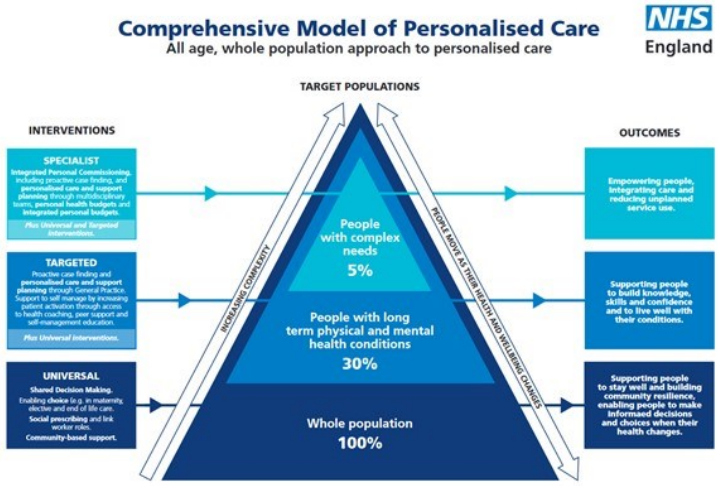


Courtesy of Angela Coulter

2

NHS England



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Implementation - My 'Takehomes'

NICE Guidelines:

- Trade off between the perfect and the practical
- Include brief decision supports(single page), as well as the IPDAS compliant, more 'engineered' PDAs. Make it even clearer that guidelines are
  - not instructions,
  - find it difficult to take Multimorbidity into account
  - always need to be balanced with 'What matters most' to the patient

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Evidence-based Decision Aids

Clinical Guidelines

- Primarily for doctor
- Evidence-based
- Describes likelihood of various outcomes
- Outlines uncertainties
- Recommendations based on values of clinical experts
- Assumes doctor makes the decisions

Patient Decision Aids

- Primarily for patient
- Evidence-based
- Describes likelihood of various outcomes
- Outlines uncertainties
- Does not make recommendations
- Assumes shared decision making

Courtesy of Angela Coulter

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Implementation - My 'Takehomes'

Put pressure on IT companies offering clinical platforms to incorporate PDAs into clinical systems (EMR)

NICE would be doing a great job of it agreed to coordinate, host, and ensure maintenance of, all good quality PDAs relevant to UK population

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Thank You
Newcastle University
Institute of Health & Society
SDMMAGICNORTH
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NHS
Health Education North East
The Health Foundation
Inspiring Improvement

1 Testimony 2: Emma Walker & Rachel Byers

Advancing Quality Alliance

NICE Shared Decision Making Guideline Committee
Expert Testimonial – Advancing Quality Alliance
21st January 2020

Background & Introduction

The Advancing Quality Alliance (AQuA) is an improvement organisation, hosted by Salford Royal NHS FT, based in the North West of England working locally, regionally and Nationally with predominantly NHS organisations. AQuA has been working in the area of Shared Decision Making for nearly 9 years, running national and regional Collaboratives, national and regional Train the Trainer programmes as well and masterclasses and bespoke work with teams, organisations and more latterly systems.

AQuA's approach is a practical, blended approach underpinned by improvement methodology, where shared decision making is seen within the wider context of person centred care with a focus on the conversation.

Culture

We know that SDM is about cultural change, it is essentially requires an organisational development approach, and we know that culture is very important.

We also know that leaders have disproportionate influence on their organisational or department's culture and therefore it is important to engage leaders to support the embedding of SDM. From our experience, where ever possible there needs to be a will or an appetite from the top or at least an interest to at least support, if not commit to this approach. In addition, the most successful teams or organisations are those with a stable leadership and are not in crisis or even at Require Improvement.

Board to frontline engagement is important – SDM needs to be the stripe in the toothpaste and we aim for intentional programmes of work rather than isolate projects that can wither over time as the key leaders leave. Ideally, SDM approaches should be aligned to a corporate aim and embedded within the quality strategy, but we know that processes and strategies are not enough and regular senior support/interest is more important in terms of driving the culture and clarity around the organisation's true North.

The aim of creating organisational capacity should be the aspiration rather than letting a thousand flowers bloom, as then the organisation or system creates 'isolated islands of assets' who do not link to each other, nor to a formal organisational strategy and will dwindle over time.

Operationally, it is always sensible to work with the willing, and insist on clinical, executive and lived experience support within teams. Teams have the benefit over individuals as they support each other through the difficult times, as do Lived Experience representatives who add legitimacy and often encourage and push teams not to give up. Allowing the teams to

2

focus on what they want to work on ensures that they have 'skin in the game' and how they can use SDM to improve their working life and the outcomes for their patients.

The biggest cultural challenge is around appetite to risk. Many organisations, Boards and managers seem very concerned about the risks of trying something new or different. They are very concerned about potential litigation and very often their perception of the negative reaction of CQC. More work needs to be done to reward the culture of intelligent risk taking.

Competency

In addressing competency in shared decision making our approach has always been to highlight that this is an opportunity to showcase what clinicians are doing well, time to reflect on where improvements could be made and consider how they evidence the positive work they do. In our experience engaging with teams is a crucial part of the process and one which should be given time and consideration, as clinicians can often feel their practice is being criticised.

Why a dripping tap? Little and continuous learning over time is important to improve and embed SDM. We have found that a single training session especially for a single clinician within a department does not change sustainable practice. We usually find that those who attend these one off events have a basic understanding, are keen to know more and want to embed SDM, but it takes more than a single enthusiastic willing clinician. A whole team approach supported over time enables us to work with people who are at different stages of 'buy in', and we provide support and opportunity to reflect, building confidence to practice differently.

We emphasise that this is about changing conversations, moving away from a paternalistic approach and realising that this approach is often the reason why people came into the profession: to support people in what matters to them, based on their values and preferences. There are a number of tools, skills and resources we share with teams. We reflect on:

- The three talk model for shared decision making https://www.bmj.com/content/359/bmj.j4891
- Ask 3 Questionshttps://www.aquanw.nhs.uk/resources/shared-decision-making/Ask%203%20Questions%20Leaflet.pdf
- Option 5 http://www.glynelwyn.com/uploads/2/4/0/4/24040341/observeroption5manual_july_13_2016.docx.pdf
- Motivational interviewing skills and understanding the importance of ascertaining people's values, using videos, role plays and exercises. One example is a film we made which illustrates how we make decisions in other areas of our lives and how

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we should expect to have the same involvement in decisions about our mental and physical health https://youtu.be/VGO5NO9-F_U

- Increasing knowledge about compliance, consent and capacity and how this is a framework that underpins shared decision making. A case study example we use to enable clinicians to reflect on their perception of risk is Jim's story https://www.youtube.com/watch?v=yEw8eVpRmoY

- Option grids, but emphasising that this is not essential to be able to do SDM, the emphasis is on eliciting preferences and working together to discuss options and make decisions together. An option grid is not an essential requirement; it can support the conversation.
.

Some of the practical approaches to ensuring that SDM is 'dripped into' their practice is to think about some of the structures in place that can support it to thrive and flourish in practice. For example, encouraging all team members to be involved in its sustainability by considering how this can be embedded into personal development and appraisals, supervision, standard items on the agenda of team meetings, part of the induction programme.

We also find that a dosing formulae can support implementation e.g. e-learning, master classes, train the trainer, a tailored approach with individual teams and development of a community of practice. For example we are working with the Therapies Department at University of Liverpool Hospitals taking this approach. Master classes have been open to all staff to raise awareness of SDM and we are working with a number of teams as a mini collaborative to target areas where SDM can demonstrate impact e.g. the super stranded patients. Ensuring that we frame this work around priorities and objectives for the organisation is essential to have support at an executive level.

Another approach is to use an online platform known as Basecamp which supports the development of a community of practice. Every project includes the tools all teams need to work together; message boards, to-dos, schedules, docs, file storage, real-time group chat, and automatic check-in questions. All staff have access to basecamp and an use this as a community of practice continuing to learn from each other.

From April 2020 AQuA will also support the development of a community of practice through the SHARP network. The SHARPNETWORK is shorthand for 'shared decision making practitioner network'. This is an international network of health professionals who have completed a course of instruction in shared decision making, have completed an assessment of their competence, and obtained membership of the network. More information about the SHARP network can be found here at http://sharpnetwork.org/ AQuA will be supporting 20 of our members to join the network by providing the licenses and assessing their competence.

Our main findings are that clinicians need time to review and reflect on their practice, to share their challenges and fears and have confidence that they will be supported by their profession and their organisation, if at a later date that decision is questioned.

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Competing Priorities

How do we make this a priority for organisations when there are competing priorities? Harms are talked about at Trust Boards- Cdiff, falls, MRSA, never events but do we really see that making decisions for people and not involving then in decisions about their care is just as harmful. Boards have a patient story which is usually a safety story and it's often tokenism. It's one example, not the thread or the strip in the toothpaste.

Clinicians need time to reflect on this and learn from case studies. We explore the impact and harm that occurs when people are not involved in decisions about their care. Our approach is to work with them to understand the drivers for doing shared decision making and the legal framework that supports it. We need to move people from a place of 'this is nice to have' or 'we do it already' to understanding that SDM is a must do.

We approach competing prioritise by framing the importance of SDM around national drivers, CQC and legal frameworks.

We showcase examples that evidence how the Mental Capacity Act is a key enabler to SDM. When clinicians fully understand how The MCA also allows people to express their preferences for care and treatment, particularly around unwise decisions, they feel more confident in supporting patient choice. Unfortunately we do hear of examples when the MCA is not adhered to and when a patient wants to make a decision that is against the clinician's preference the MCA can be used inappropriately.

Another approach is to explore the guidance on consent and the implications of the Montgomery case. In our experience this ruling has often not filtered through to front line staff and managers. Our approach is to educate and train staff and help them to see that the Montgomery case speaks the language of SDM. This can be challenged by clinicians for example, a doctor who challenges how can he be expected to talk through options and preferences when he's rushing a pregnant women through to an emergency section. Clinicians need time to understand where in the patient pathway decisions are made and how SDM needs to be embedded. Our QI approach helps teams to consider where the decision points are in the pathway.

Our approach is to look at understanding national drivers for SDM: For example The Universal Personalised Care Plan, CQC Well Led framework and KLOES, as well as NICE guidance We take the approach that SDM can help you to achieve CQC standards i.e. Caring by empowering patients to be part of their on-going care (KLOE 7) .

The Universal Personalised Care Plan has been instrumental in pushing forward the agenda for SDM in conjunction with the other 5 key elements of the UPC. For example we have worked with two teams from one organisation to embed SDM, patient activation and personalised care planning. The results have demonstrated an increase in activation in some of the most deprived areas in the borough and we have also noted the positive impact on the staff which has been shared via feedback within focus groups. This work is now one

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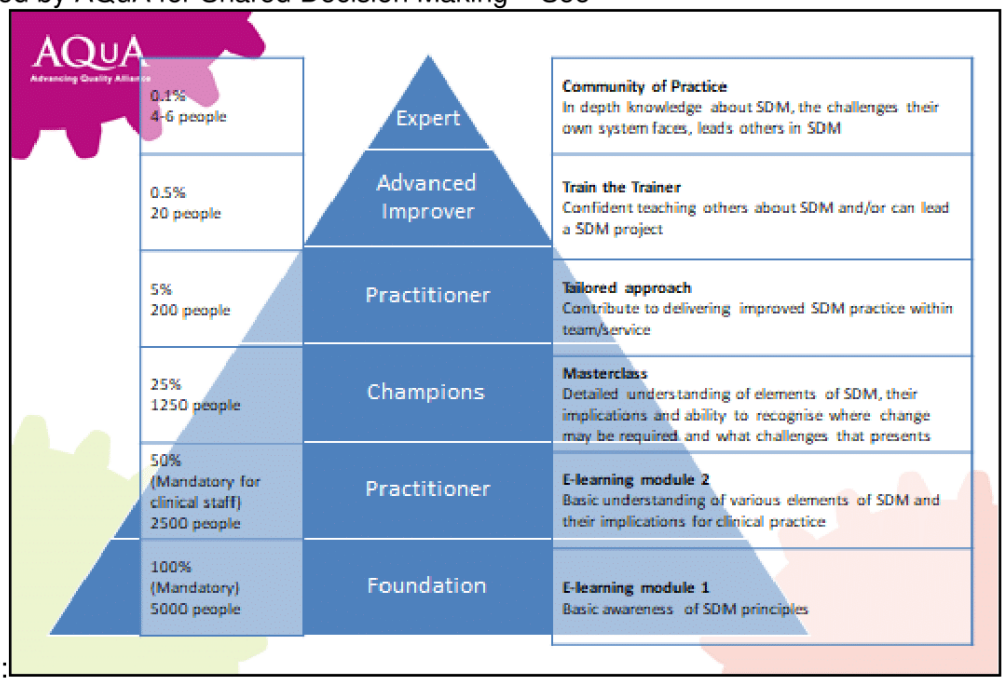
of the key priorities for the organisation. It has been written into the quality strategy and we are starting to spread the learning with district nurses and podiatry. This work has been accepted for a poster presentation at the IHI conference in Copenhagen this year.

Supporting Approaches

AQuA has always used quality improvement as the scaffolding or framework to enable teams to identify the who, what, why and how in terms of embedding SDM. QI provides a clear process and support to teams to enable them to analyse, plan, test, measure and embed changes in practice around SDM and through this approach prove that SDM has benefits which then sustains the approach and encourages others to try.

The approach also works beyond the NHS, when working with Local Authorities and third sector providers and often AQuA use the Lived Experienced Panel to deliver or support on the QI elements. The benefit of QI is that it can support a single team or individual at a micro level through to a whole system at a macro level using a collaborative approach.

The IHI (Institute of Healthcare Improvement) improvement dosing formula has been adapted by AQuA for Shared Decision Making – See below:



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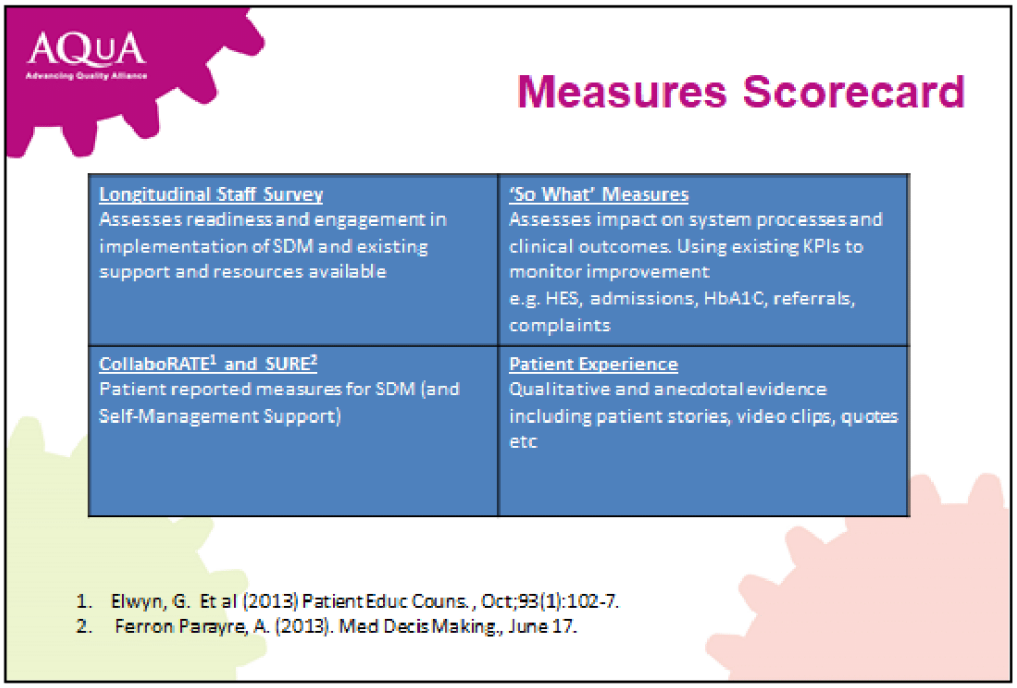
This enables an organisation or a system to think more strategically about its approach to embedding SDM and how it can join up individual projects intentionally into an wider approach aligned with the strategic direction of the system or organisation.

Specific QI tools have been very useful with teams to help embed shared decision making:

- Value Stream Mapping drives out the problems and variation and with an EBD (Experience Based Design) lens, enables staff to see things from a service user perspective
- Fishbone diagrams help with looking at future state
- Aim Statements & driver diagrams create a plan on a page which can be crafted into an elevator pitch to enable ease of communication.
- Measurement plans enable teams to focus on what they can measure to demonstrate an improvement or learning.



- Sustainability and Spread tools allow teams to identify barriers and challenges early on to help sustain their improvements through embedding SDM

Results are challenging, staff are busy and not every intervention is a success often due to competing priorities or movement of teams, but AQuA continues to adapt its approach and work with whoever is interested in improving outcomes for patients.

If you require any further information or detail, please contact:

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Emma Walker
Emma.Walker2@srft.nhs.uk

28th January 2020

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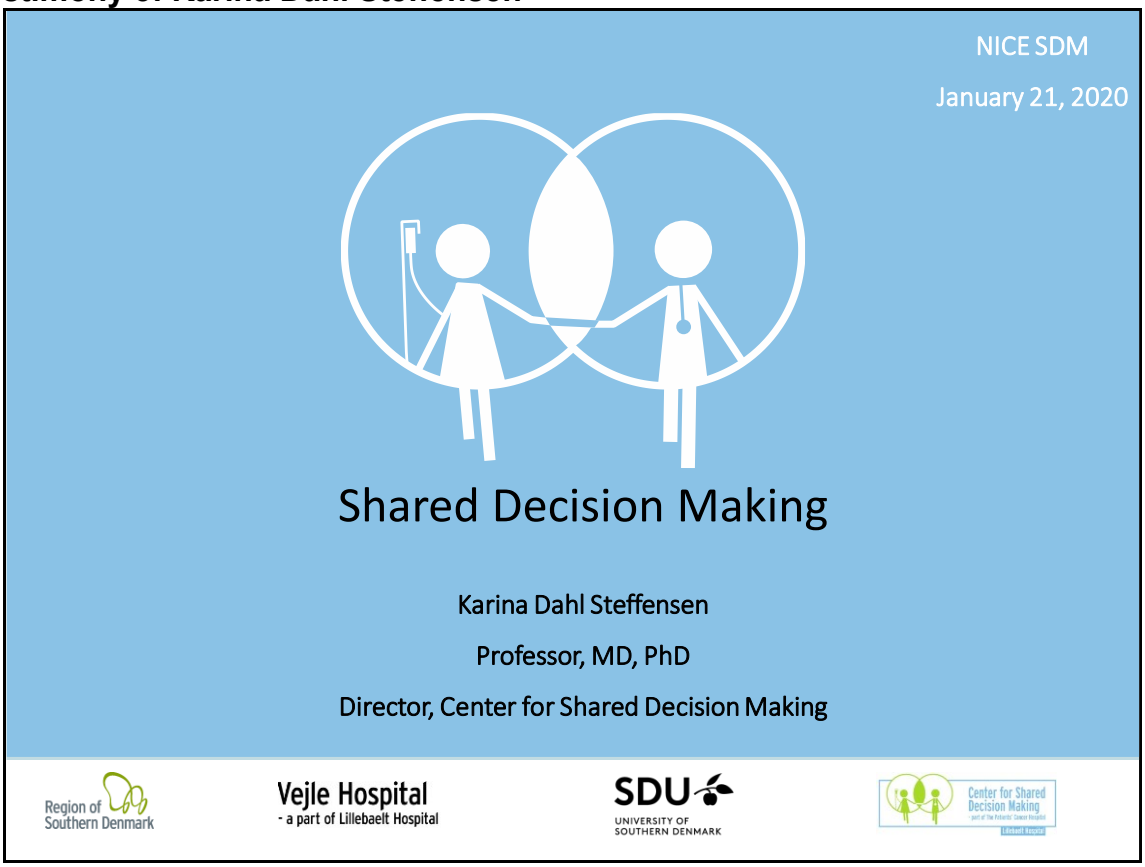
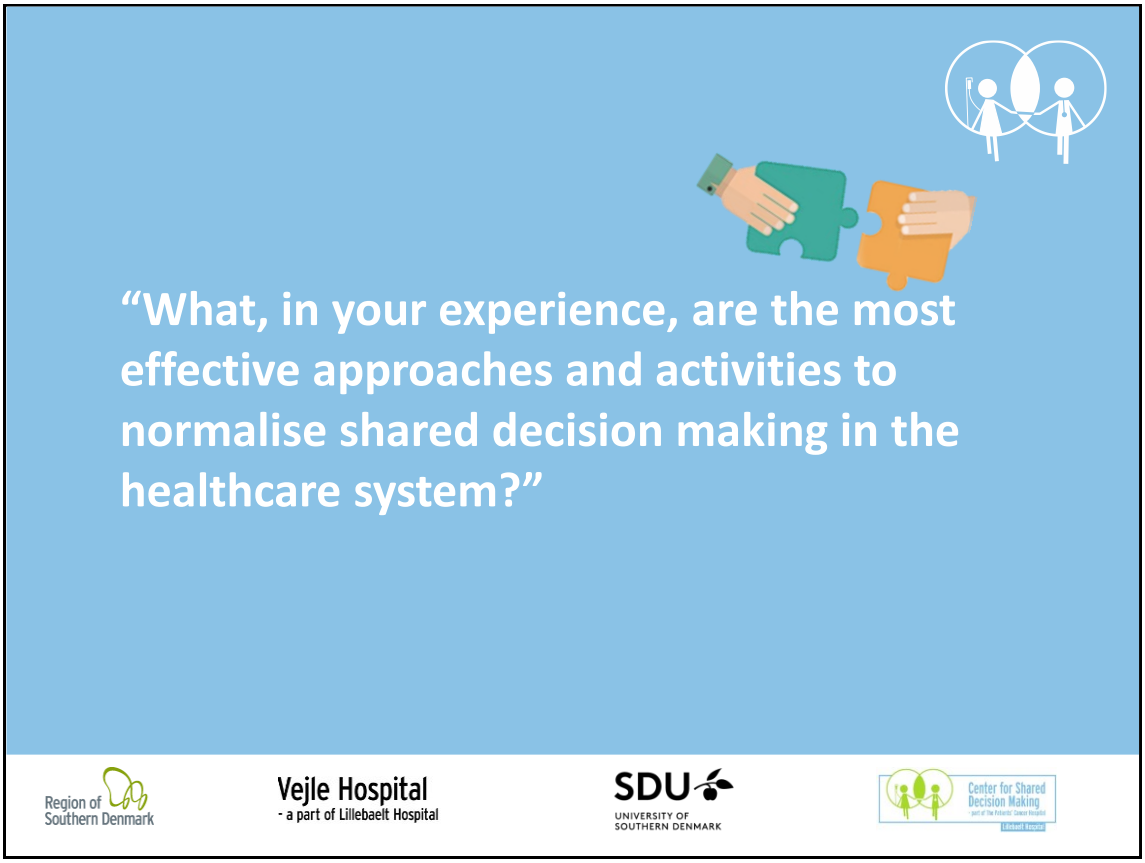
2 **Testimony 3: Karina Dahl Steffensen**



3

4 Professor Dahl Steffensen is a part-time clinician (oncologist in gynaecological cancers) and
5 Director of Shared decision making at Vejle Hospital in Southern Denmark.

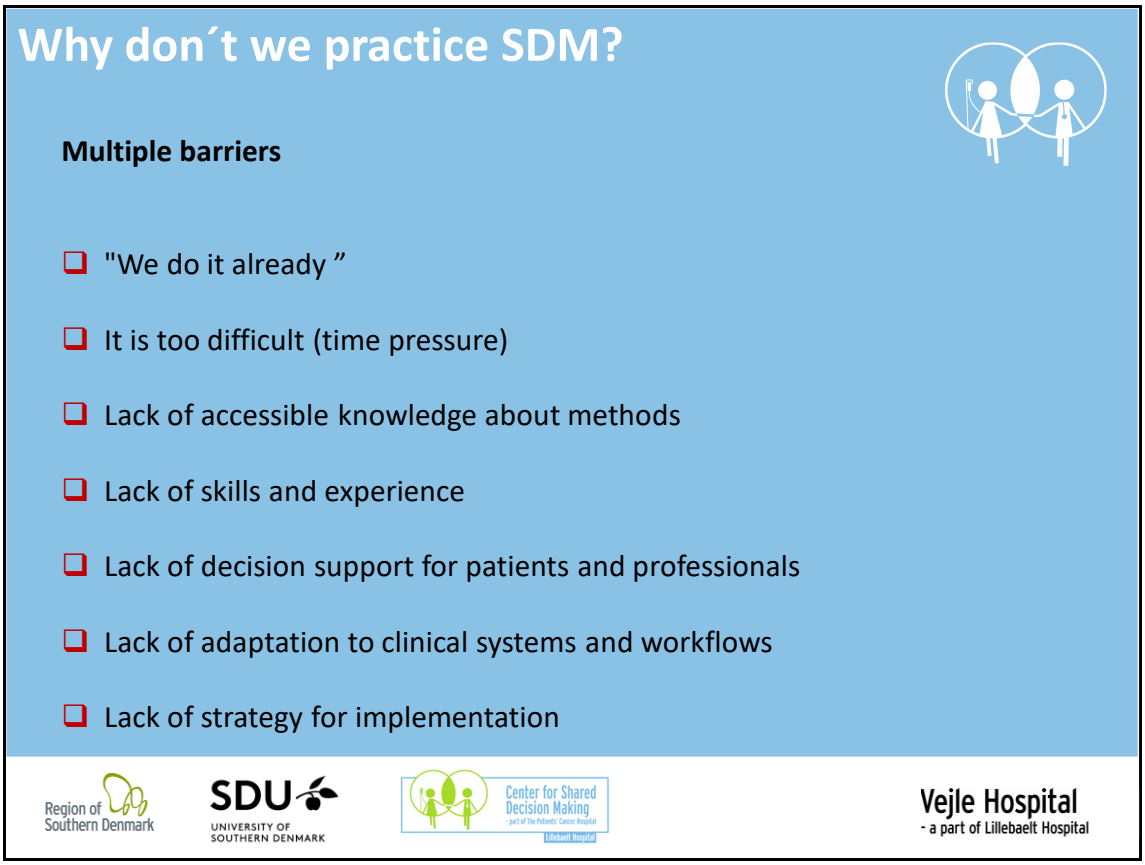
6 She has been leading that centre since 2014



The NICE SDM committee asked this question:

"What, in your experience, are the most effective approaches and activities to normalise shared decision making in the healthcare system?"

This is a complex question to answer, but I hope that reflecting on the process and successes/challenges we have encountered in our hospital will help.



What are the issues with SDM? Why is it not being more widely practiced?

The reasons given for not practicing SDM are common across different studies and cultures, with little variation. In any presentation about SDM, someone will usually mention at least on of them, and they need to be taken very seriously because they are the key obstacles to the rollout of SDM:

"We do it already ”

It is too difficult (time pressure)

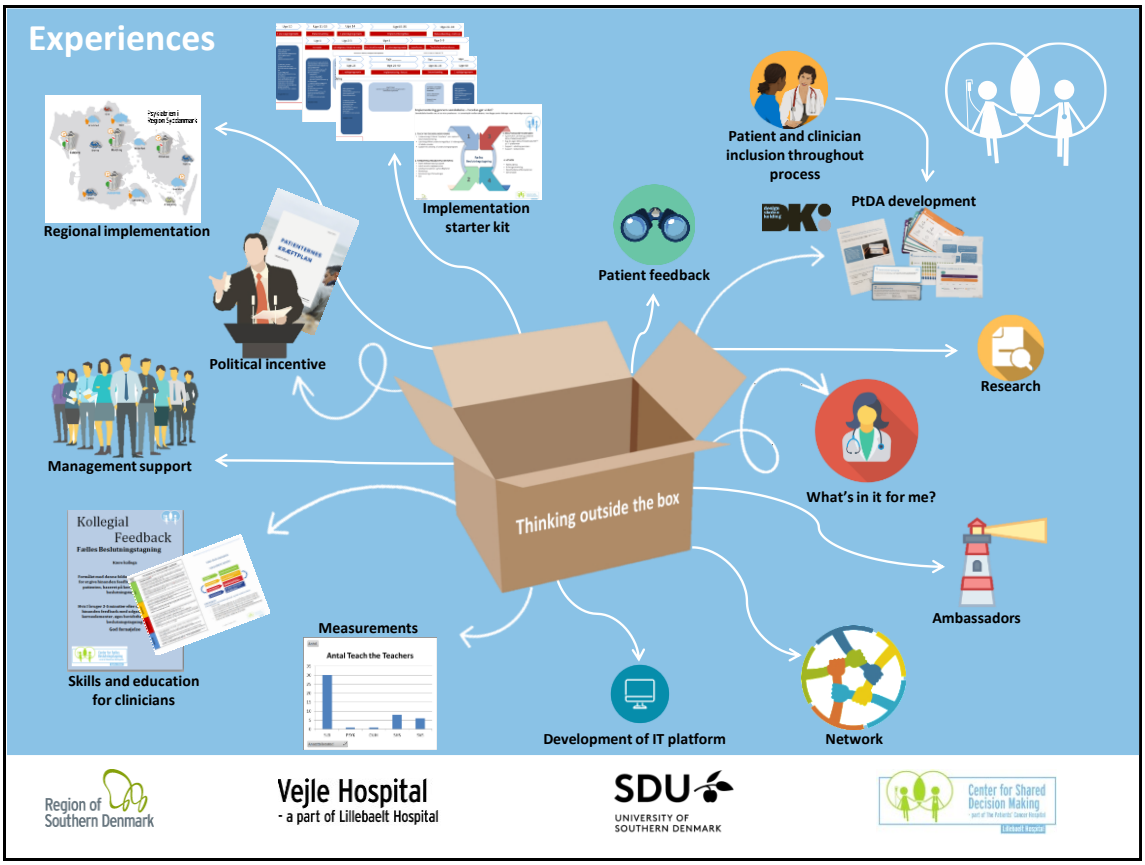
Lack of accessible knowledge about methods

Lack of skills and experience

Lack of decision support for patients and professionals

Lack of adaptation to clinical systems and workflows

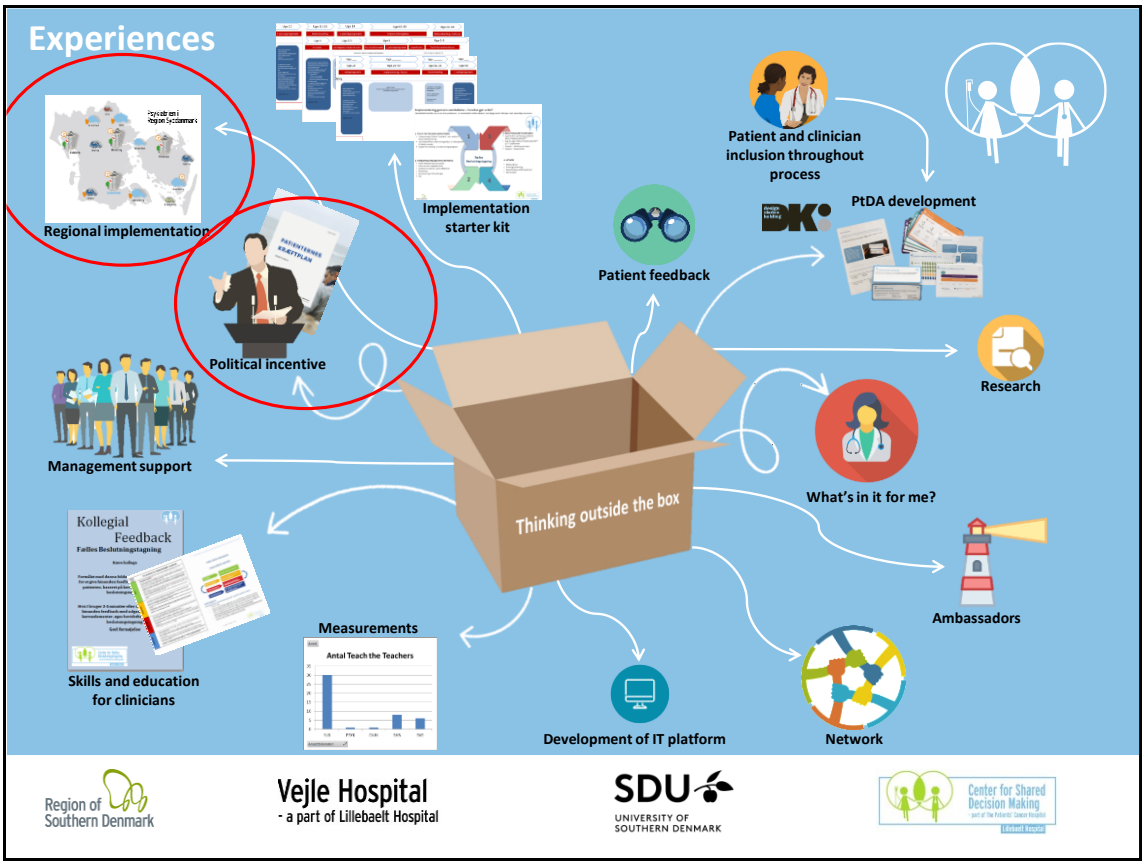
Lack of strategy for implementation



Normalizing shared decision making in the healthcare system it not an easy fix and not just a single step. It is a complex process to address all the barriers shown in the previous slide. We need to acknowledge that these are real barriers that needs to be taken seriously, but address them by working with facilitators rather than trying to tear down the barriers.

The facilitators I refer to are multiple methods of embedding SDM at a healthcare system level. I believe it is crucial to think outside the box in order to do this successfully. This presentation will go through them one by one.

It is not an easy fix. There's not one single thing you can do, but it's a process over time of implementing these multiple facilitators.

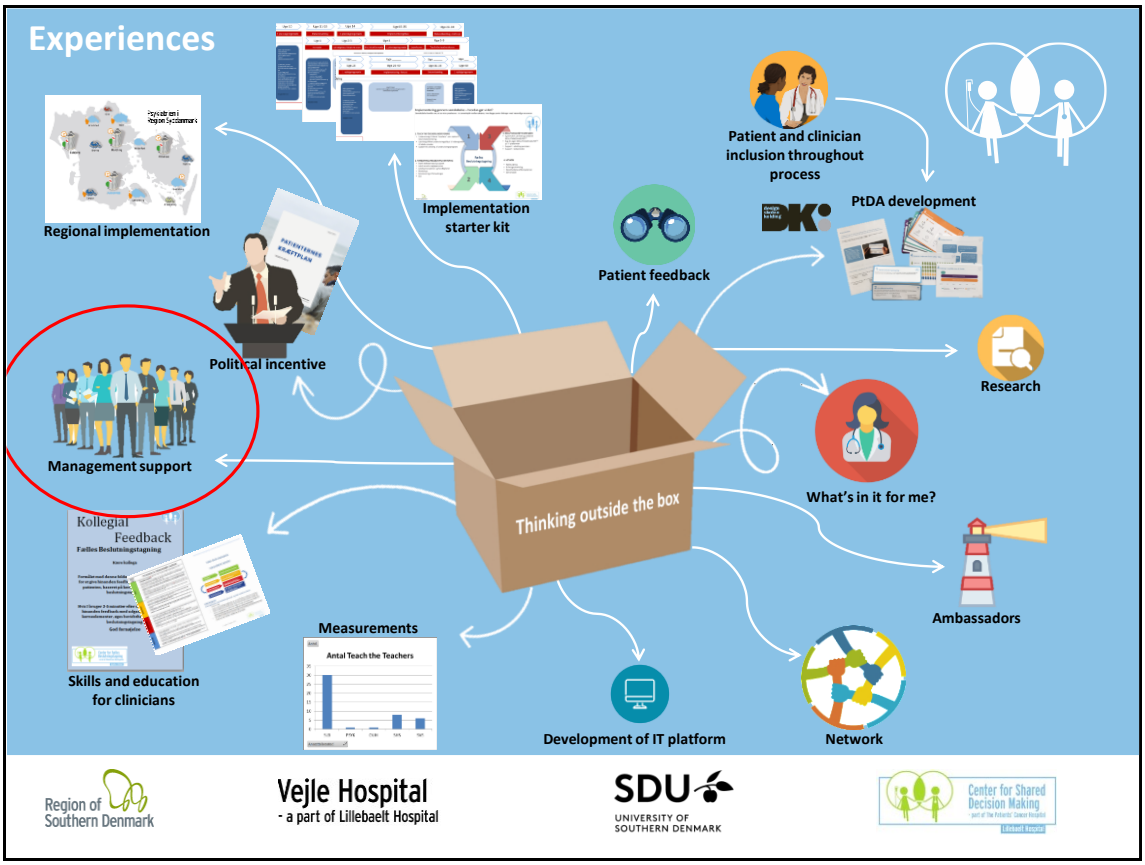


In Vejle hospital, a **political incentive** for **regional implementation** was provided by the National Danish Cancer plan IV, which stated that nine out of ten patients should feel included in the decision making concerning their treatment by 2020.

This statement prepared the grounds for pushing hospitals to embed SDM in treatment planning with cancer patients and also provided funding for research in SDM (although this was probably too much focused on the development of patient decision aids, which I will address later).

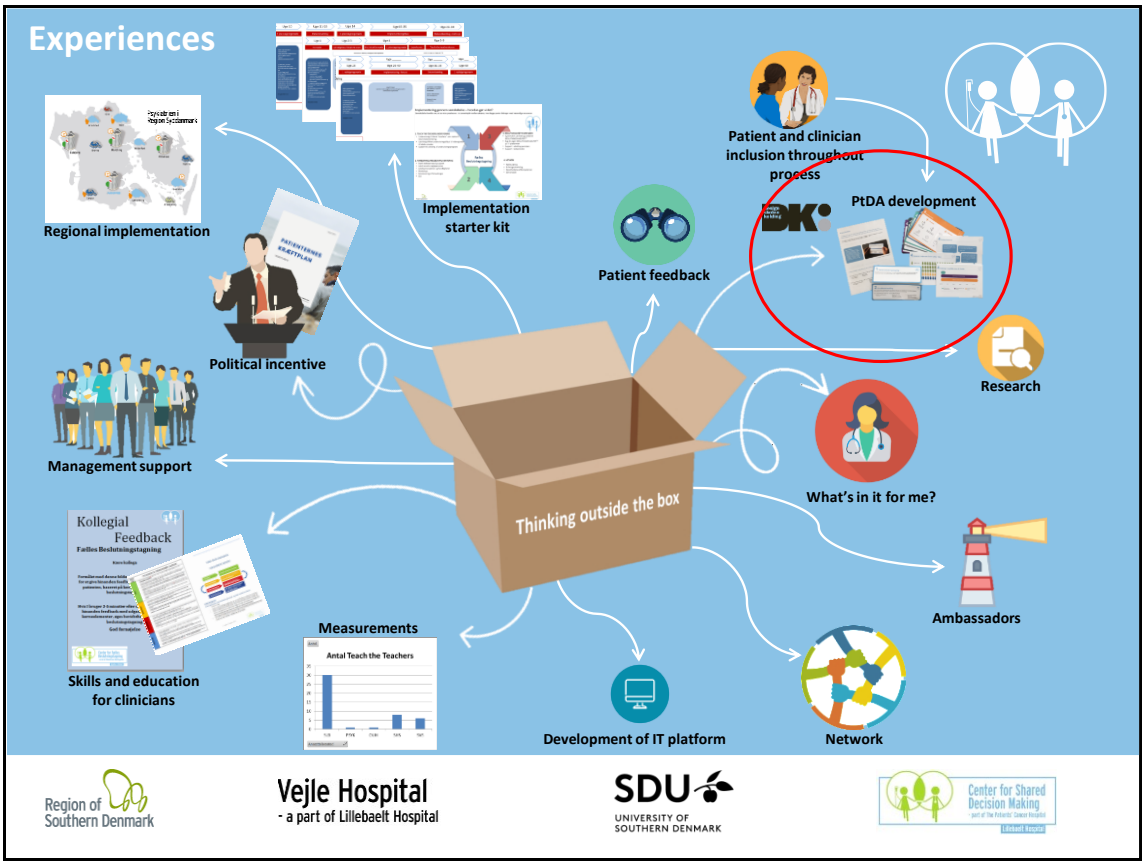
After 5 years of (predominantly) research, the Region of Southern Denmark decided to implement shared decision making across all hospital sites at a regional level.

Therefore, we are now in the midst of a regional implementation amongst the five hospital units within the Region of Southern Denmark. In the beginning we selected two to three pioneering departments at each hospital unit for the launch of SDM implementation.



Though a political incentive is important, **management support** is crucial for a successful implementation. Without buy-in from management, it can be difficult to cut through red tape, and working with shared decision making will become trapped in small organisational silos with no real influence on how to scale up and disseminate lessons learned.

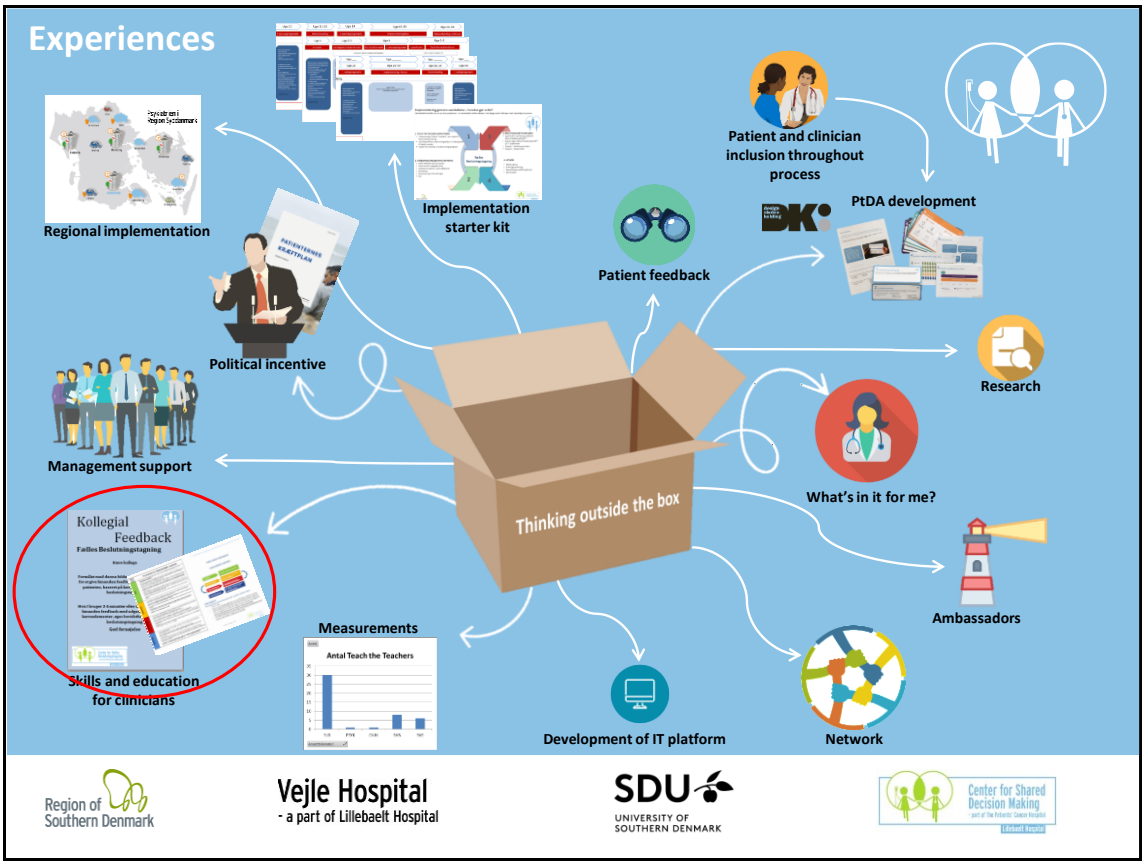
It is key to the success of SDM implementation that organisational leaders should not only 'talk the talk' they really need to 'walk the walk'.



Shared decision making is often done in conjunction with patient decision aids (PtDAs) and many of the reported positive effects of SDM come from studies that have used PtDAs as a method for implementing SDM.

Together with **Design School Kolding** (a Danish design school)**, patients and clinicians** we have **developed a within-consultation PtDA**, showing benefits and drawbacks of different treatment options in a brief visual and readable way.

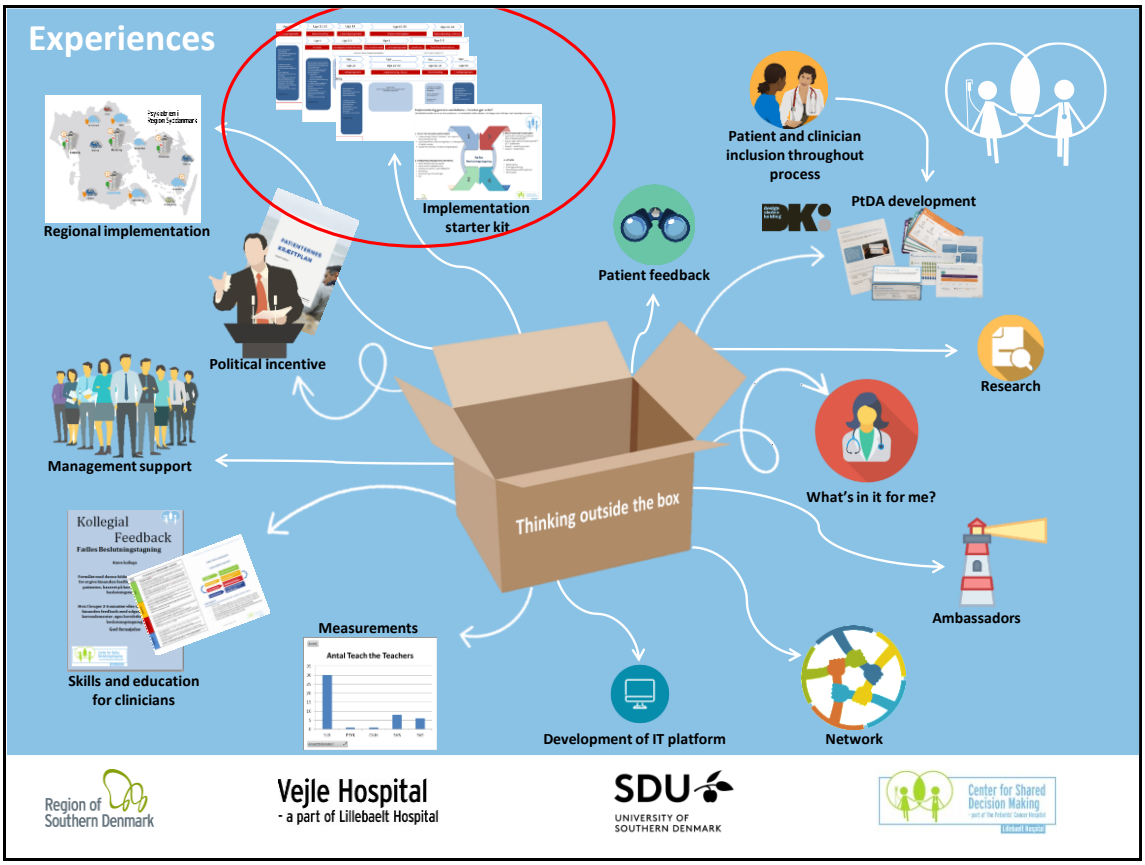
Patient Decision Aids cannot stand alone and are currently available for only a limited number of conditions, but for policy makers without pre-existing knowledge on SDM these are very concrete tools (clinicians also like them for this reason). National SDM implementation strategies are in place in several countries and often begin by focusing on PtDAs (Coulter, 2018). The use of a PtDAs does not, in itself, ensure SDM, but it is well suited to facilitate SDM and can be a kind of Trojan horse as a visible means of achieving a goal.



Skills and education for clinicians

Leaders and clinicians are taught SDM through simulation and group work. Practical training rather than theoretical. Moreover, tools have been developed to improve the skills of the clinicians.

Lillebaelt Hospital runs a training programme to create sustainable improvement in a 1-day training course for clinicians in how to communicate options and share decisions with patients. The course was developed and is now implemented as part of the regional implementation strategy. The training course is an 8-hour course based on the 'train-the-trainers' principle – so we train the trainers and the trainers are clinicians that train their peers.



Implementation starter kit

Working with implementation consultants at each of the five hospital units within the Region of Southern Denmark, two to three pioneer departments have been appointed. In order for the pioneer departments to kick start the implementation process, the Center for Shared decision making has developed an implementation starter kit with standard work flows based on an improvement model from the Virginia Mason Hospital production system and offering teach-the-teacher in shared decision making skills for clinicians and for leaders, support in development of patient decision aids, measurements etc

Each pioneer department was given a 1 year starter kit that details the steps to be taken over 40 weeks to roll out SDM in the department. It includes information about:

Meeting with management

Appointment of steering group

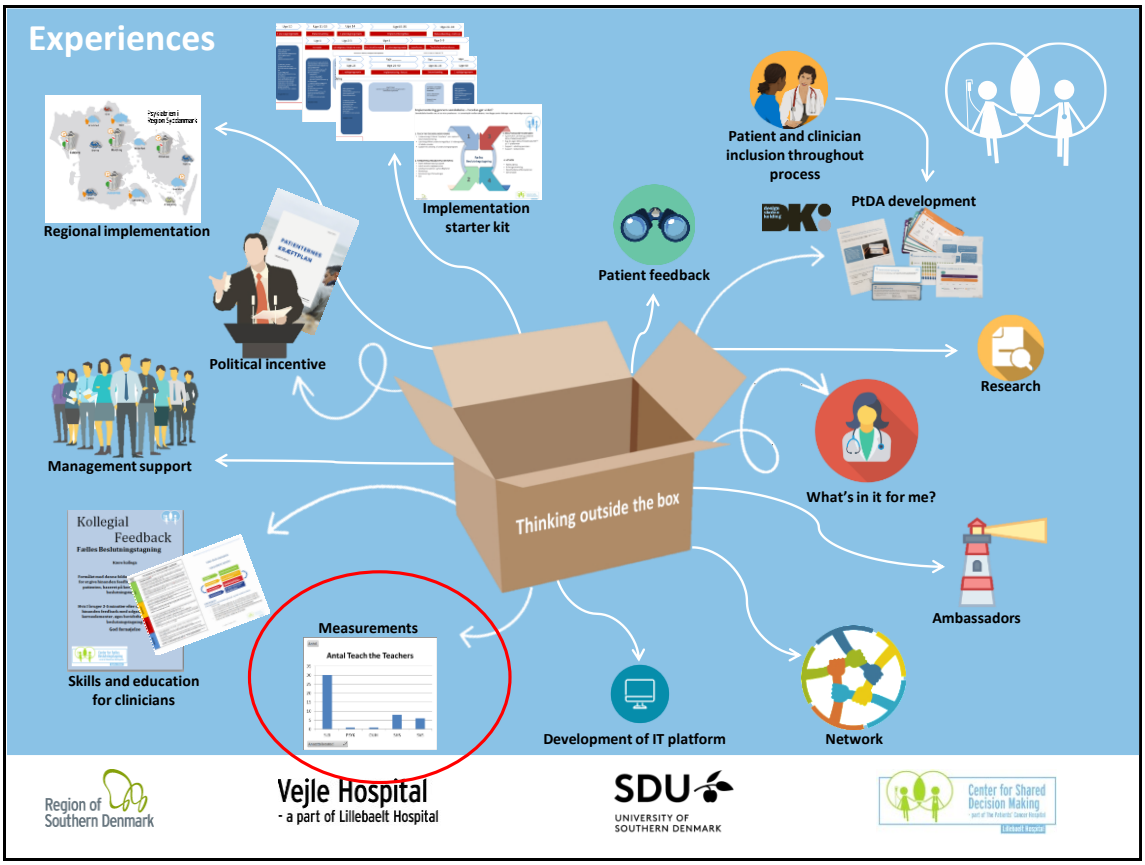
Building decision aids

Training clinicians

Peer training

It also includes a series of deadlines and standard agendas and minutes.

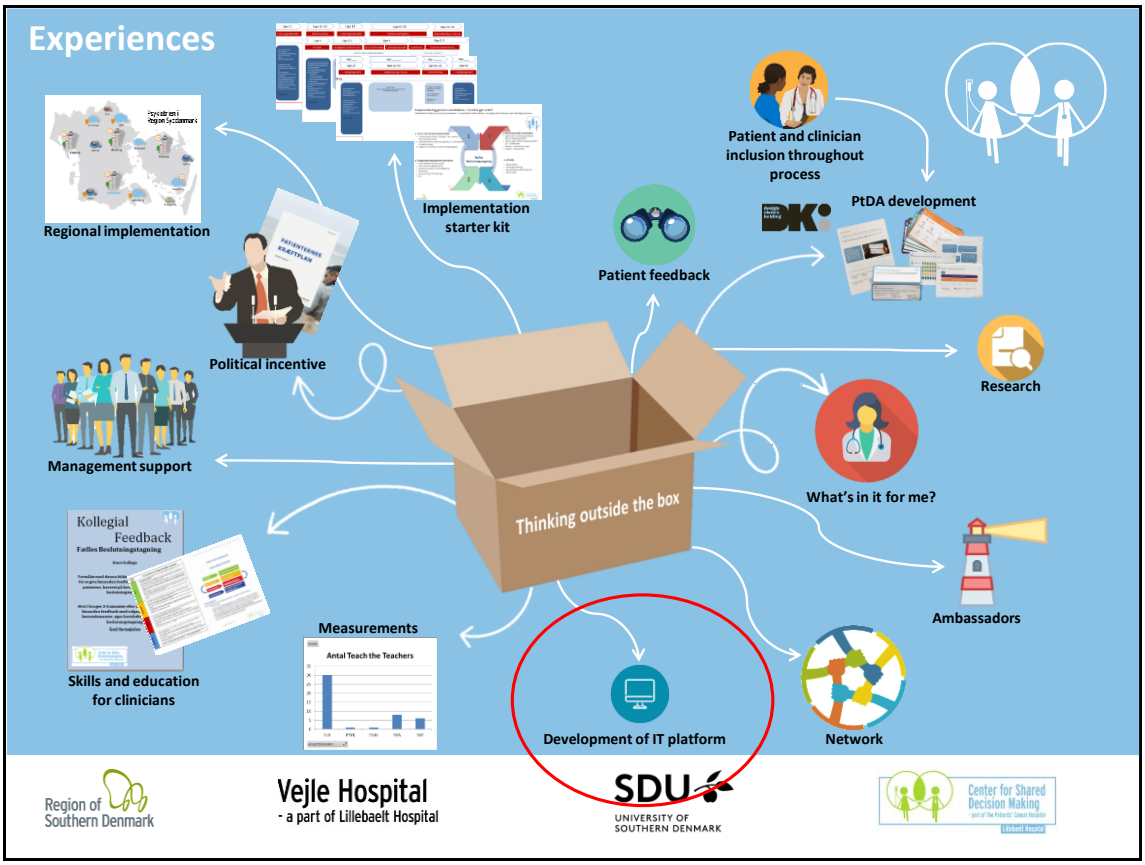
To support the rollout, there was also access to a teacher/trainer within the trust and a consultant in PtDAs, so there is help but they have to do it in their own departments.



Measurements

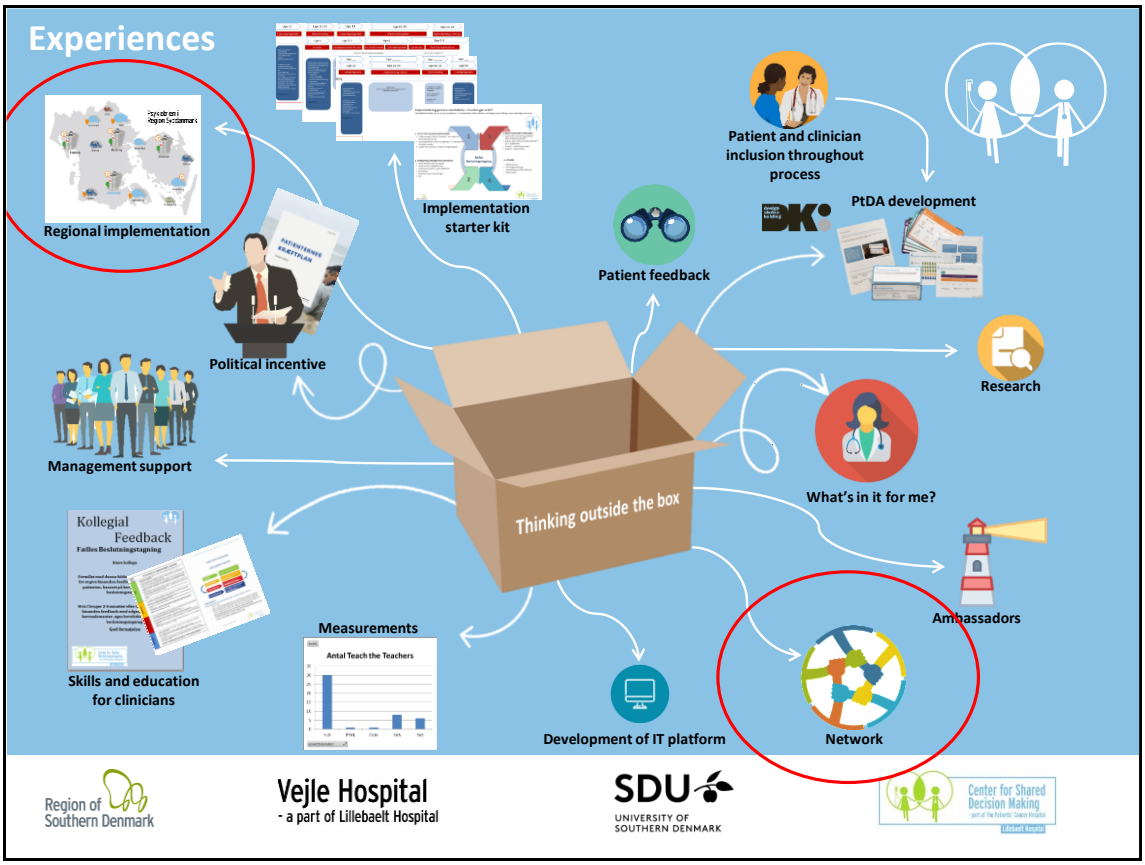
Alongside the implementation, measurements for performance and process and have been put in place. SDM can be difficult to measure, and pseudo measurements can be hard to avoid. The Center uses Option 12 as a method for measuring if and how SDM takes place during consultations. This will demonstrate how the clinician scores in SDM. There are other ways of measuring SDM, for example through surveys on patient experience. We have an annual survey of patient experiences here in Denmark where ½ million Danes are surveyed on their experiences with the public health care system and we conduct a survey monthly mini-survey of a quarter of a million in the southern region. This survey now includes two questions on patient experienced SDM.

Option 12 is resource intensive because it requires a person to sit in on consultation or listen to recording. There are also process indicators in place – number of people trained etc.



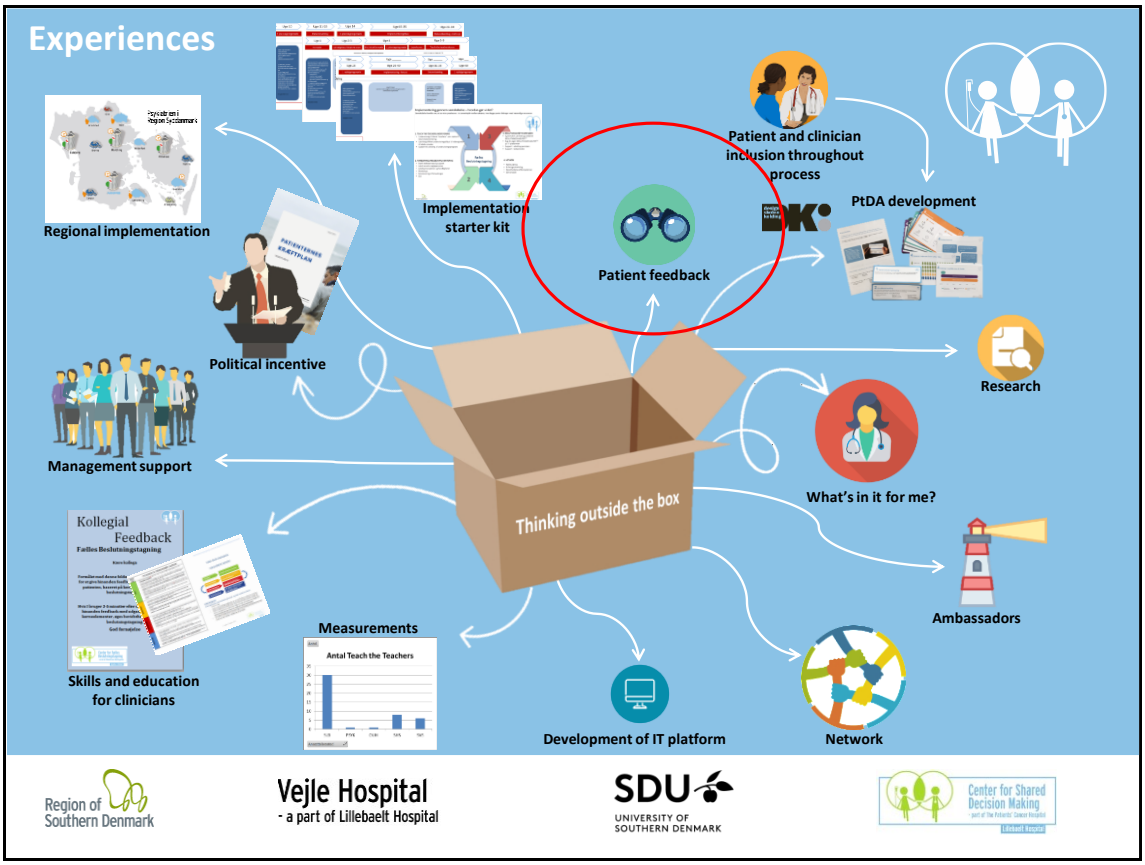
Development of IT platform

Developing PtDAs without pre-existing knowledge is quite a task and we have learned that very few clinicians are aware of the international quality criteria for PtDAs (IPDAS). Moreover, building and developing a patient decision aid from scratch is cumbersome and very time consuming. We have therefore developed an IT platform where clinicians can build patient decision aid from a generic PtDA template that can be adjusted and developed to fit any given situation for screening, treatment or diagnostic options.



A **network** of implementation consultants amongst the five hospital units within the region of Southern Denmark have been employed in order to monitor the pioneer units and facilitate the implementation process and organisational changes.

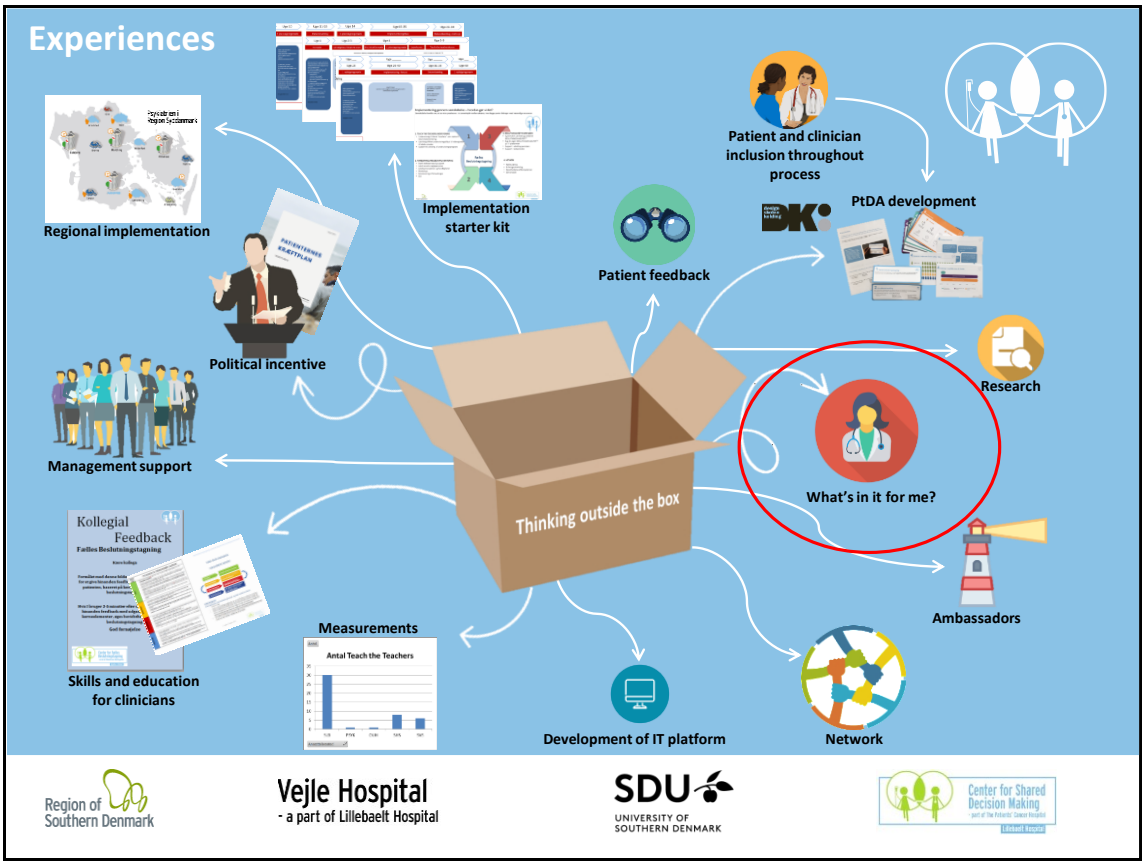
All the implementation consultant meet monthly with each other in a shared knowledge network. This is also resource intensive.



Patient feedback is essential during this kind of organisational change within the healthcare system. Also, statements from patients are extremely powerful tools to help change the culture of the hospitals and attitude of clinicians.

It is a mirror to hold up in front of the clinician and leaders. Engaging patients in boards, research committees and in the development of PtDAs has really helped pave the way to showing clinicians that patients want to be involved.

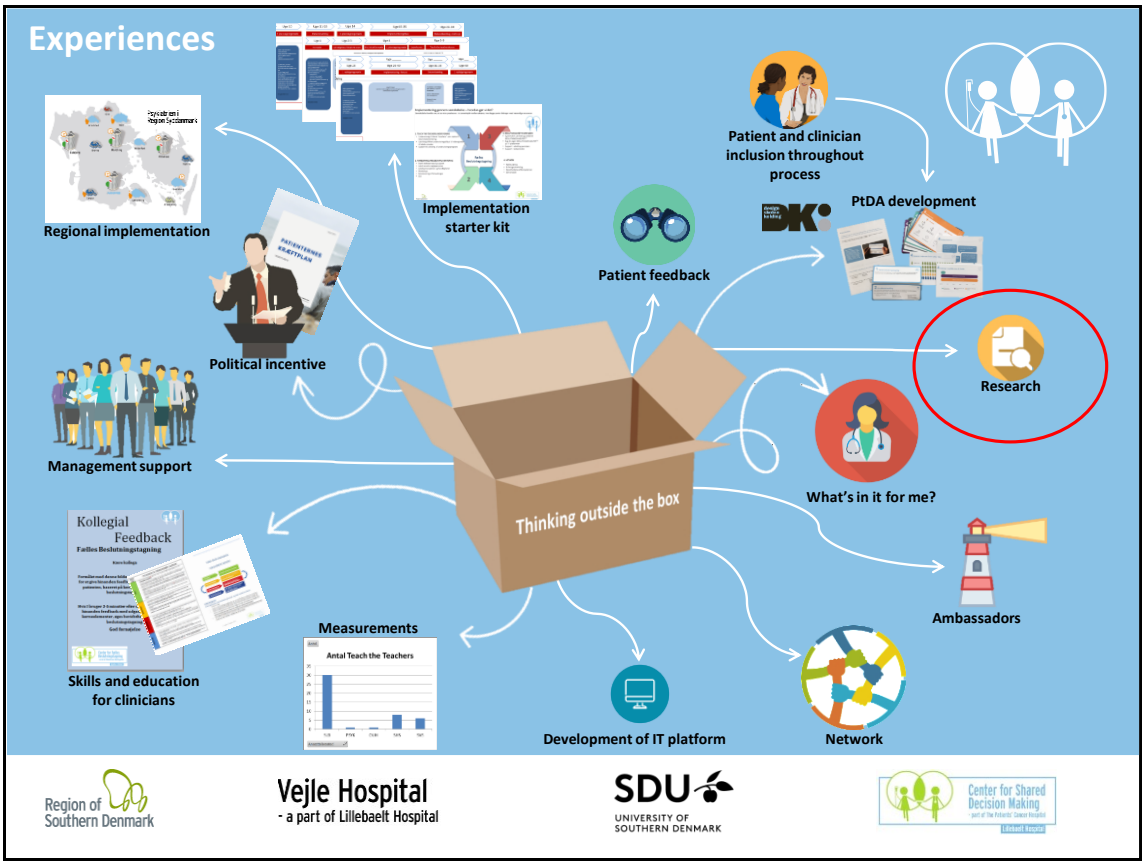
Questionnaires about patient experience that are part of the survey within the Region of Southern Denmark now include questions about SDM.



What's in it for me

My own personal experience is that you have to be invested in SDM in order to implement it into one's own practice. To me this means that I need to reflect on what's in it for me and how this influences my professional relationship with my patients. I believe there is an ethical imperative to implement SDM within the healthcare system because SDM simply is common sense to me. The most important reason for practising shared decision making is that it is the right thing to do. All clinicians have an ethical duty to inform patients about options and elicit their preferences. SDM is a way to be sure that patients are being heard and treated as people and not just as numbers within a system.

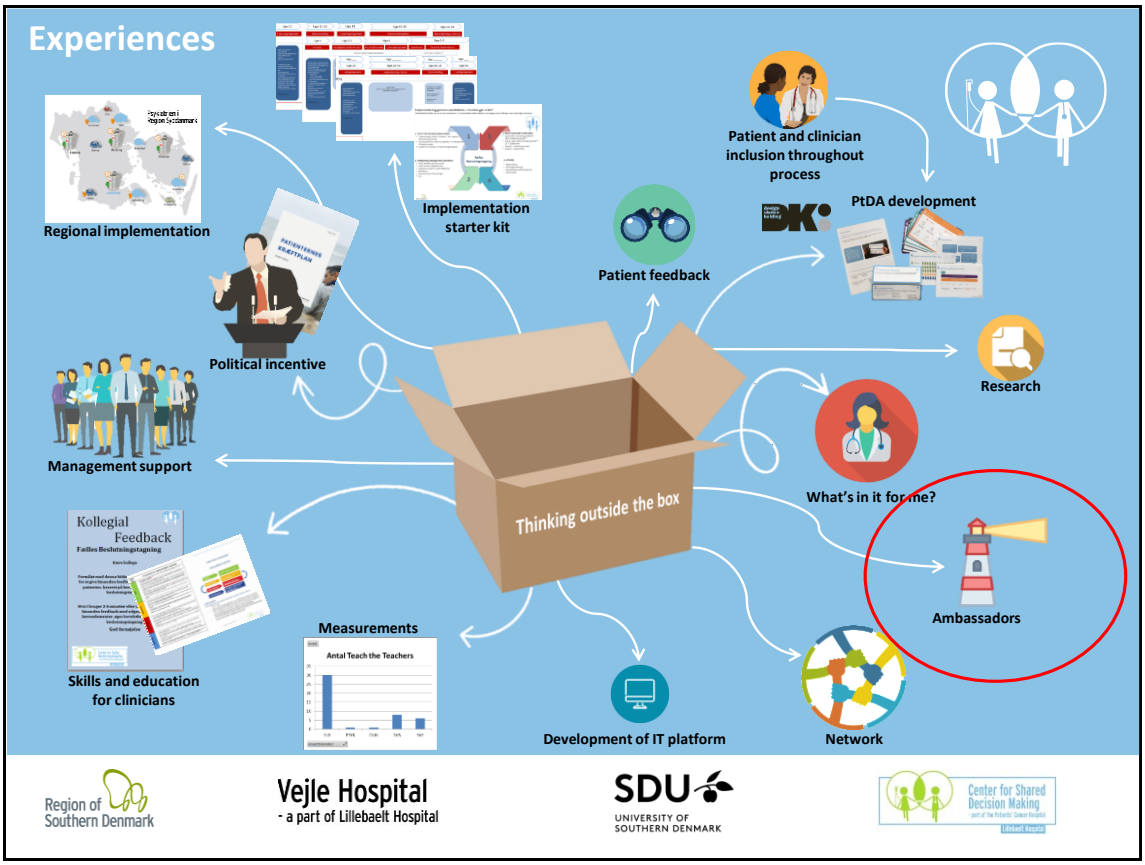
Engaging client in SDM in early consultations can also mean that future consultations are easier and shorter even if the initial SDM itself took time.



Research

Research is a high priority for clinicians as they often require evidence before they can support new methods of improving their practice. What is the evidence? – "show me it works and then I will consider it"

The Center for Shared decision making has initiated multiple research programmes on SDM and engaged key opinion leaders to lead this and to have their names on the publications. This is also a way to create buy in and can be seen as a way to engage clinicians – especially doctors - in SDM.



Ambassadors

National associations and local beacons can help pushing perspectives and attitudes towards SDM.

Recruit key champions for SDM, for example, make you local hero, the doctor that is skilled and that everyone respects the ambassador for SDM – someone that the majority of peers will follow.

This is a great method for establishing knowledge and support within a hospital unit. It can especially be helpful in the dissemination of SDM, if the associations and beacons are highly respected, as this creates an incentive for implementation of SDM.

This is one of the ways we have moved our initiative along and probably why the hospital board appointed me – a medical doctor with a track history of ovarian cancer biomarker research to build and lead this initiative and to begin with the cancer area. Identifying and recruiting key opinion leaders among hospital staff was felt to be very important to strengthen clinical relevance and sustainability and counter any resistance to change.

Moreover, in Denmark the Younger doctors/Danish Medical Association have created ambassadors for SDM and offering classes on SDM for younger doctors so they can become SDM ambassadors.


Q&A session
Want to know more?
www.cffb.dk
Region of Southern Denmark
Vejle Hospital
- a part of Lillebaelt Hospital
SDU
UNIVERSITY OF SOUTHERN DENMARK
Center for Shared Decision Making

1 Testimony 4: Paul Myres & Maria Gallagher

2

GWNEUD DEWISIADAU GYDA'N GILYDD MAKING CHOICES TOGETHER
Partneriaeth Dewis Doeth Cymru / Choosing Wisely Wales Partnership

Shared Decision Making: the story from Wales

Paul Myres
Academy of Medical Royal Colleges Wales

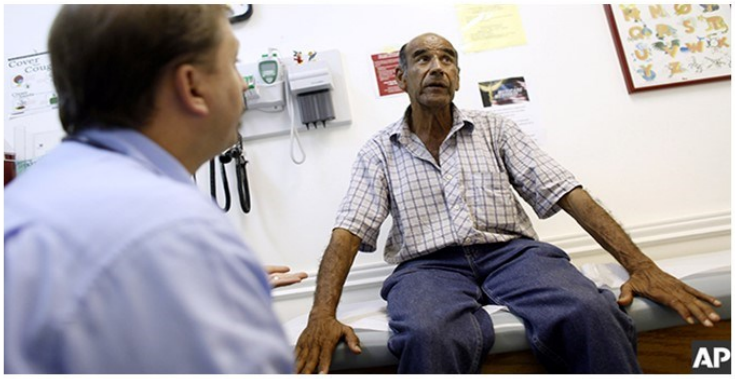
Maria Gallagher
Improvement Cymru
Choosing Wisely Wales Collaborative

AMRCW | GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales

3

"Doctor knows best"

"Patients know what's right for them"



GWNEUD DEWISIADAU GYDA'N GILYDD MAKING CHOICES TOGETHER
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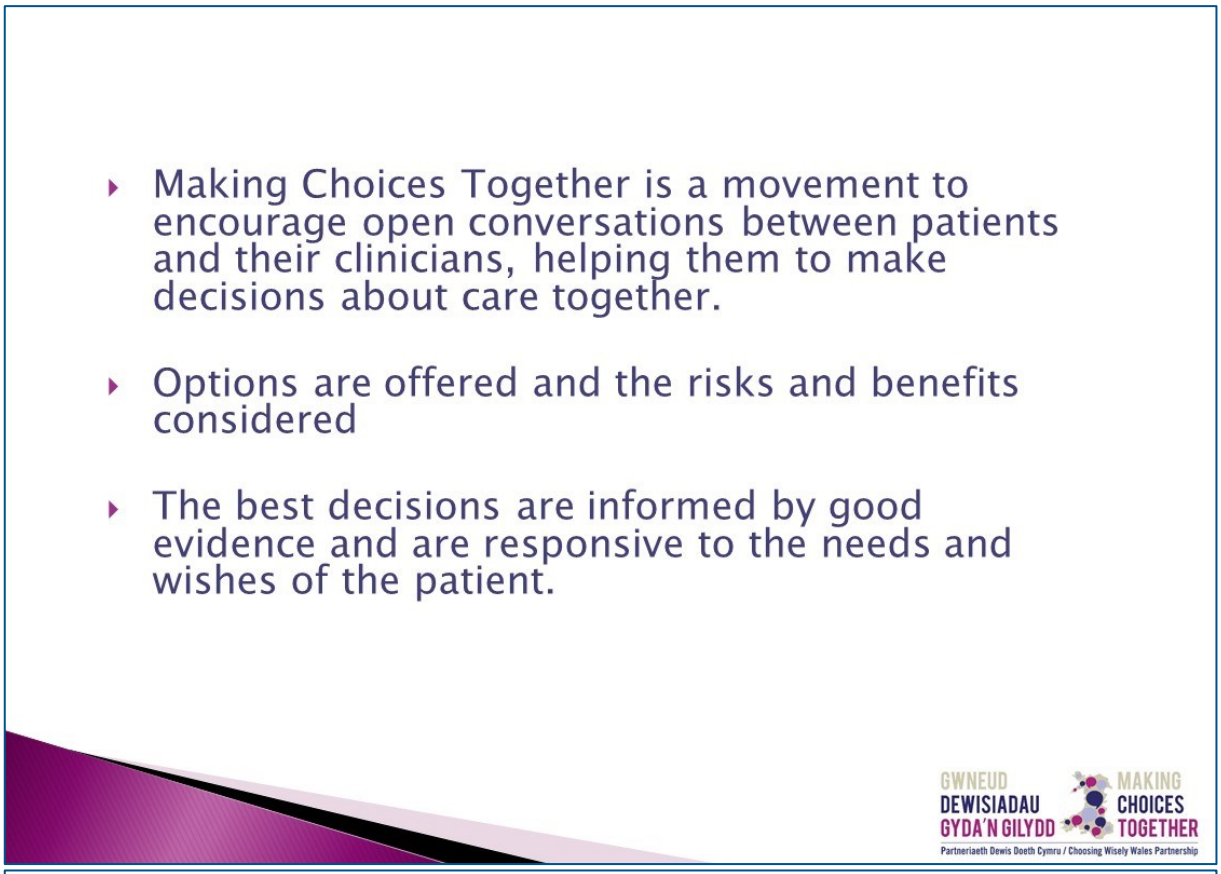
Making Choices Together is a movement to encourage open conversations between patients and their clinicians, helping them to make decisions about care together.
Options are offered and the risks and benefits considered
The best decisions are informed by good evidence and are responsive to the needs and wishes of the patient.
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MAKING CHOICES TOGETHER
Partneriaeth Dewis Doeth Cymru / Choosing Wisely Wales Partnership

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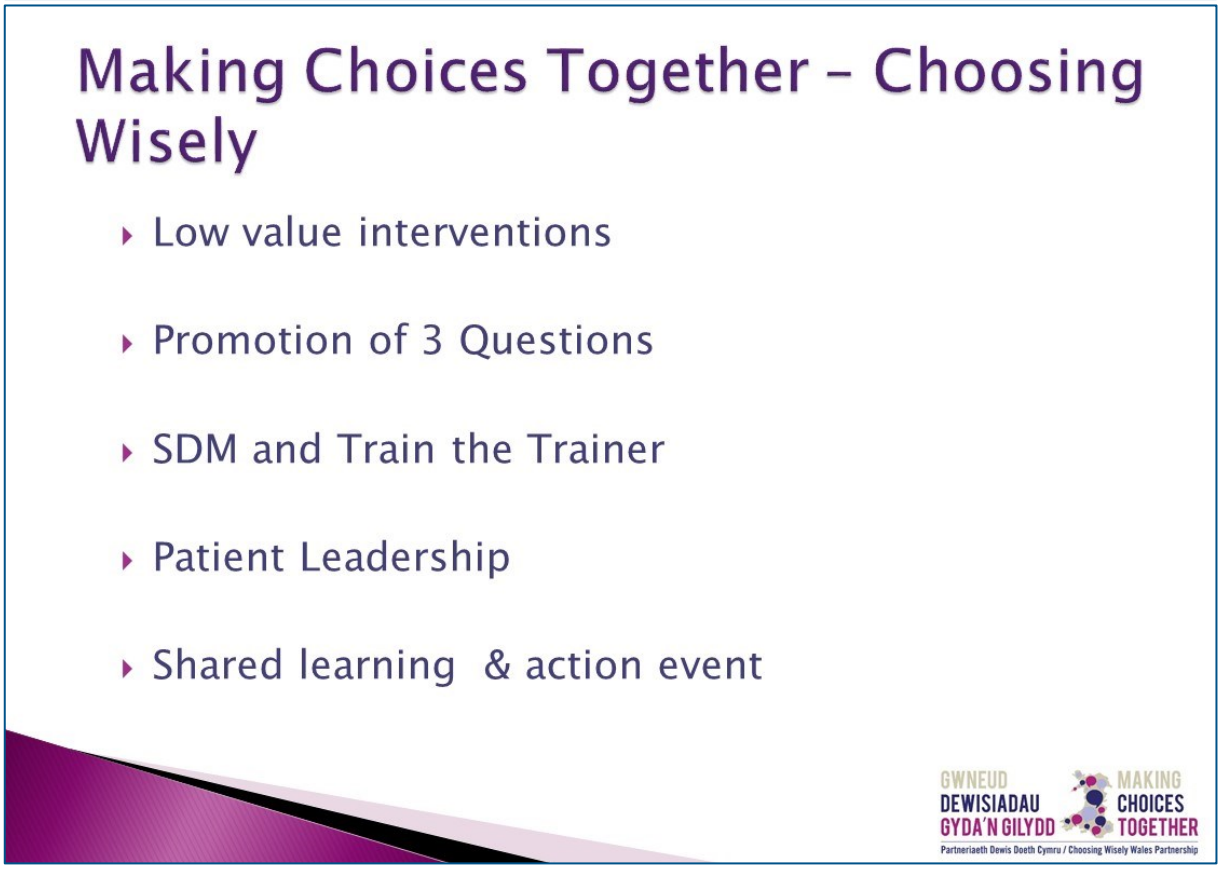
Making Choices Together – Choosing Wisely
Low value interventions
Promotion of 3 Questions
SDM and Train the Trainer
Patient Leadership
Shared learning & action event
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MAKING CHOICES TOGETHER
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2


What is shared decision making?
Clinicians and patients working together in partnership to select tests, treatments, management or support options based on clinical evidence and the patient's need and informed preferences.
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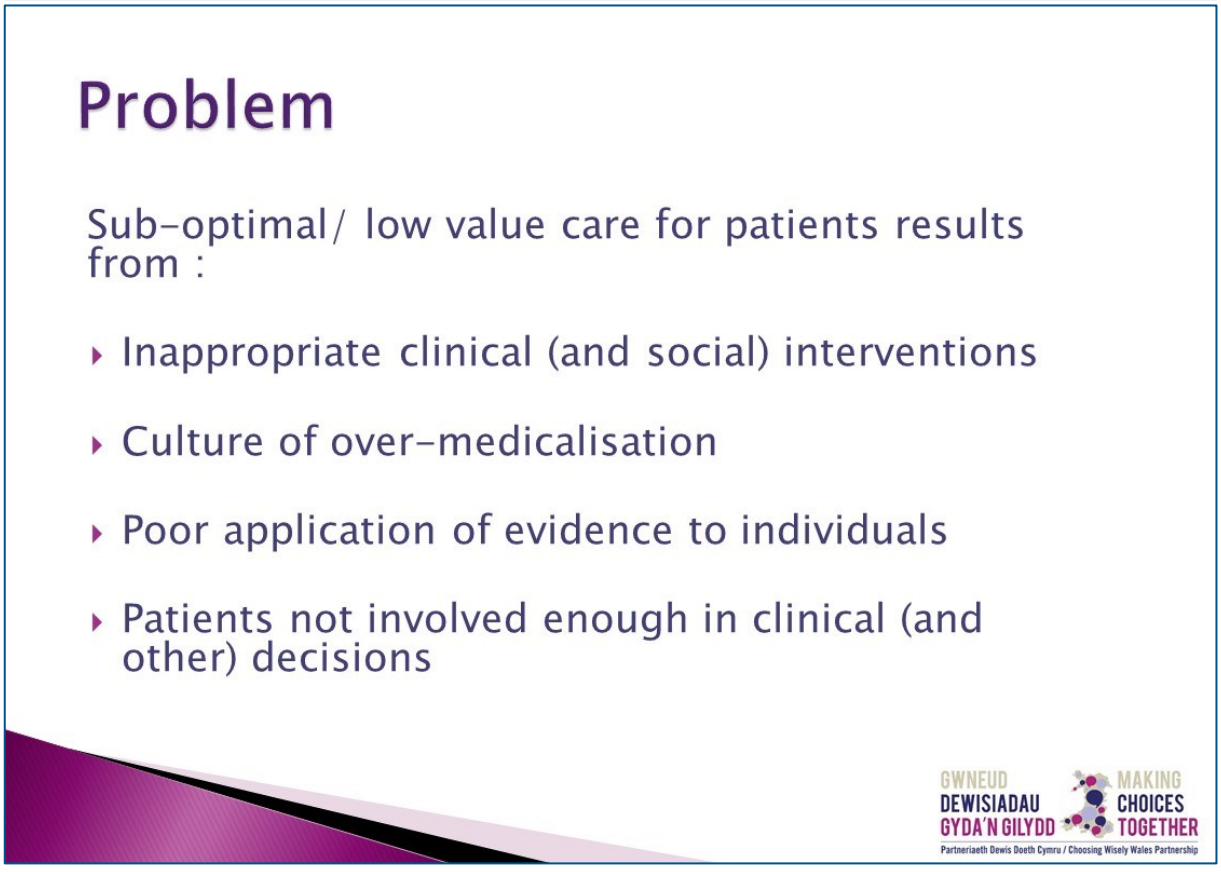
Problem
Sub-optimal/ low value care for patients results from :
Inappropriate clinical (and social) interventions
Culture of over-medicalisation
Poor application of evidence to individuals
Patients not involved enough in clinical (and other) decisions
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2


Assumptions :Why promote SDM
Patients want to be more involved in decisions
Patients and clinicians over-estimate treatment benefits and under-estimate treatment harms
What patients want and what clinicians think they want are often very different
SDM is enshrined in professional codes of conduct
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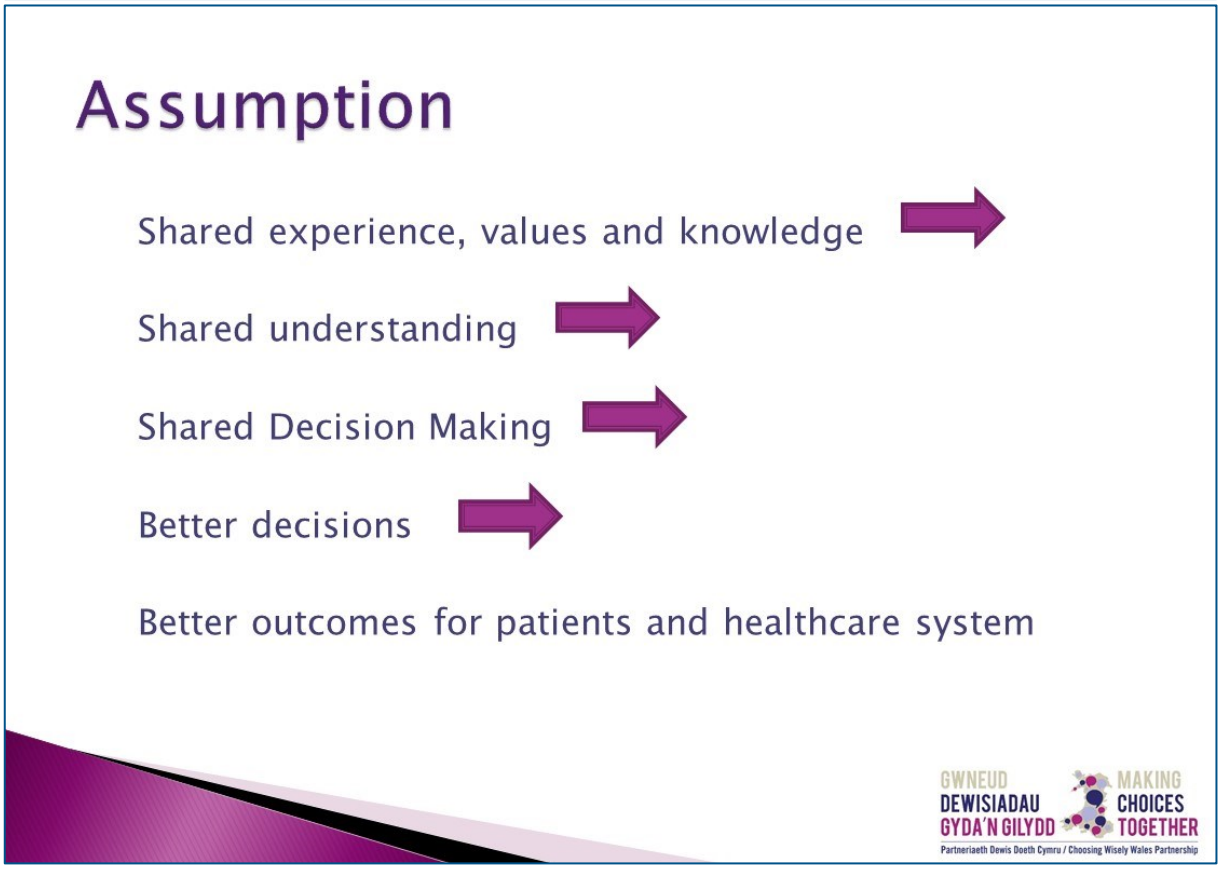
Assumption
Shared experience, values and knowledge
Shared understanding
Shared Decision Making
Better decisions
Better outcomes for patients and healthcare system
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Context – Prudent healthcare, Value(s) based healthcare

- Patient involvement
- Shared goal setting
- Shared decision making
- Service redesign – including elimination of unnecessary steps and duplication
- Reduce unwarranted variation
- Reduce overdiagnosis and overtreatment

MAGIC methods tested in Wales
Academic expertise in Cardiff University

1

Principles: Our Approach

- Much of the evidence base available to describe and address the major challenges we face are based on a deficit model.
- Deficit models focus on identifying problems and needs, requiring professional resources and often pushing people into 'services' as the only option of support.
- Assets models accentuate positive abilities and capabilities to promote solutions that activate solutions that promote autonomy, connection, and self determination – the core components of self determination theory in well-being evidence.

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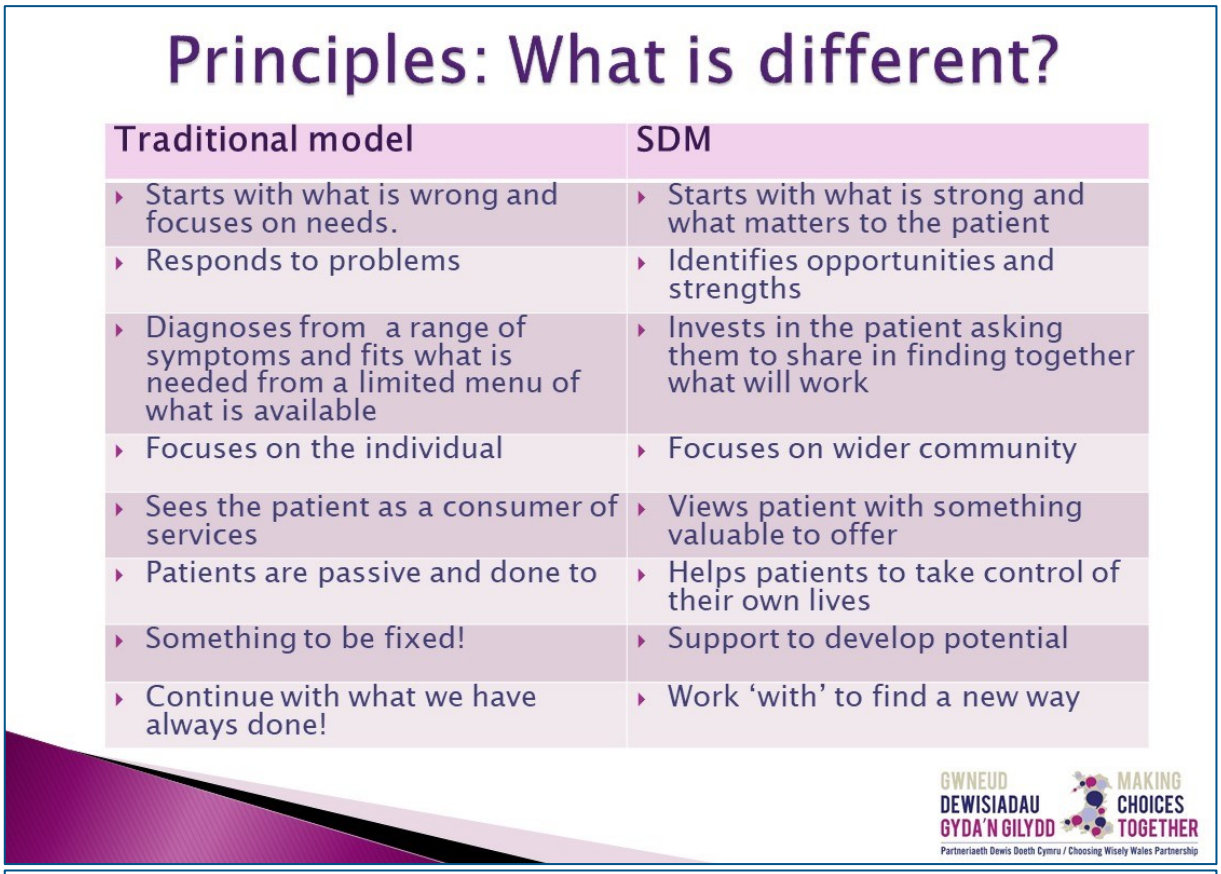
Principles: What is different?
Traditional model
SDM
Starts with what is wrong and focuses on needs.
Starts with what is strong and what matters to the patient
Responds to problems
Identifies opportunities and strengths
Diagnoses from a range of symptoms and fits what is needed from a limited menu of what is available
Invests in the patient asking them to share in finding together what will work
Focuses on the individual
Focuses on wider community
Sees the patient as a consumer of services
Views patient with something valuable to offer
Patients are passive and done to
Helps patients to take control of their own lives
Something to be fixed!
Support to develop potential
Continue with what we have always done!
Work 'with' to find a new way
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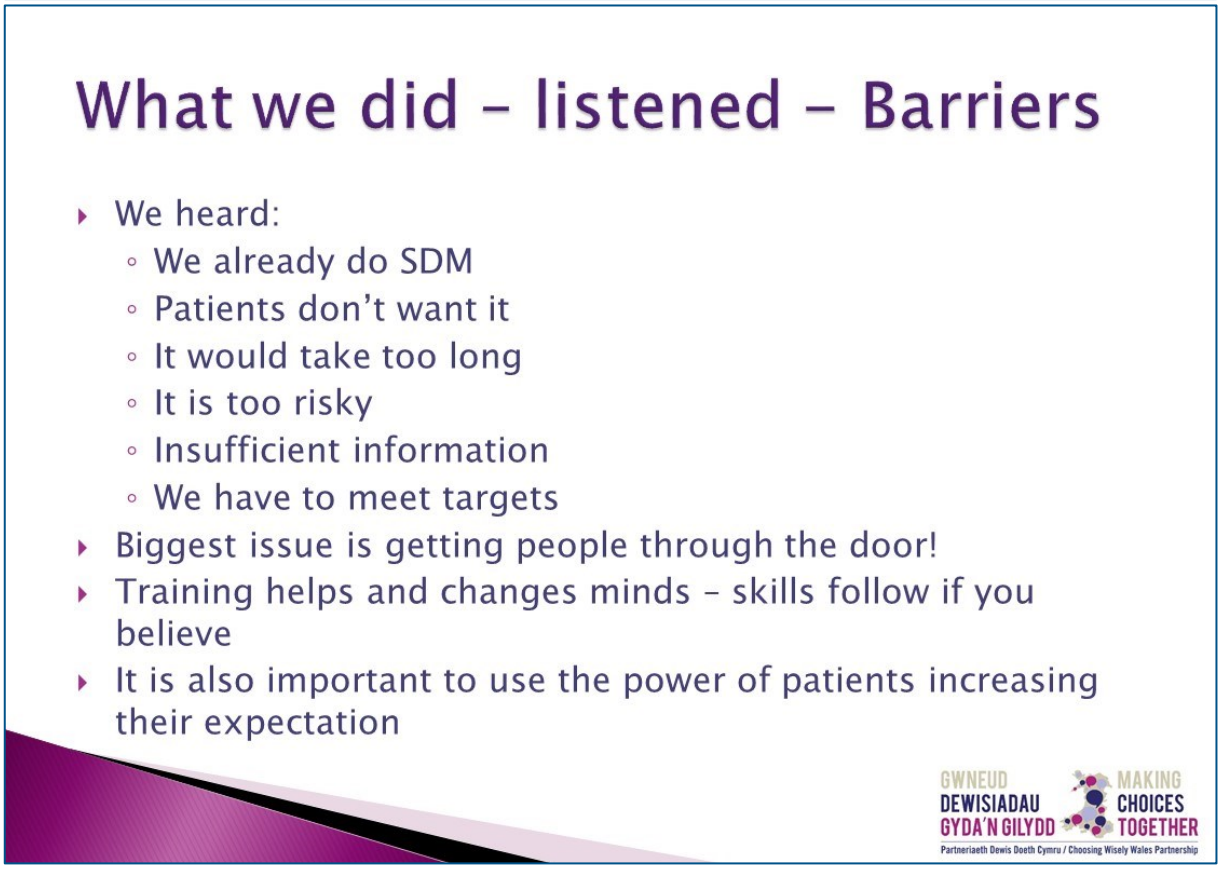
What we did – listened – Barriers
We heard:
We already do SDM
Patients don't want it
It would take too long
It is too risky
Insufficient information
We have to meet targets
Biggest issue is getting people through the door!
Training helps and changes minds – skills follow if you believe
It is also important to use the power of patients increasing their expectation
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2


What we did – awareness raising
Community Health councils
Community Groups
Professional advisory groups
Professional Associations
Health Boards
Open meetings
Clinical teams
Minister of Health & CMO
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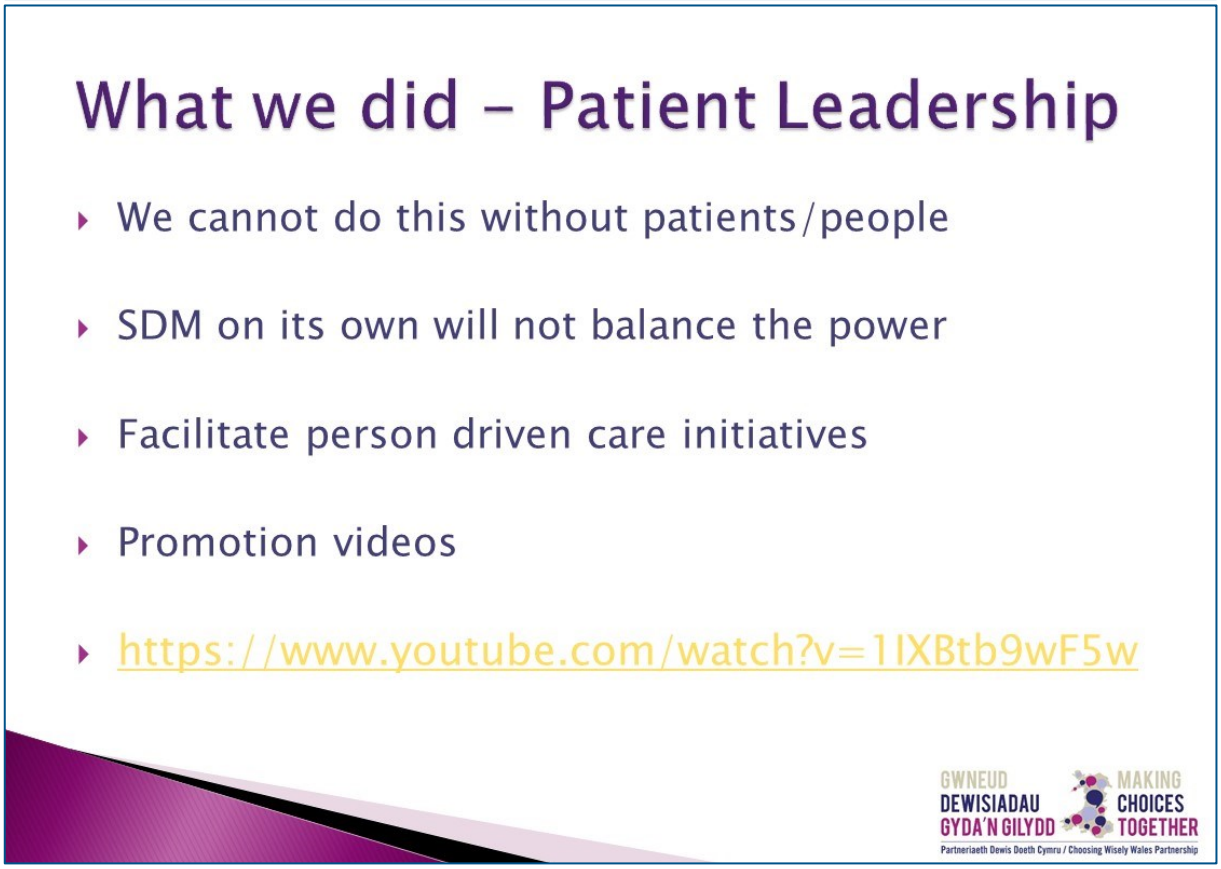
What we did – Patient Leadership
We cannot do this without patients/people
SDM on its own will not balance the power
Facilitate person driven care initiatives
Promotion videos
https://www.youtube.com/watch?v=1IXBtb9wF5w
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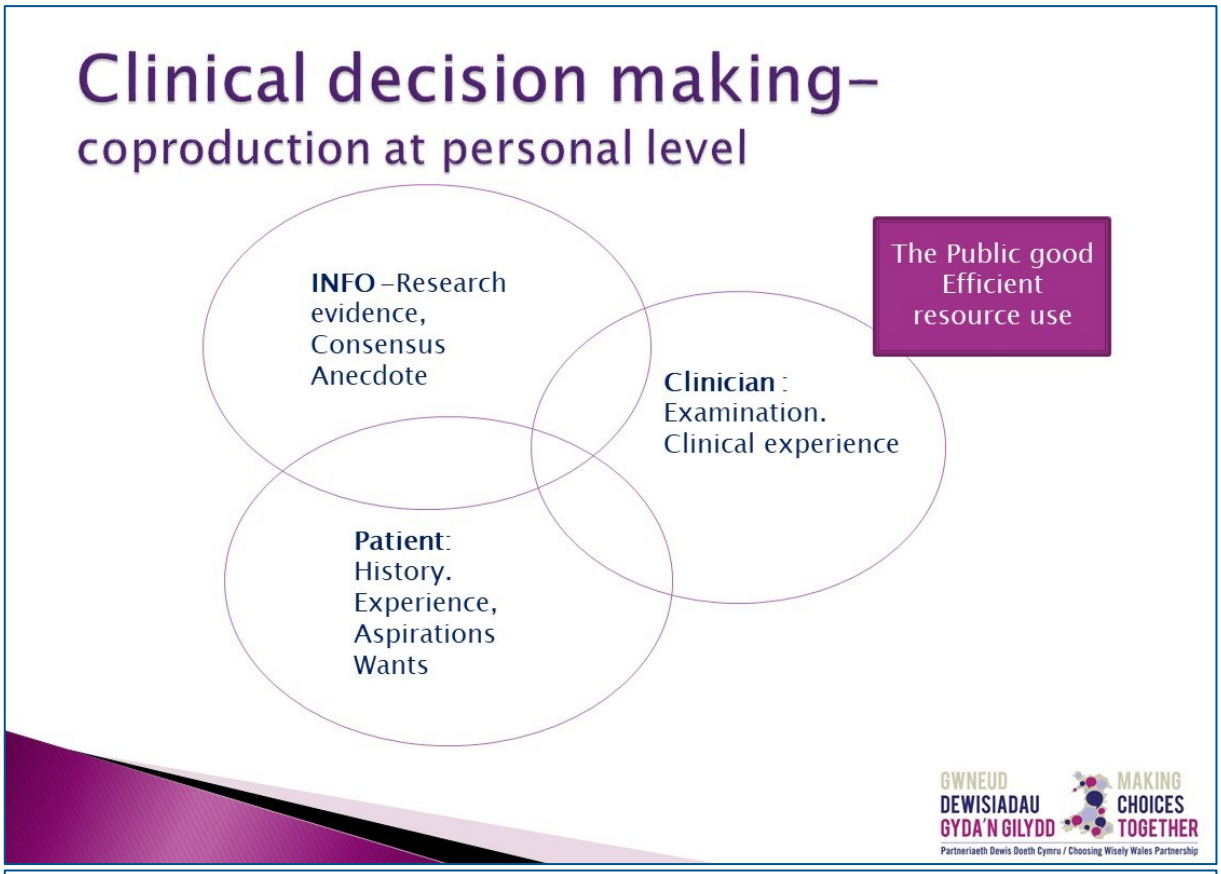
Clinical decision making–
coproduction at personal level
INFO –Research evidence, Consensus Anecdote
Clinician : Examination. Clinical experience
Patient: History. Experience, Aspirations Wants
The Public good Efficient resource use
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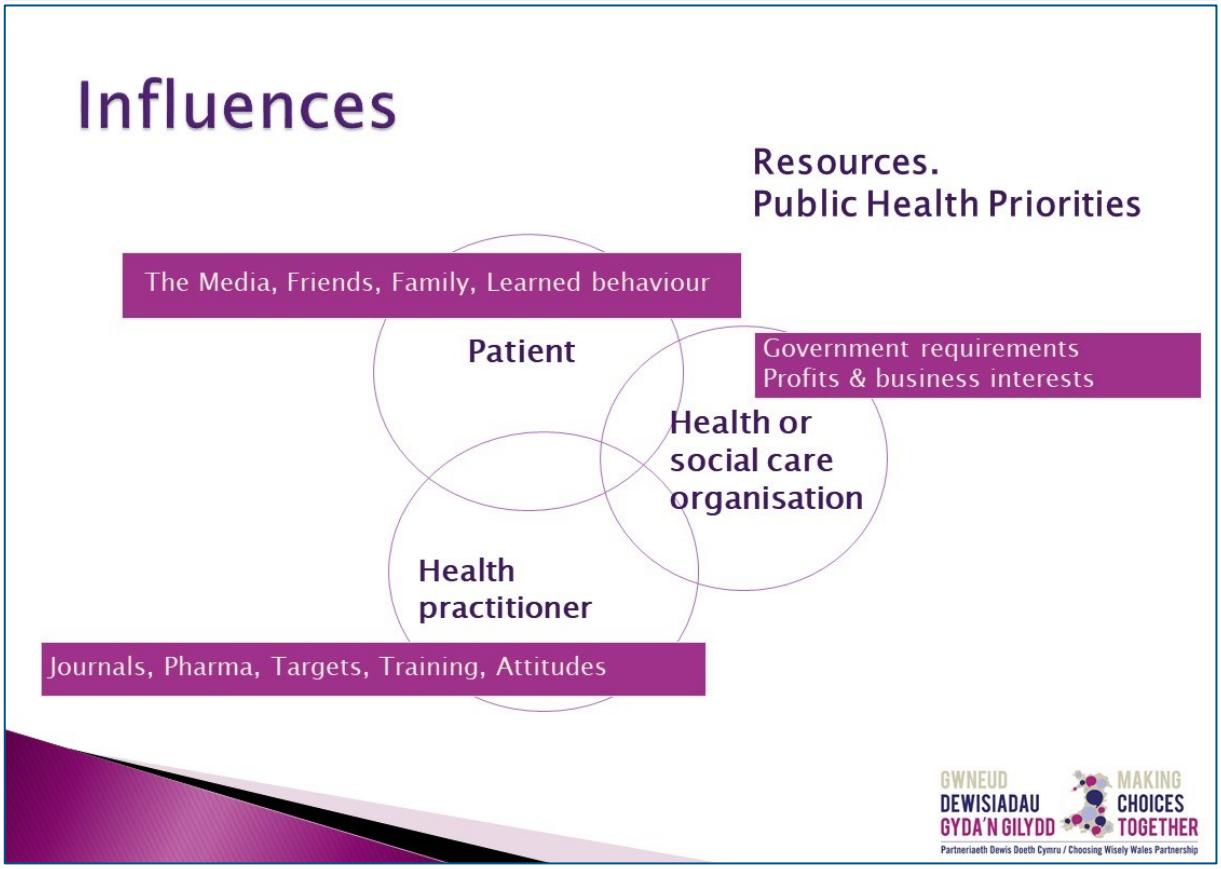
Influences
Resources.
Public Health Priorities
The Media, Friends, Family, Learned behaviour
Patient
Government requirements
Profits & business interests
Health or social care organisation
Health practitioner
Journals, Pharma, Targets, Training, Attitudes
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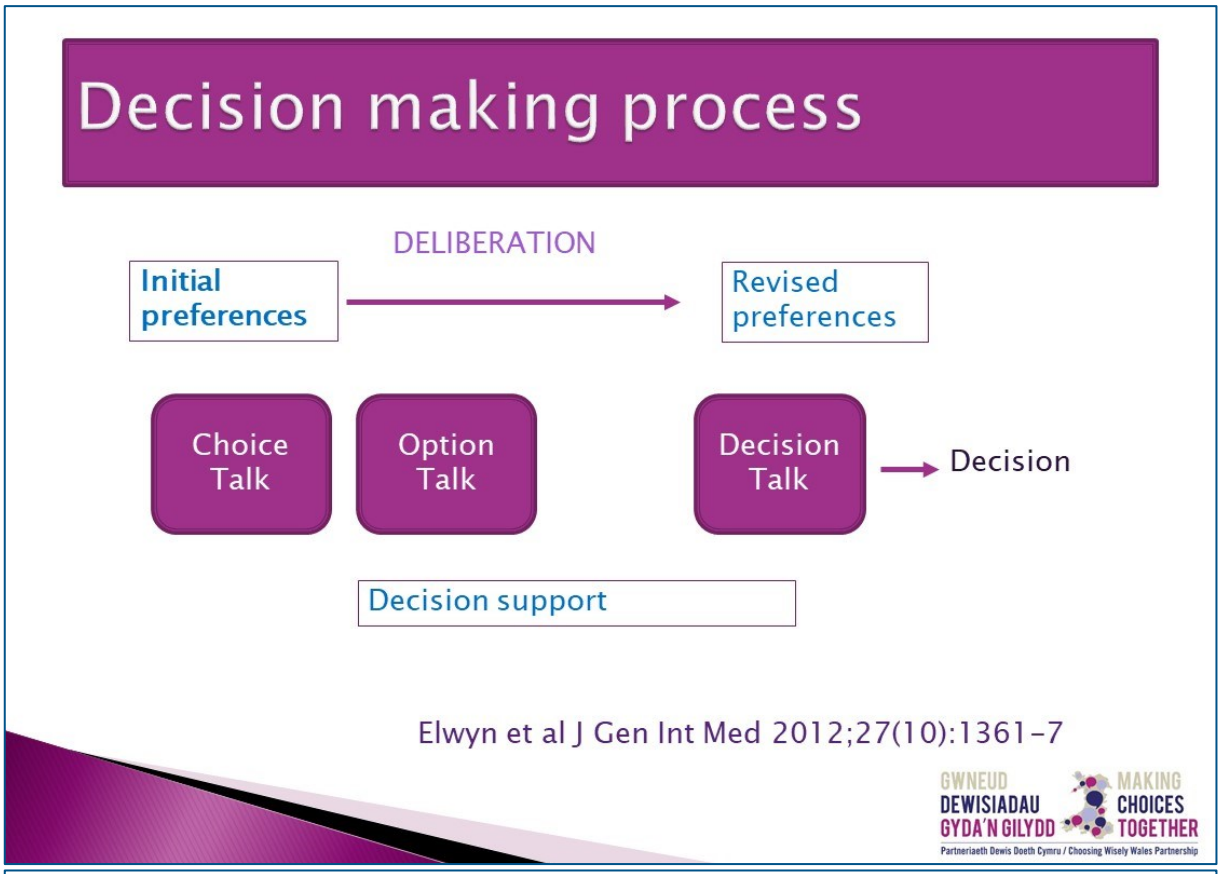
Decision making process
DELIBERATION
Initial preferences
Revised preferences
Choice Talk
Option Talk
Decision Talk
Decision
Decision support
Elwyn et al J Gen Int Med 2012;27(10):1361-7
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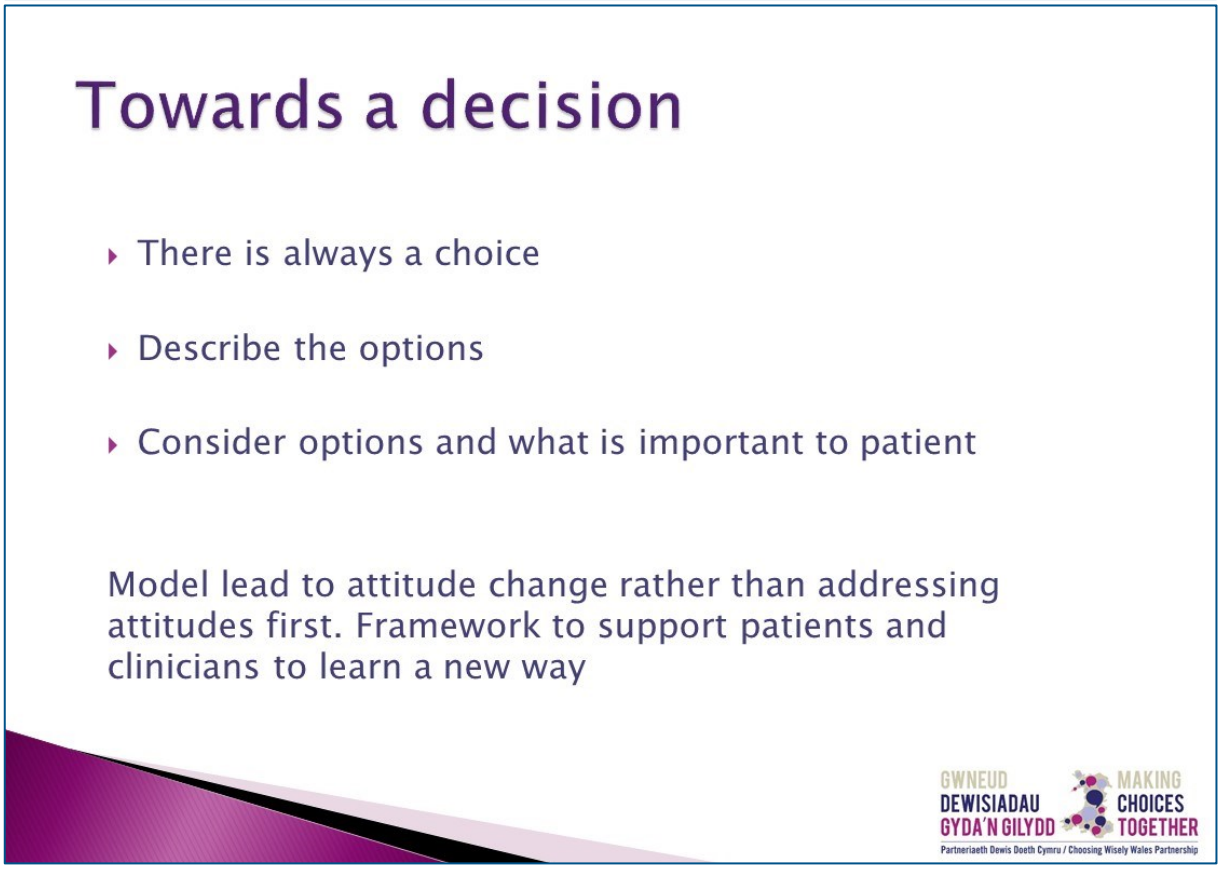
1


Towards a decision
There is always a choice
Describe the options
Consider options and what is important to patient
Model lead to attitude change rather than addressing attitudes first. Framework to support patients and clinicians to learn a new way
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2


Objectives: For clinicians:
I have used my experience and expertise to assess the problem
I have explained the options available and taken account of what is important to patient and what is possible
We have considered these options together and agreed what is the best course of action for this individual.
I have only ordered tests or undertaken procedures that have a likelihood of causing benefit with low risk of harm to the patient.
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Objectives: For organisations
We are meeting the needs and preferences of individuals interacting with our services
Our clinicians are applying evidence in the light of individual problems
There is less waste in our system
We are using community and personal assets effectively and efficiently
We are aiming to achieve outcomes relevant to individuals.
We are providing value based care
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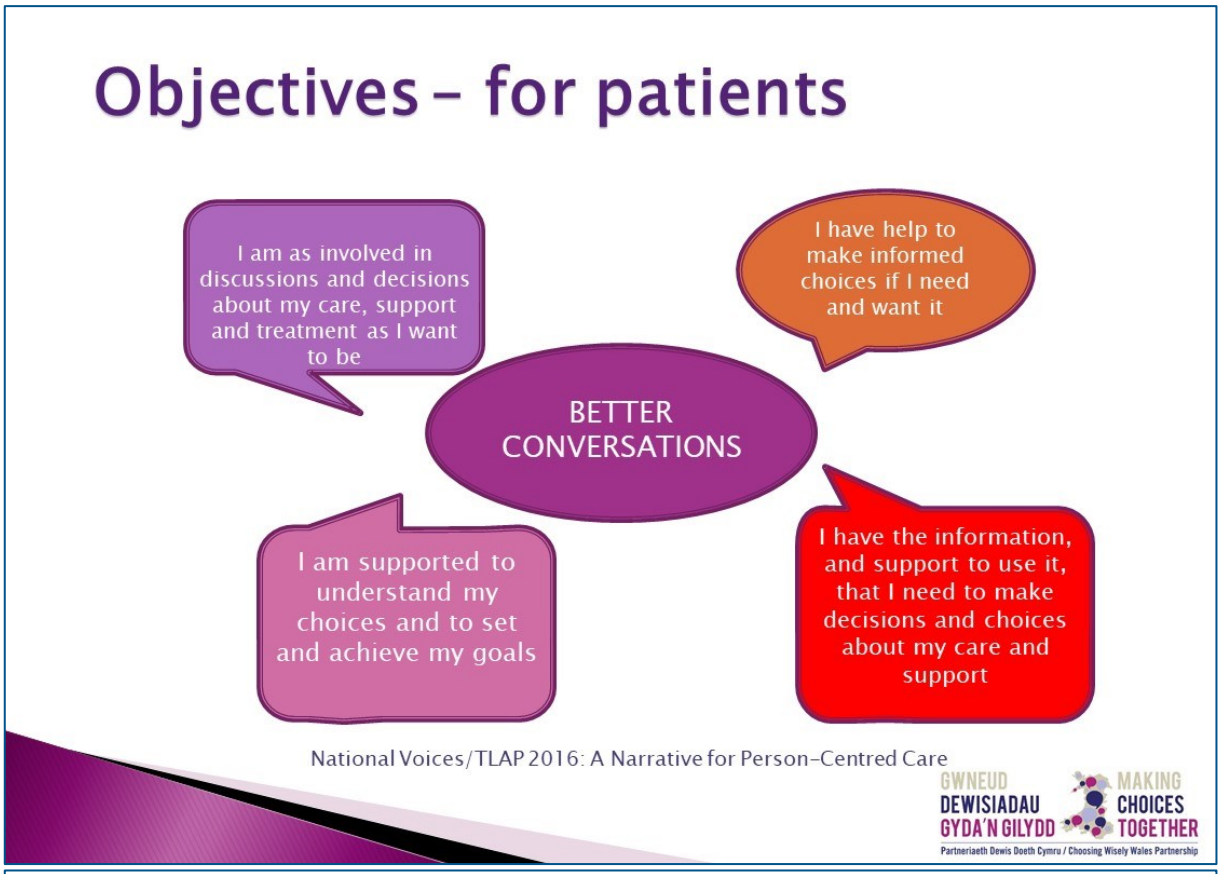
Objectives – for patients
I am as involved in discussions and decisions about my care, support and treatment as I want to be
I have help to make informed choices if I need and want it
BETTER CONVERSATIONS
I am supported to understand my choices and to set and achieve my goals
I have the information, and support to use it, that I need to make decisions and choices about my care and support
National Voices/TLAP 2016: A Narrative for Person-Centred Care
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1


SDM Training & Train the Trainer
Based on Health Foundation MAGIC programme
Adapted and delivered with Cardiff University
Very interactive
Role plays – focusing on skills rather than knowledge
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2

What we did

Activity	Purpose
Awareness raising	To activate people to proactively participate in decisions about their care and treatment with the aim of empowering people to make decisions about their care ensuring that treatment decisions are based on what matters to them, including the use of a co-produced decision aid
Low value interventions	To identify and share a list of clinical interventions where evidence suggests the chances of benefit are low
Shared decision making	To produce a cohort of SDM trainers in Wales to roll out training to clinical teams in Health Boards and primary care
Patient Leadership	To involve and support patients, service users and carers to become transformational agents of change with a focus on improving the quality of health and social care
Learning and sharing event	To share existing knowledge around SDM and to enable teams planning a service improvement involving shared decision making to consolidate the aims and objectives of the project and start action planning
MCT pilot programmes	As part of MCT's deliverables, the programme team were asked to work in close partnership with the service to develop a framework to implement MCT effectively within a health board, embedding a culture of SDM into clinical practice.

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What we did – SDM training

- SDM promotional workshops
- SDM Workshops delivered to
  - NHS Teams (incl Velindre Breast, ABHB physio, ABMU Community Child Health, North Wrexham Cluster, East BCUHB elderly Rehabilitation)
  - GP surgeries
- SDM Train the Trainer programmes of learning
  - During 2018 and 2019 delivered 9 workshops throughout Wales
  - 81 participants attended Workshop 1
  - 52 participants attended Workshop 2 and are now actively delivering SDM training
- Shared learning event

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2

1


ASK 3 QUESTIONS
1
What are my options?
Once I know what is important to you we can discuss all the possible options and together we can make the best choice for you. That's shared decision making.
2
What are the benefits and risks?
3
What can I do to help myself?
Join the conversation
@1000LivesWales
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2


R-Outcomes
MEASURE WHAT MATTERS
Your Measures
About the decisions agreed today
How much do you agree?
Strongly agree
Agree
Neutral
Disagree
We discussed what matters to me
I understand what my options are
I understand the benefits of all my options
I understand the risks/side-effects of all my options
I felt fully involved
I know what I need to do to help myself
AMRCN
GIG CYMRU NHS WALES
Iechyd Cyhoeddus Cymru
Public Health Wales


Our Achievements
ABUHB Physio Team cascading to whole directorate and evaluating outcomes
Patients more involved in care pathway development, Velindre
HEIW dental team trained and taking package to all Dental practices in Wales (Health Education and Improvement Wales)
HEIW Pharmacy Team trained and will include SDM into service improvement
SDM module now integral to IQT (Improving Quality together) Training in Wales
SDM resource pack to facilitate delivery
Embedding SDM as key component of Value Based Health Care
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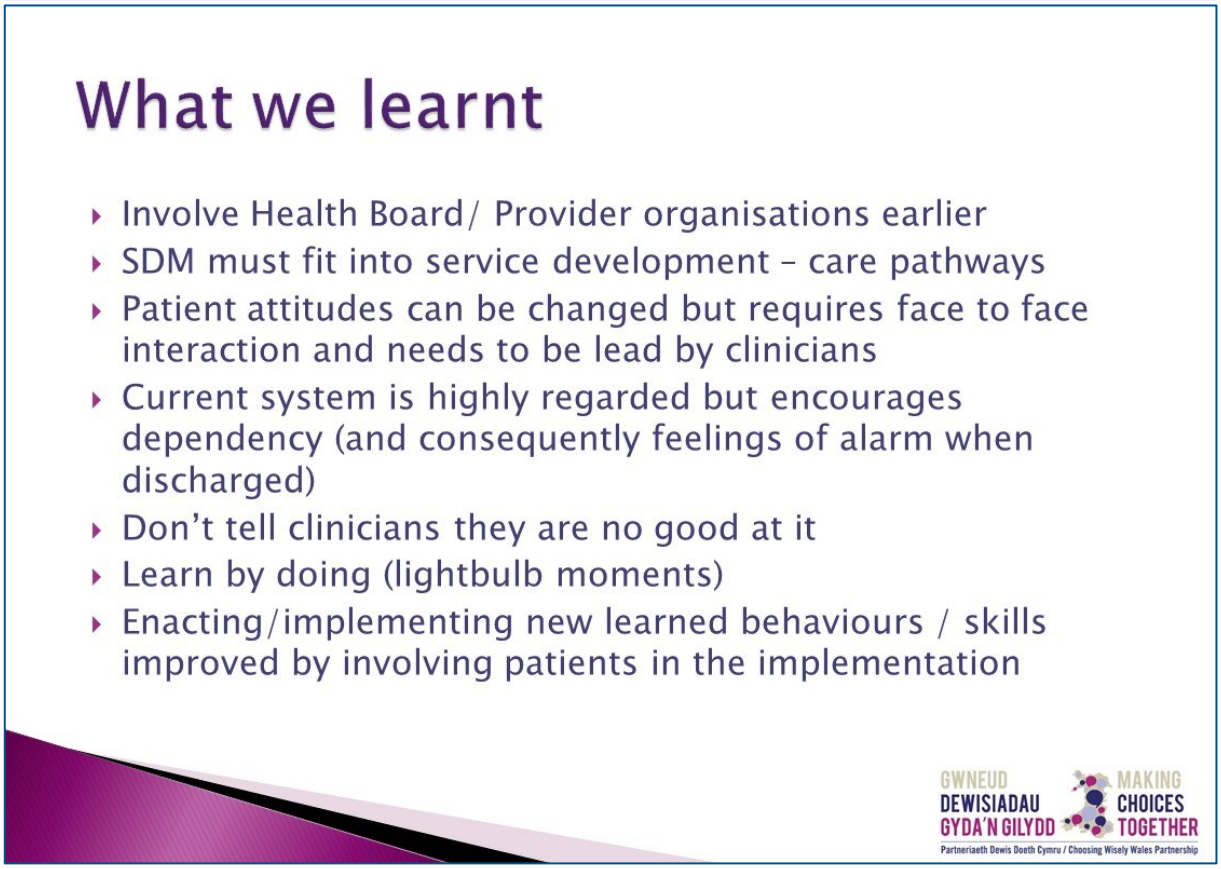
What we learnt
Involve Health Board/ Provider organisations earlier
SDM must fit into service development – care pathways
Patient attitudes can be changed but requires face to face interaction and needs to be lead by clinicians
Current system is highly regarded but encourages dependency (and consequently feelings of alarm when discharged)
Don't tell clinicians they are no good at it
Learn by doing (lightbulb moments)
Enacting/implementing new learned behaviours / skills improved by involving patients in the implementation
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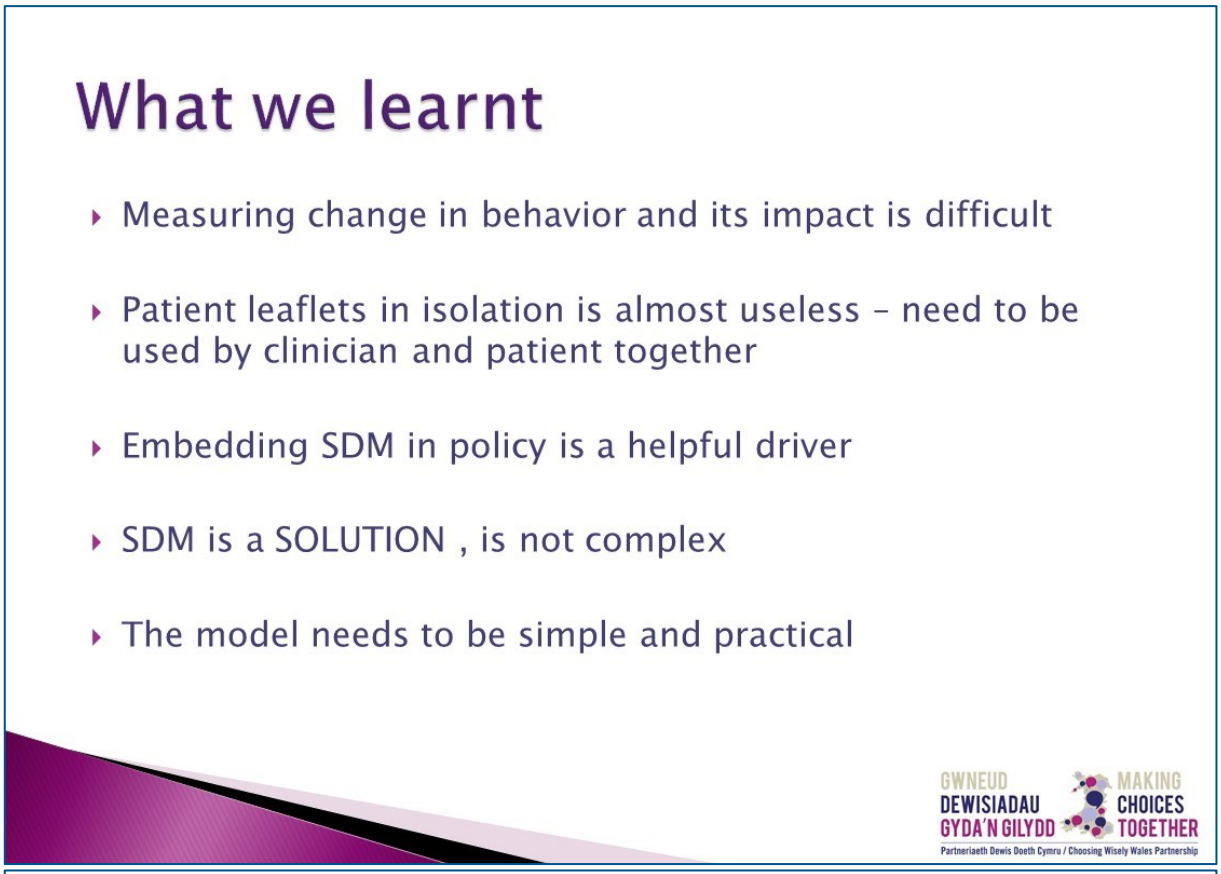
What we learnt
Measuring change in behavior and its impact is difficult
Patient leaflets in isolation is almost useless – need to be used by clinician and patient together
Embedding SDM in policy is a helpful driver
SDM is a SOLUTION , is not complex
The model needs to be simple and practical
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1


Thank You
Diolch
Insert name of presentation on Master Slide
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2

Testimony 5: Lesley Preece & David Gilbert

Sussex MSK Partnership
Central

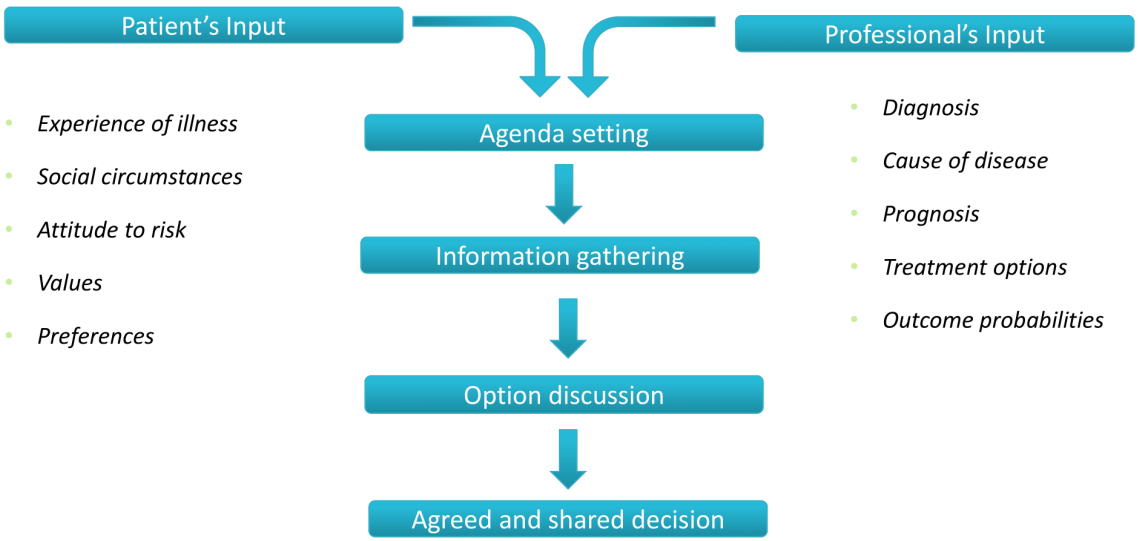
"What, in your experience, are the most effective approaches and activities to normalise (make normal) shared decision making in the healthcare system?"

David Gilbert – Patient Director
Lesley Preece – Patient Partner

Sussex MSK Partnership
Central

- It requires an attitude of respect reinforced at every level of the healthcare system
- *SDM is about balancing power, responsibility, information and knowledge*
- It is embedded in Access , Inclusion, and the acceptance of Diversity
- *For the patient it starts way before the appointment.*
- For all staff it starts with the ethos of the service – and the language used
- *It is so much more than the King's Fund diagram of the structure of a SDM conversation…*

SDM Conversation Structure



Adapted from The King's Fund (2013)

Balancing power, responsibility, information & knowledge

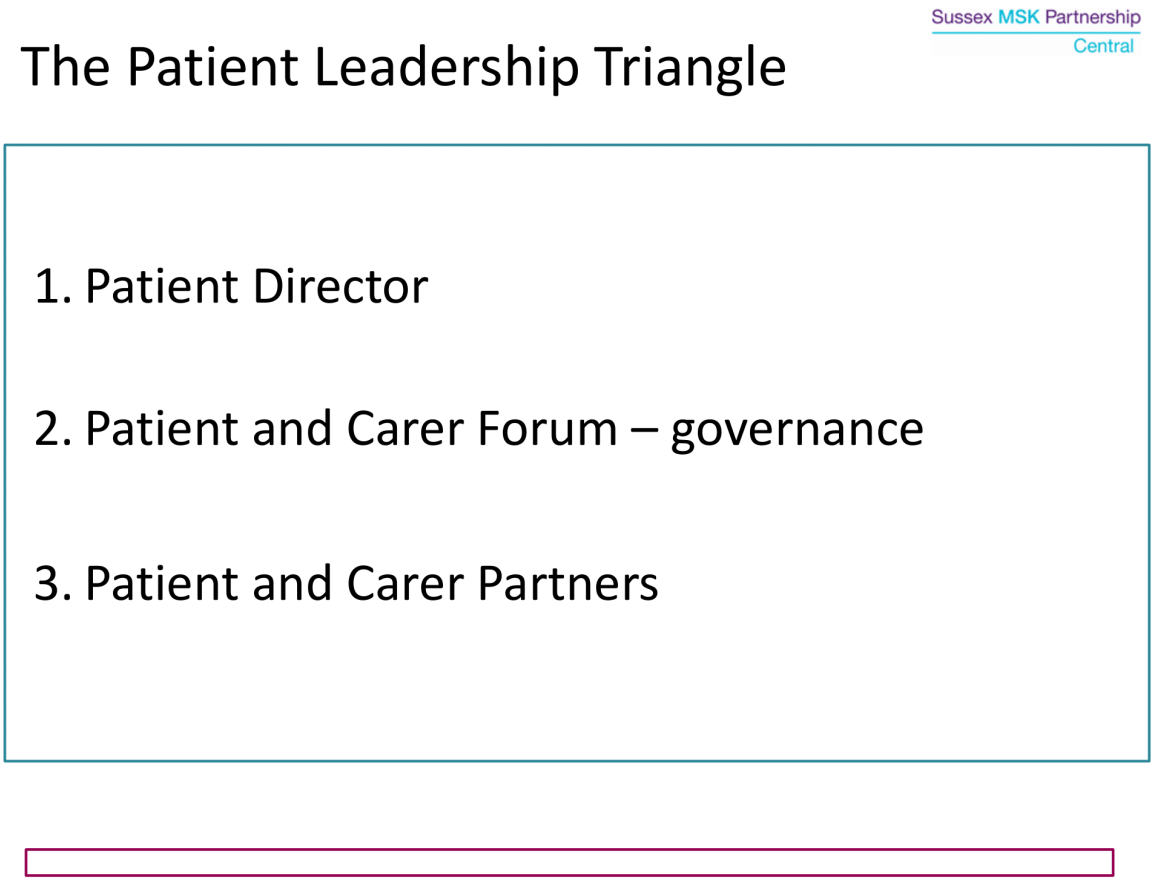
Sussex MSK Partnership Central

PATIENT		CLINICIAN & ALL STAFF
How appointments are made.		How staff are appointed (Statement in JD and Person Spec.)
Setting patient expectations. (Web-site, etc.)		How the induction process supports attitudes of respect.
Reminders on letters that patients have a responsibility to tell the service of any special help they need.		How staff are supported in their teams (difficult conversations / medical jargon, etc)
Suggesting how one might prepare – questions – medications – investigations		On-going training / CPD requirements; observation, etc
Knowing what matters, personally.		How staff speak and write to patients.
Making it as easy as possible for patients to arrive cool, calm, collected.		The time they have available in which to do this.
Greeting, waiting, meeting and seating.		Greeting, meeting, and seating.
	APPOINTMENT Contracting – time I – Issue G – Goals R – Realities O – Options W – Will do Agreed and Shared Decision	
What the patient takes away from the appointment.		What the clinician takes away from the appointment.
What the Clinic Outcome Letter (COL) says.		What the Clinic Outcome Letter (COL) says.
Patient right of reply if not felt to be a correct presentation.		How the service responds if patient questions the accuracy of the COL.

Patient Leadership – jewels from the [illegible] of suffering

Sussex MSK Partnership Central

- People who have been through stuff, know stuff and can help improve stuff
- Traditional approaches to engagement do not work
  - Lots of activity at the margins - Lack of impact
  - Reliant on 'feedback' & 'representation' modes
  - No patient/carer influence over decision-making
  - The emergence of Patient Leadership



Footnote: Expert witness provided an additional link to more info after meeting - https://www.inhealthassociates.co.uk/publication/the-patient-leadership-triangle/

1. Patient Director

Sussex MSK Partnership Central

- Senior leadership for the work
- Shared-decision making at senior level
- Modelling collaborative leadership behaviours
- Embedding partnership culture
- Embedding policies, systems and processes
- Co-ordinating patient-centred work
- Aligning patient-centred work with corporate priorities
- Facilitating dialogue between patients, carers & staff (support/clinical)

2. Patient and Carer Forum

Sussex MSK Partnership Central

- Part of formal governance structures
- Meets quarterly – different stakeholders together
- Formal role
  - Oversight of patient-centred work (Insight, Involvement, Information, link to Chloe Stewart's work on SDM and self-management)
  - Catalysing 'Patient-centred improvement'
- Informal role
  - Model collaborative dialogue
  - Safe space to have honest conversations about difficult stuff

3. Patient and Carer Partners

Sussex MSK Partnership Central

- Pool of valued, paid, supported, trained people with MSK conditions
- Augments other 'engagement' and 'insight' work
- Patient Leaders/Partners – not 'representative'
- From feedback -> story-teller -> partner
- Questioner/advisor/critical friend/supporter – 'we can help'
- Roles in improvement
- Roles in governance (clinical quality group, MDTs)

Some final reflections

Sussex MSK Partnership Central

- Please do not think that by using one of the only two validated tools to measure SDM, an effective change can be made
- The descriptors may capture a small amount of good practice at the point of decision but they do not provide any information about what needs to happen for patients to be able to share in the appointment process as equal decision-makers
- Basic, respectful, communication skills are essential to the process. When we are busy, under pressure, running out of time, having a bad day, or the IT system is incredibly slow, they can fall away.
- At worst, SDM will come to be defined by the limiting descriptors of the tool.

Appendix I – Excluded studies

Study	Code [Reason]
Anderson, D (1997) Shared decision-making programs: descriptive analysis of experience with shared decision-making programs in VA. Title to be Checked: 12	- Not a relevant study design *not actual review*
Baijens, S W E, Huppelschoten, A G, Van Dillen, J et al. (2018) Improving shared decision-making in a clinical obstetric ward by using the three questions intervention, a pilot study. BMC pregnancy and childbirth 18(1): 283	- Not looking at normalising or embedding SDM in a healthcare system
Deinzer, A, Babel, H, Veelken, R et al. (2006) Shared decision-making with hypertensive patients. Results of an implementation in Germany. Deutsche medizinische wochenschrift (1946) 131(46): 2592-2596	- Study not reported in English
Durand, M.-A., DiMilia, P.R., Song, J. et al. (2018) Shared decision making embedded in the undergraduate medical curriculum: A scoping review. PLoS ONE 13(11): e0207012	- Not a relevant study design *Scoping review*
Flynn, D., Knoedler, M.A., Hess, E.P. et al. (2012) Engaging patients in health care decisions in the emergency department through shared decision-making: A systematic review. Academic Emergency Medicine 19(8): 959-967	- Not looking at normalising or embedding SDM in a healthcare system *RQ1.1 type SLR*
Johnson, Rachel A, Huntley, Alyson, Hughes, Rachael A et al. (2018) Interventions to support shared decision making for hypertension: A systematic review of controlled studies. Health expectations : an international journal of public participation in health care and health policy 21(6): 1191-1207	- Not looking at normalising or embedding SDM in a healthcare system *RQ1.1 type SLR*
Lovell, Karina, Bee, Penny, Brooks, Helen et al. (2018) Embedding shared decision-making in the care of patients with severe and enduring mental health problems: The EQUIP pragmatic cluster randomised trial. PloS one 13(8): e0201533	- Not looking at normalising or embedding SDM in a healthcare system *Hints at embedding SDM, but looking at the content is more of a RQ1.1. Despite definition suggesting embedding of SDM*
Martinez-Gonzalez, Nahara Anani, Plate, Andreas, Senn, Oliver et al. (2018) Shared decision-making for prostate cancer screening and treatment: a systematic review of	- Not looking at normalising or embedding SDM in a healthcare system *RQ1.1 type SLR*

Study	Code [Reason]
randomised controlled trials. Swiss medical weekly 148: w14584	
Michalsen, Andrej, Long, Ann C, DeKeyser Ganz, Freda et al. (2019) Interprofessional Shared Decision-Making in the ICU: A Systematic Review and Recommendations From an Expert Panel. Critical care medicine 47(9): 1258-1266	- Study does not contain a relevant intervention *Not Patient-Practitioner SDM, interdepartmental SDM, had this looked at the effects of interdepartmental SDM on external SDM would have been an include..*
Pham, C., Lizarondo, L., Karnon, J. et al. (2019) Strategies for implementing shared decision making in elective surgery by health care practitioners: A systematic review. Journal of Evaluation in Clinical Practice	- Not looking at normalising or embedding SDM in a healthcare system *RQ1.1 SLR: Effectiveness of SDM interventions not embedding or normalising.*
Ponce, O.J., May, C.R., Montori, V.M. et al. (2020) Normalization of a conversation tool to promote shared decision making about anticoagulation in patients with atrial fibrillation within a practical randomized trial of its effectiveness: A cross-sectional study. Trials 21(1): 395	- Study does not contain a relevant intervention *Measures normalisation of PDA not SDM itself.*
Ritter, Simon, Stirnemann, Jerome, Breckwoldt, Jan et al. (2019) Shared Decision-Making Training in Internal Medicine: A Multisite Intervention Study. Journal of graduate medical education 11(4suppl): 146-151	- Not looking at normalising or embedding SDM in a healthcare system *Practitioner training falls under RQ1.1*
Sassen, Barbara, Kok, Gerjo, Schepers, Jan et al. (2014) Supporting health care professionals to improve the processes of shared decision making and self-management in a web-based intervention: randomized controlled trial. Journal of medical Internet research 16(10): e211	- Not looking at normalising or embedding SDM in a healthcare system
Shade, Lindsay, Reeves, Kelly, Rees, Jennifer et al. (2020) Research nurses as practice facilitators to disseminate an asthma shared decision making intervention. BMC nursing 19: 40	- Data not reported in an extractable format *No reportable SDM outcomes. Survey only*
Simmons, Magenta Bender, Batchelor, Samantha, Dimopoulos-Bick, Tara et al. (2017) The Choice Project: Peer Workers Promoting Shared Decision Making at a Youth Mental Health Service. Psychiatric services (Washington, D.C.) 68(8): 764-770	- Not looking at normalising or embedding SDM in a healthcare system *Not adults and more 1.1 type question. think this may actually be in review?*
Singh Ospina, N., Toloza, F.J.K., Barrera, F. et al. (2020) Educational programs to teach shared	- Not a relevant study design

Study	Code [Reason]
decision making to medical trainees: A systematic review. Patient Education and Counseling 103(6): 1082-1094	
Siyam, T., Shahid, A., Perram, M. et al. (2019) A scoping review of interventions to promote the adoption of shared decision-making (SDM) among health care professionals in clinical practice. Patient Education and Counseling 102(6): 1057-1066	- Not looking at normalising or embedding SDM in a healthcare system
Tapp, H., Shade, L., Mahabaleshwarkar, R. et al. (2017) Results from a pragmatic prospective cohort study: Shared decision making improves outcomes for children with asthma. Journal of Asthma 54(4): 392-402	- Not a relevant study design *prospective cohort study*
van der Sanden, Wil J M, Mettes, Dirk G, Plasschaert, Alphons J M et al. (2005) Effectiveness of clinical practice guideline implementation on lower third molar management in improving clinical decision-making: a randomized controlled trial. European journal of oral sciences 113(5): 349-54	- Not looking at normalising or embedding SDM in a healthcare system *Not looking at SDM*
Volk, Robert J, Shokar, Navkiran K, Leal, Viola B et al. (2014) Development and pilot testing of an online case-based approach to shared decision making skills training for clinicians. BMC medical informatics and decision making 14: 95	- Not a relevant study design *not a trial*
Young, Henry N, Bell, Robert A, Epstein, Ronald M et al. (2008) Physicians' shared decision-making behaviors in depression care. Archives of internal medicine 168(13): 1404-8	- Not looking at normalising or embedding SDM in a healthcare system *No intervewntion trying to normalise SDM, just observing its implenetation*
Zandstra, D, Busser, J A S, Aarts, J W M et al. (2017) Interventions to support shared decision-making for women with heavy menstrual bleeding: A systematic review. European journal of obstetrics, gynecology, and reproductive biology 211: 156-163	- Not looking at normalising or embedding SDM in a healthcare system *SDM effectiveness not normalising/embedding*

1

2

1 Appendix J – References to included studies

Goossens, B., Sevenants, A., Declercq, A. et al. (2020) Improving shared decision-making in advance care planning: Implementation of a cluster randomized staff intervention in dementia care. Patient Education and Counseling 103(4): 839-847

Koerner, Mirjam, Wirtz, Markus, Michaelis, Martina et al. (2014) A multicentre cluster-randomized controlled study to evaluate a train-the-trainer programme for implementing internal and external participation in medical rehabilitation. Clinical rehabilitation 28(1): 20-35

Koerner, Mirjam, Ehrhardt, Heike, Steger, Anne-Kathrin et al. (2012) Interprofessional SDM train-the-trainer program "Fit for SDM": provider satisfaction and impact on participation. Patient education and counseling 89(1): 122-8

O'Leary, Kevin J, Killarney, Audrey, Hansen, Luke O et al. (2016) Effect of patient-centred bedside rounds on hospitalised patients' decision control, activation and satisfaction with care. BMJ quality & safety 25(12): 921-928

2

3 Appendix K: Research recommendations

Research question	What are the best ways to measure shared decision making in different contexts with different populations and which reflect the complexity across encounters and people involved?
Population	Populations where SDM is taking place.
Intervention	SDM intervention
Comparators	The same SDM intervention with different SDM outcome measures, both objective and subjective
Outcome measures	Difference in SDM measure results.
Study designs	RCTs Systematic reviews of RCTs
Subgroups of interest	N/A

4

Potential criterion	Explanation
Importance to patients, service users or the population	Better measures of SDM will better capture the effects of SDM for patients and practitioners and help ascertain which SDM interventions are effective and how.
Relevance to NICE guidance	High priority: Committee highlighted that there is a lot of disagreement currently about the best ways to measure SDM and what each SDM measure is actually capturing. Appraising these measures will allow SDM to be measured more consistently and accurately, leading to more reliable data and thus a larger evidence base to make better recommendations.
Current evidence base	There is a lack of evidence comparing different SDM measures to each other.
Equality	No obvious equality issues.
Feasibility	Possible in any setting where SDM is taking place, but objective measures require recording of appointments which has a resource implication.

5