National Institute for Health and Care Excellence

Medicines Optimisation

Guideline Consultation Table

10 October - 7 November 2014

ID	Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
188e	SH	Janssen	1	Full	General	General	Janssen also notes that although there is a recognised body of evidence underpinning clinical decision-making behaviour change principles the database searches used for this guideline didn't include the journals that would include relevant literature to support these principles. Therefore we would suggest that further research is considered in this area.	Thank you for your comment. The GDG can only make research recommendations based on areas where there is no evidence available when it has been searched for.
260e	SH	Gloucestershire Hospitals NHS Foundation Trust	4	Full	4.2	32	Recommendation 18- We would support the move to a named community pharmacist for each patient as proposed in prescription for excellence in Scotland. With the recommendations in 'Now or Never', it is difficult to see how community pharmacists can effectively engage with the medicines optimisation agenda if they do not have the whole picture in front of them. It would be useful to involve community pharmacies within the system so that discharge summaries can be automatically sent to nominated pharmacies instead of having to print off the details and then fax.	Thank you for your comment. Following further discussion by the GDG, the GDG agreed to retain the term as 'nominated'. While the GDG recognised the benefits of sharing information about medicines, the strength of the recommendation reflects the available evidence.
384e	SH	European Medicines Group	1	Full	General	General	The achievement of Medicines Optimisation as a strategy which puts patients at the centre of healthcare and focuses on health outcomes and patient experience, as opposed to a focus on systems to contain use of and spend on	Thank you for your comment. Your comment may be considered as part of the implementation needs analysis.

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							medicines, will require considerable cultural change across the NHS.	
455e	SH	Guild of Healthcare Pharmacists	4	Full	4.2	32	Recommendation 18- We would support the move to a named community pharmacist for each patient as proposed in prescription for excellence in Scotland. With the recommendations in 'Now or Never', it is difficult to see how community pharmacists can effectively engage with the medicines optimisation agenda if they do not have the whole picture in front of them. It would be useful to involve community pharmacies within the system so that discharge summaries can be automatically sent to nominated pharmacies instead of having to print off the details and then fax.	Thank you for your comment. Following further discussion by the GDG, the GDG agreed to keep the term as 'nominated'.
477e	SH	Association of the British Pharmaceutical Industry	1	Full	General	General	ABPI has noted that within the document there is a significant emphasis on medicines safety, some regard given to wastage and limited acknowledgement to other principles that recognise the value of medicines to the NHS and patients. The evidence base that has been used for the guideline is limited in its scope for demonstrating a range of activities already starting to be adopted in pockets within practice that have the potential to achieve improved outcomes for patients. There is little published evidence to support making strong recommendations for a balanced and blended approach across a range of activities which does not align to the 4 principles published last year. In order to overcome this limitation, ABPI would suggest to NICE that a more balanced approach to medicines optimisation and the 4 principles should be reflected in the introductory pages and in any additional resource materials and implementation activities that NICE may be	Thank you for your comment. The Royal Pharmaceutical Society guide on Medicines optimisation has been mentioned in the introductory text. The aim of the introduction for this NICE guideline is to introduce the concept of medicines optimisation and highlight areas where work has been carried out for the topic. The document has been hyperlinked for the user to obtain further information. The four key principles as stated in the Royal Pharmaceutical Society guidance Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England*' are included in this guideline.

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							planning for example at regional implementation workshops.	Relevant text has been added in to reflect your comment. This comment will be considered in the implementation needs analysis.
1	SH	NHS Choices	1	General	General	General	The Digital Assessment Service welcome the guidance and have no comments on its content.	Thank you for your comment.
2	SH	Baxter Healthcare	1	Full	4.2	34	Baxter would like to draw attention to the lack of clarity on which setting(s) self-management takes place in the first paragraph on self-management plans. There is no mention of home setting at present, which we believe should be included.	Thank you for your comment. As stated in the scope and section 2.4, this guideline covers all children, young people and adults groups using medicines in all settings. Additional wording has been added to reflect your comment.
3	SH	Baxter Healthcare	2	Full	4.2	34	Baxter ask if NICE will consider inserting the following bullet point or add to the bullet point 'how to use the plan' • Any special training needs for different administration routes	Thank you for your comment. Following further discussion by the GDG it concluded that list in this recommendation is not intended to be exhaustive but includes the minimum dataset. Additional information may be needed depending on the person's needs. This would be for the health professional to determine and would fall under 'any other instructions the person needs to safely and effectively self-manage their medicines' in the recommendation.
4	SH	Baxter Healthcare	3	Full	4.2	34-5	Baxter ask if NICE will consider inserting the following bullet point: • Technology available for remote monitoring of patient treatment to support	Thank you for your comment. The list in recommendation was agreed by the GDG as the minimum information to include in the

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							appropriate use of medicines and provide warning of potential side effects.	self-management plan. Self-management plans should be individualised and tailored to the person's needs, this includes providing any other additional information that meets the person's needs to support self-management. Where such technology for monitoring exists, this would be part of the tailored approach when drawing up the self-management plan with the person. The GDG was aware that not all medicines may have remote monitoring technologies in place.
5	SH	Baxter Healthcare	4	Full	4.2	36	Baxter ask if NICE will consider rewording as: 'Consider training and education needs, **particularly on innovative technologies**, to support health professionals and patients in developing the appropriate skills and expertise to use patient decision aids effectively in consultations about medicines.'	Thank you for your comment. The purpose of this review question was to look at the clinical and economic evidence for patient decision aids. The GDG developed high level recommendations based on key principles of the intervention found from evidence, rather than looking at particulars of the intervention being reviewed. Training and education to support use of patient decision aids was discussed by the GDG, however the details of what this would involve was not discussed as it is out of scope.
6	SH	Baxter Healthcare	5	Full	4.2	36	Baxter ask if NICE will consider including an additional point: • Consider technology that connects existing Systems, Electronic Medical	Thank you for your comment. The purpose of this review question clinical decision support was defined as 'an active,

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							Records, Radiology and laboratory results such as Infection Surveillance Software to enable prompt interventions in infection episodes. To further enhance and monitor appropriate drug selection and administration at point of care, surveillance software should be taken into account as a method of ensuring appropriate antimicrobial stewardship and broader surveillance of medication; which will also help manage adverse drug events.	computerised intervention that occurs at the time and location of prescribing, to support prescribers with decision-making'. This would exclude technologies that connect systems or for surveillance purposes.
7	SH	Baxter Healthcare	6	Full	4.2	General	Baxter would ask NICE to include a section on the preparation and administration of medicines as there is little or no emphasis on the route of administration of medicines at present. For example the preparation of some medications can be optimised through appropriate vial sharing and the administration of some medications can be optimised through dose banding. Commissioning Intentions 2015/16 for Prescribed Specialised Services, Section on Chemotherapy Drugs, p.88 refers to the need for all trusts "*to work with area teams to maximise opportunities for **dose banding** and **vial sharing** where such activity does not exist".* We would like this principle to be also embedded in the consultation document.	Thank you for your comment. This is outside the scope of this guideline.
8	SH	Baxter Healthcare	7	Full	6	General	Baxter Healthcare recognises that although there are a number of references made to *home setting* in the context of *home care* throughout the draft consultation document, a more precise definition would be helpful for example to differentiate between patients' home and care homes. This would help further identify specific requirements to	Thank you for your comment. Remote monitoring is outside the scope of this guideline. The settings to which this guideline applies are included in the scope. The GDG developed recommendations based on key

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							enable self-management at home *versus* care home. Remote monitoring, for example, is likely to play an even greater role in home setting than at care homes.	principles of the intervention, rather than looking at particulars of the intervention being reviewed.
37a	SH	East Lancashire Hospitals NHS Trust	1	Full	4.2	32	With respect to the concept of sharing discharge medication with community pharmacies. I believe there should be more emphasis on this. I am currently working with the Royal Pharmaceutical Society's Innovators' Forum to produce a toolkit to be launched in December 2014 which is aimed at supporting health economies implement referral systems (ideally electronic ones) to ensure eligible patients are entered into relevant post-discharge schemes aimed at improving medicines adherence i.e. New Medicine Service (NMS), post-discharge MUR (or Discharge Medication Review (DMR) in Wales); or simply to ensure changes to mediation for patients using blister packs or at Care Homes have changes logged on to their PMR to prevent accidental changes at the next dispensing un-doing intentional changes in hospital. In August 2014 research evidence was published into the benefits and outcomes of the NMS (*http://www.nottingham.ac.uk/~pazmjb/nms/downloads/report/files/assets/basic-html/index.html#1*) and DMR (*http://www.cpwales.org.uk/Contractors-Area/Pharmacy-Contact---Services/DMR/DMR-Evaluation_Final-Report_13082014.aspx*).	Thank you for your comment. The recommendations were based on the available evidence for medicines-related communication systems when the person moves from one care setting to another. The search of evidence did not specifically look at the sharing of information about medicines at discharge with community pharmacies. However the GDG recognised that patients should be encouraged to share information with other relevant health professionals, such as their nominated community pharmacist. Implementation of sharing discharge medication information across care settings would be determined locally and on the availability of resources.
37b	SH	East Lancashire Hospitals NHS Trust	1	Full	4.2	32	In my health economy later this month (Nov 2014) we launch Refer-to-Pharmacy, an integrated electronic referral system that will send consenting patients' referral and e-discharge letter to their community pharmacist for the actions described above. The system has been conceived to make it easy to replicate and spread to other	Thank you for your comment. Please submit this as a local practice example if this system supports implementation of the NICE guideline recommendations, so other organisations can learn from your experience. See

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							health economies. For further details and to see the patient-facing information film which will be played on demand on bedside TVs to explain what we want our patients to be involved with visit: http://www.elht.nhs.uk.refer. I believe that patients should come in to hospital expecting to be referred to their community pharmacist post-discharge, and that leaders within the local health economy should demand that such referral scheme are put in place to make it quick and easy for hospital teams to make referrals en masse, which will be the only way to get outcome in great enough numbers to demonstrate the perceived virtuous outcomes.	http://www.nice.org.uk/about/What-we-do/Our-Programmes/Local-Practice-Collection.
37c	SH	East Lancashire Hospitals NHS Trust	1	Full	4.2	32	I also believe that is an area for research. My Trust is working with the School of Pharmacy at Manchester University, which is on the verge of commencing a feasibility study into this very service (preliminary work is due to commence in December 2014). The work is aimed at obtaining some outcome data (e.g. are hospital admissions/re-admissions reduced in referred patients), to get opinions for patients and health professionals on the referral scheme, and to evaluate what research routes should be and can be explored in future studies.	Thank you for your comment.
38	SH	Swansea University	1	Full	1.1	6	The introduction refers only to England / NHS England. Since NICE is designed for all 4 countries in the UK, equivalent statistics and references are needed for each of the devolved governments. A table would be useful to readers.	Thank you for your comment. The way NICE was established in legislation means that our guidance is officially England-only. Therefore, NICE guidelines are written in the context of health and social care in England.
39	SH	Swansea University	2	Full	3.1	16-7	The final review questions make no mention of monitoring patients for adverse drug reactions.	Thank you for your comment. The relevant text has now been added

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							This is an important consideration. Medication reviews generally focus on lists of prescriptions, and may occur without the patient being present. Optimal use of medicines needs to consider the impact of the prescribed regimen on the patient, particularly any putative adverse effects and the potential to ameliorate these by health promotion.	to reflect this comment following further discussion by the GDG.
40	SH	Swansea University	3	Full	3.3.6	23	When evaluating medicines' management studies, the generalisability of the evidence should be considered. The sample recruited may favour the better educated and those most willing to engage with their healthcare professionals. As such, they may not be representative of the wider population. I suggest that volunteer bias be included in this section (Jordan et al 2013).	Thank you for your comment. All studies were quality assessed using the appropriate NICE methodology checklist (see NICE guidelines manual 2012 appendices B–I).
41	SH	Swansea University	4	Full	4.1	29	Recommendation 8 Structured review of possible adverse drug reactions should be added to the strategies to identify safety incidents. Some of our work in this area has uncovered serious adverse reactions, such as coupled beats, severe hypertension and orthostatic hypotension in 10% of patients (Jordan 2002, Jordan et al 2002). We suggest that you add "patient review for possible adverse drug reactions" to recommendation 8.	Thank you for your comment. The recommendations were based on the available evidence for 'systems for identifying, reporting and learning from medicines-related patient safety incidents'. No evidence that met our review protocol criteria was identified for structured review of possible adverse drug reactions.
42	SH	Swansea University	5	Full	4.2	33	Medication review should include a full list of patients' adverse drug reactions. This benefits patients (Jordan et al 2004, 2014, Gabe et al 2014).	Thank you for your comment. The relevant text has now been added to reflect this comment following further discussion by the GDG.
43	SH	Swansea University	6	Full	5.7	61	Recommendation 10 Consider using a screening tool ... The option of using the West Wales Adverse Drug Reaction Profile might be offered with references (Jordan et al 2004, 2014, Gabe et al 2014).	Thank you for your comment. The type of screening tool used may vary locally and so specific tools have not been listed although this may be considered as part of the implementation needs analysis in relation to recommendations in the

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								guideline.
44	SH	Swansea University	7	Full	8.5	115	The text indicates the numbers of trials indicating the benefits of medication review, but it is not clear which trials are referred to at each point. Therefore, it is impossible to assess the statements. Please could references be added to the text in the traditional manner?	Thank you for your comment. Evidence statements summarise the key features of the clinical effectiveness evidence presented. The full guideline follows a standard NICE template and is presented in line with the NICE guidelines manual (2012).
45	SH	Swansea University	8	Full	8.1	101	There is useful discussion of medication review, but this does not appear to encompass review of adverse drug reactions. We have evidence that nurse-led systematic review of adverse drug reactions results in important clinical gains for some patients. We feel that this should be mentioned in this guidance. Our approach is clinically and cost effective because nurses know their patients and are well placed to report their problems and 10-25 minutes of nursing time is affordable (Gabe et al 2014, Jordan et al 2014). We suggest that you add "patient review for possible adverse drug reactions" to level 3 (Box 1).	Thank you for your comment. Adverse drug reactions have been covered in 'systems for identifying, reporting and learning from medicines-related patient safety incidents' section.
46	SH	Swansea University	9	Full	8.3	104	Table 21: The numbers of participants in each study is needed.	Thank you for your comment. The details of each included study are provided in the evidence tables in the appendices of the guideline.
47	SH	Swansea University	10	Full	8.7	121	Medication review should also include a review of putative adverse drug reactions (Gabe et al 2011, Gabe et al 2014, Jordan et al 2014, Jordan & Kyriacos 2014).	Thank you for your comment. The relevant text has now been added to reflect this comment following further discussion by the GDG.
48	SH	Swansea University	11	Appendix C	C1.2.3	23	Search strategy for medication review. It is surprising that 'adverse drug reaction' was not included in the search terms.	Thank you for your comment. Adverse drug reactions have been covered in 'systems for identifying, reporting and learning from medicines-related patient safety

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								incidents' section.
49	SH	Swansea University	12	Full	General	General	The text is generally well written, but would benefit from clearer referencing in parts.	Thank you for your comment. The full guideline follows a standard NICE template and is presented in line with the NICE guidelines manual (2012).
50	SH	Swansea University	13	Full	General	General	There is little reference to medicines' management and medicines' review in acute care. It might be appropriate to provide separate guidelines for acute and long-term medicines management.	Thank you for your comment. The evidence for medication review was looked at in all care settings for the purpose of this review question. Recommendations have been based on the available evidence and GDG expertise. Recommendations apply to all care settings where medication reviews can be carried out.
51	SH	Royal College of Paediatrics and Child Health	1	Full	5.3.2	47	May be worth mentioning here who the reporting of medicine-related patient safety incidents was done by.	Thank you for your comment. The process of reporting medicine-related patient safety incidents varied between studies. Details are included in the Evidence Tables – see appendix D.1.2.
52	SH	Royal College of Paediatrics and Child Health	2	Full	5.6	56	'*The GDG recognised that not all medicines-related patient safety incidents cause the same level of harm, or potential harm, to patients.*' **A comparison of harm potential between adult and paediatric patient populations is important.**	Thank you for your comment. The linking evidence to recommendations (LETR) table captured the discussions by the GDG relating to the evidence presented. Specific examples, such as the potential harm of medicines-related patient safety incidents in children were not discussed by the GDG. Therefore, this was not included in the LETR table.
53	SH	Royal College of Paediatrics and	3	Full	5.7	60	Add a point, **Ensure that all staff receive appropriate training on identifying and**	Thank you for your comment. This has been added following further

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		Child Health					**reporting medicine related patient safety incidents.**	discussion by the GDG.
54	SH	Royal College of Paediatrics and Child Health	4	Full	6.3	64	*Examples where communication may need to happen should also include* ***when patients are transitioning from paediatric to adult services, either within the same trust or across different trusts***	Thank you for your comment. The relevant text has now been added to reflect this comment.
55	SH	Royal College of Paediatrics and Child Health	5	Full	6.6	73	*'The GDG recognised that organisations need to make that systems are consistent with all medicines prescribed, especially when medicines are only prescribed from a specific setting, for example, hospital-only medicines' should also include* ***medications delivered through homecare***	Thank you for your comment. The linking evidence to recommendations (LETR) table captured the discussions by the GDG relating to the evidence presented. This example of medicines delivered through homecare was not discussed by the GDG. Therefore, this was not included in the LETR table.
56	SH	Royal College of Paediatrics and Child Health	6	Full	6.6	74	*'Locally, care providers should consider sharing this information with other individuals, particularly the community pharmacist' may also be worth including* ***specialist clinics providing care***	Thank you for your comment. The linking evidence to recommendations (LETR) table captured the discussions by the GDG relating to the evidence presented. Sharing information with community pharmacists was discussed extensively by the GDG. Other individuals would need to be considered and determined locally, depending on the service being provided. Specialist clinics were not discussed by the GDG. Therefore, this was not included in the LETR table.
57	SH	Royal College of Paediatrics and Child Health	7	Full	6.6	75	*'details of other relevant contacts identified by the patient and/or their carers (for example, their nominated community pharmacy) may also add* ***specialist clinics providing care***	Thank you for your comment. The linking evidence to recommendations (LETR) table captured the discussions by the

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								GDG relating to the evidence presented. Sharing information with community pharmacists was discussed extensively by the GDG. Other individuals would need to be considered and determined locally, depending on the service being provided. Specialist clinics were not discussed by the GDG. Therefore, this was not included in the LETR table.
58	SH	Royal College of Paediatrics and Child Health	8	Full	6.6	76	*Other information that should be included in the communication document may be **special requirements ie. Storage, high cost medications, specially commissioned medications***	Thank you for your comment. The linking evidence to recommendations (LETR) table captured the discussions by the GDG relating to the evidence presented. These examples were not discussed specifically by the GDG, but would be captured in 'other information'. Therefore, this was not included in the LETR table.
59	SH	Royal College of Paediatrics and Child Health	9	Full	7.1	79	*Purpose of meds rec: 'changes to meds communicated' not included and this is a purpose of meds rec e.g. with pt., GP etc.*	Thank you for your comment. The relevant text has now been added to reflect this comment.
60	SH	Royal College of Paediatrics and Child Health	10	Full	7.1	80	*Omission of the word "**to**" in sentence "or it may be used **?to** identify what the patient was taking.*	Thank you for your comment. The relevant text has now been added to reflect this comment.
61	SH	Royal College of Paediatrics and Child Health	11	Full	7.1	80	*?include "patient carer" as people involved in meds. Rec. e.g. wife/daughter for stroke patient, mother/father for children*	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
62	SH	Royal College of Paediatrics and Child Health	12	Full	7.1	General	*Inconsistency with use of hyphen with cost-effectiveness & cost effectiveness*	Thank you for your comment. This has now been amended to reflect this comment.

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63	SH	Royal College of Paediatrics and Child Health	13	Full	7.4	86	*Change show to* ***shown*** *in the sentence "The structure of the model is* ***show*** *in figure 2 and copies"*	Thank you for your comment. The relevant text has now been added to reflect this comment.
64	SH	Royal College of Paediatrics and Child Health	14	Full	8.1	101	The quote in paragraph 3 'the guidance also considers…carrying out medicines reviews' but it is not clear what a 'medicines review' is in this context.	Thank you for your comment. This guidance has been included in the introduction to the question for information. For further information about this see Good practice in prescribing and managing medicines and devices.
65	SH	Royal College of Paediatrics and Child Health	15	Full	8.1 (and 8.6)	General (pages 101, 117, 118)	There is no mention that patient's individual illnesses can pose medication-related risks (e.g. chronic kidney disease, porphyria) which may benefit from medicines review *e.g. would fit under the section starting p117 "Patients who are at particular risk of medicine-related problems - for example:"*	Thank you for your comment. The relevant text has now been added to reflect this comment.
66	SH	Royal College of Paediatrics and Child Health	16	Full	8.3	102	Recommend clarifying what eligibility criteria was met *i.e. Thirteen studies met the eligibility criteria for medicine reviews and were included.*	Thank you for your comment. The methods used to identify, include and review evidence is detailed in section 3 of the guideline.
67	SH	Royal College of Paediatrics and Child Health	17	Full	8.7	121	We are surprised that there are no research recommendations considering how inconclusive the evidence is. E.g. research into appropriate frequency of reviews, cost-effectiveness, medicines review in children.	Thank you for your comment. Following further discussion by the GDG, a research recommendation has been identified and developed for medication reviews where there was limited or no evidence.
68	SH	Royal College of Paediatrics and Child Health	18	Full	1.1	General	*Omission of the word* ***"care"*** *in the sentence 'When a patient is taking multiple medicines this is called 'polypharmacy', a term that has been used in health* ***?care*** *for many years.'*	Thank you for your comment. The relevant text has now been added to reflect this comment.
69	SH	Royal College of Paediatrics and Child Health	19	Full	9.1	122	***Reword the paragraph:*** *'The programme acknowledges that there has already 20been a shift from patients being only*	Thank you for your comment. The relevant text has now been amended to reflect this comment.

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							the recipients of their care to wanting to be involved in decisions about their care and treatment.' ***Reword?*** *The programme acknowledges that there has already been a shift from patients being **not** only the recipients of their care, **but** wanting to be involved in decisions about their care and treatment.'*	
70	SH	Royal College of Paediatrics and Child Health	20	Full	9.1	122	***Reword the paragraph:*** *'Furthermore, it highlights that self-management approaches can be designed individually to reduce the severity of symptoms and improve patients' confidence in managing their condition, although this depends on the patients' desire to be involved and engaged in their health care.'* ***Reword?*** *'Furthermore, it highlights that self-management approaches can be designed individually to reduce the severity of symptoms and improve patients' confidence in managing their condition**;** **depending** on the patients' desire to be involved and engaged in their health care.'*	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
71	SH	Royal College of Paediatrics and Child Health	21	Full	9.5	General (pages 130-1)	*Where it refers to low / moderate quality evidence, a reference to the criteria used to make these definitions (which is available in the appendix) would be useful?*	Thank you for your comment. In addition to the details in the appendices, appraisal of evidence is described in section 3 of the guideline along with the criteria used to downgrade the evidence, before the start of the review questions.
72	SH	Royal College of Paediatrics and Child Health	22	Full	9.5	General (pages 130-1)	*Discusses the studies collectively but referencing each study would be useful for the reader.*	Thank you for your comment. Evidence statements summarise the key features of the clinical

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							e.g. *'Three studies reported quality of life as an outcome.'* ***Which three studies? Ref?***	effectiveness evidence presented and follow standard NICE style. The full guideline follows a standard NICE template and is presented in line with the NICE guidelines manual (2012).
73	SH	Royal College of Paediatrics and Child Health	23	Full	9.6	133	*The comment:* *'resources needed would be locally determined'* *May introduce in-equality of care, as resources available locally may vary? Particularly when it involves highly specialised services.*	Thank you for your comment. This will be considered as part of the implementation needs analysis.
74	SH	Royal College of Paediatrics and Child Health	24	Full	9	133	***With regards to the following paragraph:*** *'Economic evidence showed that this reduction in resource use led to patient self-management plans being a cost-effective use of resources in several disease areas'* ***e.g. ……..*** ***Examples of these 'disease areas'***	Thank you for your comment. The specific examples of disease areas are hypertension and asthma. The paragraph will be updated to include these examples.
75	SH	Royal College of Paediatrics and Child Health	25	Full	9 .6	133	*As the evidence in this section is limited to a few conditions (asthma, COPD, hypertension and diabetes), none of which included high cost drugs or drugs with specific storage requirements (e.g. a temperature regulated and monitored fridge) It may be worth doing some cost prediction work.*	Thank you for your comment. This is outside the scope of this guideline.
76	SH	Royal College of Paediatrics and Child Health	26	Full	9.6	134	***Paragraph poorly arranged.*** ***Reword the paragraph,*** *'The majority of the included studies were carried……'* ***e.g.*** *X of the X included studies were carried out in an adult population. Of the X studies, one study looked at self-management plans for asthma in*	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.

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							both adolescent and adult populations. One study looked at self-management plans for asthma in children alone.	
77	SH	Royal College of Paediatrics and Child Health	27	Full	9 .6	135	***With regards to the principles of the self-management:*** • *'The circumstances in which the person should refer to, r seek the advice from , a health care professional'* ***It would be useful to include:*** ***who to contact / referral pathway / sign posting details.***	Thank you for your comment. The list in this recommendation not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health professional to determine.
78	SH	Royal College of Paediatrics and Child Health	28	Full	9.7	134	***Addition of word 'tool' and example of risk assessment tool?*** • *'The person's knowledge and skills needed to use the plan, using a risk assessment**? tool** if needed' **e.g. of tool?***	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health professional to determine. The use of a risk assessment tool did not form part of the evidence review and there may be other methods of risk assessment that me be used.
79	SH	Royal College of Paediatrics and Child Health	29	Full	9.7	134	***Addition of word 'may' in following sentence:*** • ***'**Any support the person **?may** need'*	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
80	SH	Royal College of Paediatrics and Child Health	30	Full	9.7	136	***Reword the following paragraph?*** • *'Any strength or dose restrictions or limitations of a medicine that may be taken under the plan, how long a medicine may be taken for, or what*	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.

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							medicines that may be self-administered under the plan are being used' ***Reword?*** • ***'A list of the medicines that may be self –administered under the plan and their permitted frequency of use; including** any strength or dose restrictions or limitations **and** how long a medicine may be taken for.*	
81	SH	Royal College of Paediatrics and Child Health	31	Full	9.7	136	***Include contact detail / referral pathway with the following point?*** • *The circumstances in which the person should refer to, or seek the advice from, a health professional…**? & contact details / referral pathway***	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health professional to determine.
82	SH	Royal College of Paediatrics and Child Health	32	Full	9	General	*Throughout section 9, it states that the self-management plan should be reviewed on a regular basis. A definition of 'regular basis' would be useful for the clinician, however difficult as each condition / patient varies?* *Some of our patients have annual reviews but would still be suitable for a self-management plan with the correct amount of support and a detailed self-referral pathway.*	Thank you for your comment. Following further discussion by the GDG, they agreed that regular review would depend on the person's needs, but this would be for the health professional to determine.
83	SH	Royal College of Paediatrics and Child Health	33	Full	9	General	*Section 9 suggests that complex patients should be excluded from self-management plans. However, there is a cohort of complex patients that know their condition and symptoms very well.* *These patients may be suitable for the self-*	Thank you for your comment. The evidence found was limited only to patients with a single long-term condition where management was not complex. Although the management of complex patients

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							management plan and should not be excluded. They should be assessed on an individual basis.	was briefly discussed by the GDG, they were unable to make recommendations for self-management of complex patients as they had no evidence to base the recommendations on. It would be up to the health professional and the person to determine if a self-management plan is appropriate for that individual.
84	SH	Royal College of Paediatrics and Child Health	34	Full	9	General	*The inclusion of Self- referral pathways for patients with self-management plans.*	Thank you for your comment. Following further discussion with the GDG, they concluded this is already covered in the bullet points in a recommendation.
85	SH	Royal College of Paediatrics and Child Health	35	Full	1.1	10	(Paragraph 5) Patients with capacity have the right **TO** make an informed decision and can refuse to take their medicines.	Thank you for your comment. The relevant text has now been added to reflect this comment.
86	SH	Royal College of Paediatrics and Child Health	36	Full	10.3.1	144	Key critical outcomes identified by the GDG of some RCT's includes medicines adherence but the area not covered in 1.1 mentions adherence – contradiction	Thank you for your comment. Medicines adherence was used as an outcome measure for several review questions, however there was no specific review question on this as there is already a NICE clinical guideline on it – see Medicines adherence. NICE clinical guideline 76 (2009).
87	SH	Royal College of Paediatrics and Child Health	37	Full	10.6	158	The**Y** agreed that this was an important aspect of undergraduate curricula but this was outside the scope of this guideline.	Thank you for your comment. The relevant text has now been added to reflect this comment.
88	SH	Royal College of Paediatrics and Child Health	38	Full	General	General	Practical issues should also be addressed within patient decision aids for example e.g. within the IMD speciality patients may require a fridge at	Thank you for your comment. The evidence presented to the GDG did not include the specific content

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							home to store the drug. Patients may have to have initial infusions in hospital before being transferred to homecare and some patients if they react need to be aware that they may have to come back to hospital (usually in the tertiary centre away from where they live locally) to manage the reaction and have infusions in hospital until safe to be discharged back to the community	of patient decision aids. The GDG recognised that the quality of the patient decision aid was an important consideration and a recommendation was made to reflect this.
89	SH	Royal College of Paediatrics and Child Health	39	Full	General	General	Within IMD many UL medications are needed. Patient decision aids should address this as well	Thank you for your comment. The evidence presented to the GDG did not include the specific content of patient decision aids. The GDG recognised that the quality of the patient decision aid was an important consideration and a recommendation was made to reflect this.
90	SH	Royal College of Paediatrics and Child Health	40	Appendix C	C1.2	20	Pub med not used as a search engine	Thank you for your comment. NICE do not currently use PubMed as a routine source. We use Medline and Medline In-Process. For further information on sources for searching please see section 5 of the NICE guidelines manual (2012).
91	SH	Royal College of Paediatrics and Child Health	41	Appendix C	C1.2.5	24	You mention in 1.1 that areas that will not be covered are "consent" and "patient education". However the search criteria does use these words – contradiction	Thank you for your comment. These terms were included in the search strategy to account for the variable indexing of studies in this topic and to ensure relevant studies were not missed. Inclusion and exclusion criteria applied at sifting stage would ensure consistency.
92	SH	Royal College of	42	Appendix C	C5.6	117	It would be good to know the reasons why these	Thank you for your comment.

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		Paediatrics and Child Health					clinical studies were not relevant. From the title many of them do look very relevant	Clinical studies that did not have the relevant intervention or outcomes as described in the review protocol were excluded on this basis.
93	SH	Royal College of Paediatrics and Child Health	43	Full	11.3	166	In your evidence review you have excluded studies published prior to 2009. There was significant research on cost-utility/benefit and patient outcome in the first ten years of this century, such that electronic prescribing AND decision support had become mandatory in the USA by 2008. By excluding these important formative years the GDG may have biased the evidence review	Thank you for your comment. The definition of clinical decision support varied amongst the studies and most studies were excluded where it did not meet the definition agreed by the GDG outlined in the review protocol. The GDG was aware of advancement in technologies where the type of clinical decision support used 10 years ago would be different compared with modern day clinical decision support systems which could affect the outcomes used to measure this intervention. By including only the last 5 years of studies, the GDG agreed that it would be more applicable to current day practice. For economic evidence, no studies published between 2000 and 2009 met the inclusion criteria. So by changing the dates we did not lose any economic evidence.
94	SH	Royal College of Paediatrics and Child Health	44	Full	11.3	167	You have omitted studies pertaining to dose-calculation software of pre-existing medication. I do not understand why this has been omitted as it is pertinent to the Guideline and well within the scope of MO.	Thank you for your comment. For the purpose of the review question clinical decision support is defined as 'an active, computerised intervention that occurs at the time and location of prescribing, to support prescribers with decision-

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								making'. This review question looked at evidence where active alerts formed part of the clinical decision support when initiating or changing medicines. Dose-calculation software was excluded where there was no active alert and/or the system did not support a clinician with starting or initiating medicines.
95	SH	Royal College of Paediatrics and Child Health	45	Full	11.7	178	Recommendation 44 – should be worded "…to support clinical decision making and safe prescribing…"	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
96	SH	Royal College of Paediatrics and Child Health	46	Full	11.7	178	Mandatory alerts that are non-customisable for medicines never events limits the benefits. Consideration should be given to other areas – for instance, children's doses not exceeding the usual adult maximum	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. The specific types of alerts did not form part of the evidence review.
97	SH	Royal College of Paediatrics and Child Health	47	Full	11.7	178	"Up to date" needs to be defined in this context. Consider the current discussions taking place around the electronic and print versions of the BNF being substantively different, and how this is being managed. NICE should stipulate what is acceptably "up to date."	Thank you for your comment. The GDG agreed that the term up-to-date is used widely in practice and does not need further defining in the guideline. It involves using recent evidence which may be in the form of information or practice.
98	SH	Royal College of Paediatrics and Child Health	48	Full	12	185-7	Well referenced section. Studies cited for cross-sector working only included adults with chronic conditions. Need information on paediatric setting.	Thank you for your comment. There was no evidence found that met the review protocol criteria for cross-sector working in paediatric setting.
99	SH	Multiple Sclerosis Trust	1	Full	General	General	The MS Trust is responding to this consultation on behalf of our supporters, who are people with MS,	Thank you for your comment.

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							their family, friends and carers. Overall, the MS Trust is happy with this clinical guideline, which makes sensible recommendations around medicines optimisation. We have some comments, however, as outlined below. We have confined our comments to the recommendations.	
100	SH	Multiple Sclerosis Trust	2	Full	General	General	Throughout the Guideline, there is a presumption that medicines optimisation, including medicines review and medicines reconciliation, is confined to prescription medicines – with one exception, in recommendation 29, around medication review. I am concerned that this doesn't take sufficient account of people's tendency to self-medicate with over the counter and alternative or complementary medicines, and that there needs to be greater account taken of these in certain situations, such as medicines-related communication systems, medicines reconciliation. I have made specific comments in relation to the relevant recommendations below.	Thank you for your comment. The evidence found was mainly around prescribed medicines, however, for the purpose of this guideline and as outlined in the scope. In this guideline, the term 'medicines' covers all healthcare treatments, such as oral medicines, topical medicines, inhaled products, injections, wound care products, appliances and vaccines.
101	SH	Multiple Sclerosis Trust	3	Full	General	General	Throughout the Guideline, there is a presumption about intellectual capacity/cognitive ability to make decisions and give informed consent, especially around medication review, self-management plans and patient decision aids. Would it be possible to refer to appropriate NICE or other guidance in these sections around how shared decision making should take place where an individual is known to lack capacity, or where their capacity is in doubt?	Thank you for your comment. Health and social care practitioners should follow the code of practice that accompanies the Mental Capacity Act in their everyday practice. Therefore this is important to consider in all aspects of healthcare. The GDG discussed and agreed that to refer to this in specific sections would detract from the importance of it being considered throughout. Links to relevant guidance can be found in person-centred care (see section 1.2) of the full guideline.

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102	SH	Multiple Sclerosis Trust	4	Full	4.2	31	(Rec 12) Is it possible and/or appropriate to share information about medicines with the individual, their GP and another named individual such as a care co-ordinator where this is applicable? Elsewhere the government has committed to ensuring people with long-term conditions and the elderly have a named individual who is responsible for their care; while in many cases this will be their GP it is not true for all and I would like to see the care co-ordinator able to access all relevant medicines information.	Thank you for your comment. This has been amended to reflect your comment following further discussion by the GDG. The person to share the information with would depend on the care setting.
103	SH	Multiple Sclerosis Trust	5	Full	4.2	31	(Rec 14) As currently worded, the recommendation states: "Encourage people to tell their GP, community pharmacist and any other relevant people if they have been in hospital and to inform these people about any changes to their medicines" Is it possible to word this recommendation to ensure that a list of people who should be informed is included on the medicines information that is provided in a patient-friendly format at discharge, outlined in recommendation 13?	Thank you for your comment. Following further discussion by the GDG, this recommendation has been taken out.
104	SH	Multiple Sclerosis Trust	6	Full	4.2	32	(Rec 15) "Proactively share complete and accurate information about medicines in a timely way, ideally within 48 hours of the person being transferred, to ensure that patient safety is not compromised" I appreciate that there was some discussion by the GDG around the optimal length of time to allow for medicines information to be communicated within settings, around setting realistic guidance, and around the fact that 48 hours is still challenging within a primary care setting. I also note that NICE technical guidance	Thank you for your comment. Following further discussion by the GDG, this recommendation has been amended to 'ideally within 24 hours'. The GDG can only make research recommendations based on areas where there is no evidence available when it has been searched for.

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							recommends sorting this out within 24 hours of admission to hospital. However, 48 hours can be far too long for some individuals, particularly if they are discharged to another setting with continuing medication needs that may have changed. 48 hours can be a long time if a patient is receiving 4-hourly medication, and it seems very likely that there will be some issues around patient safety without optimal medicines communication in that period. I acknowledge that these issues are greatest in primary care, and would like to see a recommendation – perhaps a research recommendation – to identify models of care that can improve the timeliness of communication of medicines information on discharge to primary care.	
105	SH	Multiple Sclerosis Trust	7	Full	4.2	32	(Rec 17) "details of other relevant contacts" – expand this point to include care co-ordinators or similar, as outlined above in my response to recommendation 12.	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
106	SH	Multiple Sclerosis Trust	8	Full	4.2	32	(Rec 17) Consider adding a point about any storage requirements for the medicine, eg controlled medicine, refrigeration required etc	Thank you for your comment. The list in this recommendation is not exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.

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107	SH	Multiple Sclerosis Trust	9	Full	4.2	32	(Rec 17) Consider adding a point about any supply issues there may be with the medicine, eg homecare delivery only. This may affect re-prescription or ensuring that medicines arrive in the right place, if the individual's care setting has altered	Thank you for your comment. The relevant text has now been amended to reflect this comment.
108	SH	Multiple Sclerosis Trust	10	Full	4.2	32	(Rec 17) Consider adding a point about any self-medication with over-the-counter or complementary medicines that the individual may be known to be taking in addition to prescribed medicines	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
109	SH	Multiple Sclerosis Trust	11	Full	General	32-3	(Medicines reconciliation section) Consider adding a point that medicines reconciliation should include any self-medication with over-the-counter or complementary medicines that the individual may be known to be taking or to have been taking in addition to prescribed medicines?	Thank you for your comment. The relevant text has now been added to reflect this comment.
110	SH	Multiple Sclerosis Trust	12	Full	4.2	33	(Rec 20) "In an acute setting, accurately list all of the person's medicines (medicines reconciliation) within 24 hours" Essentially this is the same point as I made in point 5, above. 24 hours can be a long time for some individuals, particularly if they need to receive medication in a timely fashion and their symptoms will worsen without it. I would like to see the recommendation reworded to something like "within 24 hours or less if possible".	Thank you for your comment. This recommendation has been reworded following further discussion by the GDG.

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111	SH	Multiple Sclerosis Trust	13	Full	General	34	(Self management plans section) Given that it is stated government policy to ensure that everyone with a chronic or long-term condition should be given a care plan, is it worth linking self-management plans to these? For example, the recommendation could say something like "self-management plans may form part of an individual's overall care plan"	Thank you for your comment. The relevant text has now been added to reflect this comment.
112	SH	Multiple Sclerosis Trust	14	Full	4.2	34-5	(Rec31) Consider adding, 'consider including any known common interactions of medicines being taken under the plan, including interactions with self-administered complementary medicines the individual may be taking'. By this I do not mean that the self-management plan should replace the PIL for the medication, more as a prompt that clinician and patient should discuss any additional medicines that may not be recorded on the self-management plan. For example, it is very common to find people with MS who may be unaware that some of the dietary supplements they may be self-administering might be contra-indicated when taken with some of their prescription medications.	Thank you for your comment. Following further discussion by the GDG they concluded that list in this recommendation not intended to be exhaustive but includes the minimum dataset. Additional information may be needed depending on the person's needs, but this would be for the health professional and this would fall under ''any other instructions the person needs to safely and effectively self-manage their medicines' in the recommendation.
113	SH	NHS Solihull CCG	1	Full	General	General	Detailed comments below, but our principal comment is that the document would benefit from being much more succinct. We recognise that this is the full guideline rather than the NICE guideline, but advise from GPs is that practising clinicians are unlikely to read this as it is written.	Thank you for your comment. The format is considered by the NICE editorial team and follows NICE style. A NICE guideline, full guideline, information for the public and pathway versions will be published.
114	SH	NHS Solihull CCG	2	Full	1.1	8	Introduction is very wordy and would benefit from being condensed. Headings to orientate the reader would be helpful. Definition of medicines optimisation needs to be in the first paragraph, not at the bottom of the page.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.

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115	SH	NHS Solihull CCG	3	Full	General	General	Would recommend enumerating each recommendation under its own heading rather than as a single list. Forty nine recommendations look very daunting, and are unlikely to be read.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
116	SH	NHS Solihull CCG	4	Full	4.2	General	All recommendations need to be annotated to make it clear whether they apply to the hospital setting, general practice, community/intermediate care, care home or other setting.	Thank you for your comment. A 'who should take action' section for the recommendations has been included in the guideline.
117	SH	NHS Solihull CCG	5	Full	4.2	General	Meds related communication systems – general comment. This section tries to cover both admission to acute/community bedded care from GP care, and discharge from acute/community bedded care back to GP care. It would be more helpful to separate admission from transfer/discharge and include it in a separate sub-section. This should include a separate recommendation on the requirements for information transfer on admission, including a minimum data set equivalent to that in rec 17 for discharge information.	Thank you for your comment. This wording has been amended following further discussion by the GDG.
118	SH	NHS Solihull CCG	6	Full	4.2	General	Meds related communication systems – general comment. This section would benefit from guidance on managing communications relating to monitored dosage systems when patients are being discharged from hospital to community/GP care.	Thank you for your comment. The GDG agreed that the principles of effective communication when a patient moves from one care setting to another will apply to all patients and settings covered by the scope of the guideline. Where relevant information about monitored dosage systems is required, then this can be included in 'other information' as this will not be applicable for all patients.
119	SH	NHS Solihull CCG	7	Full	4.2	General	Meds related communication systems – general comment. This section refers only to admissions/discharges.	Thank you for your comment. The literature search aimed to identify evidence when patients move from

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							It would be beneficial also to include guidance on communication relating to medicines optimisation when patients are referred for an out-patient opinion, and communication with the general practice following the appointment.	one care setting to another, in all settings as outlined in the guideline. Evidence was only identified for hospital discharge that met the criteria outlined in the review protocol, and this evidence was considered by the GDG. The GDG agreed that the principles would apply to other health and social care settings.
120	SH	NHS Solihull CCG	8	Full	4.2	31	Recommendation 12 – needs clarification. Does this mean that GP should be advised of meds changes when patient moves from one ward to another? Is the focus really on providing info relating to their medicines, (eg how and when to take them) to patients and carers?	Thank you for your comment. This has been amended to reflect your comment following further discussion by the GDG. The person to share the information with would depend on the care setting.
121	SH	NHS Solihull CCG	9	Full	4.2	31	Recommendation 13 – needs to include transfer from bedded community care (eg intermediate care) as well as from hospital	Thank you for your comment. This has been amended to reflect your comment following further discussion by the GDG.
122	SH	NHS Solihull CCG	10	Full	4.2	31	Recommendation 14 – could include recommendation to show the complete and accurate list mandated in rec 13 to these health care professionals	Thank you for your comment. Recommendation 13 has been removed following further discussion by the GDG.
123	SH	NHS Solihull CCG	11	Full	4.2	32	Recommendation 15, 16 and 17 should be moved before the current rec 13 and 14. Whilst recognising that it is difficult to be definitive about the timescale, the current wording gives the impression that it is open-ended. It would be useful if it could be expressed as a range of times eg 48-72 hours, to give commissioners and providers more explicit guidance.	Thank you for your comment. The ordering of the recommendations have been agreed by the GDG. Following further discussion by the GDG the timescale has been changed to 24 hours.
124	SH	NHS Solihull CCG	12	Full	4.2	32	Recommendation 17 – excellent content, but some will not apply when patient moves from primary to secondary/community care.(see	Thank you for your comment. Following further discussion by the GDG the relevant text had been

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							comment on line 5 above)	amended to reflect your comment.
125	SH	NHS Solihull CCG	13	Full	4.2	39	Expand recommendation 49 to make it clear that this includes involving a pharmacist when new pathways of care are being designed and commissioned.	Thank you for your comment. This wording has been amended following further discussion by the GDG.
126	SH	NHS Solihull CCG	14	Full	4.2	General	The guideline would benefit from some explicit recommendations relating to provision of medicines-related information to patients outside the context of self-management plans or patient decision aids.	Thank you for your comment. Recommendations have been developed by the GDG using the available evidence for the review questions. Where the intervention requires information to be given to patients, this has been discussed by the GDG and developed as part of the recommendation.
127a	SH	Northumbria Healthcare NHS Foundation Trust	1	Full	General	General	Useful as a repository of evidence but, for some organisations, it may not provide much impetus for significant change or challenge.	Thank you for your comment.

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127b	SH	Northumbria Healthcare NHS Foundation Trust	1	Full	General	General	We are concerned that in some of the commentary of the report ('linking evidence to recommendations') there are examples where the GDG has appeared to make recommendations for reasons of expediency e.g. "the GDG was aware that pharmacists and trained technicians carry out medicines reconciliation in hospital settings. However, during out-of-hours this may not be possible. Other health professionals such as nurses may therefore need to carry it out instead". We suggest that this is an opportunity to first advocate review and change to try and increase availability of those professionals who are best trained/able to perform this function? There obviously though remains a clear need to acknowledge a requirement for other professionals to be competent in and undertaking medicines reconciliation too, particularly where Pharmacy staff are not normally involved in the process.	Thank you for your comment. This guideline did not look at the evidence for staffing levels to carry out the intervention and so cannot develop a recommendation to address this. Another recommendation acknowledges the requirement for other professionals to be competent in undertaking medicines reconciliation.
127c	SH	Northumbria Healthcare NHS Foundation Trust	1	Full	General	General	It is clear that there a dearth of evidence in some keys areas of practice. GDG could strengthen their recommendations about where research should be targeted.	Thank you for your comment. The research recommendations are developed using the NICE research recommendations process and methods guide, which supports NICE guidance producers in making research recommendations (for example, from identifying uncertainties to prioritising research recommendations.

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128a	SH	Northumbria Healthcare NHS Foundation Trust	2	Full	General	General	**Medicines reconciliation** – Major flaw in the presentation of the report which causes significant confusion and potential risk. Medicines reconciliation is a process which reconciles what is recorded at presentation with what the patient actually takes and is appropriate to the clinical context for that patient. It is not a record of what the patient has hitherto been prescribed. The report is inconsistent throughout on this point, and also offers an unsuitable definition. However, elsewhere it is acknowledged that 'when optimising a patient's medicines it is important to identify what medicines they are taking'. This is a better definition.	Thank you for your comment. The GDG agreed that definition for medicines reconciliation should be used as defined by the Institute for Healthcare Improvement as stated in the text.
128b	SH	Northumbria Healthcare NHS Foundation Trust	2	Full	General	General	Little mentioned and no recommendation to use multiple/all sources of information at point of admission for purposes of triangulation i.e. safer to use more than one source of information (ref: previous NPC guidance; previous NICE/NPSA guidance). Plus no mention of potential utility of SCR for this purpose, particularly for patients who arrive as emergencies or outside office hours (see comment below).	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. The details of the intervention did not form part of the evidence review. This may be considered as part of the implementation needs analysis.
129	SH	Northumbria Healthcare NHS Foundation Trust	3	Full	General	General	**Medication review** – Given the background (% patients with multi-morbidity, demographics, >3 LTCs, and importance of patient choice etc.), it is surprising that there is not more emphasis in the report placed on the potential role for de-prescribing. – No mention of how often or at what level. – We understand that STOPP START must be mentioned but it can be difficult	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. De-prescribing and looking at the details of the process of medicines review did not form part of the evidence review**.** This may be considered as part of the implementation needs analysis.

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							to use in practise. Is there any way in which a more pragmatic approach to medicines review could be recommended, i.e. simply state that there should be an assessment of whether medicines are inappropriate/not needed, identifying missing medicines and ensuring appropriate monitoring. It is intuitive/common sense to say so but the need for this fundamental practise may be overlooked if not stated.	
130	SH	Northumbria Healthcare NHS Foundation Trust	4	Full	General	General	**Capacity** – There is no mention of the need to assess a patient's mental capacity as part of the process of any review, self-management, use of decision aids etc. We think that this should be included at all relevant points in the document.	Thank you for your comment. Health and social care practitioners should follow the code of practice that accompanies the Mental Capacity Act in their everyday practice. Therefore this is important to consider in all aspects of healthcare. The GDG discussed and agreed that to refer to this in specific sections would detract from the importance of it being considered throughout. Links to relevant guidance can be found in person-centred care (see section 1.2) of the full guideline.
131	SH	Northumbria Healthcare NHS Foundation Trust	5	Full	4.1	29	Starting line 23: For patients who are admitted and discharged very promptly with no changes to medicines we allow prescribers to write 'no changes to medicines' on immediate discharge summaries. Transcribing information for no obvious reason just increases risk of error without any benefit.	Thank you for your comment. Local processes may vary. This guideline provides recommendations based on the available evidence and also takes into consideration those people who may transfer to a new care setting but their medicines remained unchanged. In these

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								circumstances it would be good practice for the receiving care setting to obtain a list of medicines to determine that no changes have been made to enable a person's care to be continued.
132	SH	Northumbria Healthcare NHS Foundation Trust	6	Full	4.1	30	Line 2-3: this recommendation is also applicable when a new medicine is started in outpatients (or following A&E attendance)? It would be good practice to say so.	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found and can apply to a number of settings.
133	SH	Northumbria Healthcare NHS Foundation Trust	7	Full	4.2	31	Line 38-44: Should include effort to check patient's understanding. This and capacity should form part of any information exchange with patient and/or their family.	Thank you for your comment. Health and social care practitioners should follow the code of practice that accompanies the Mental Capacity Act in their everyday practice. Therefore this is important to consider in all aspects of healthcare. The GDG discussed and agreed that to refer to this in specific sections would detract from the importance of it being considered throughout. Links to relevant guidance can be found in person-centred care (see section 1.2) of the full guideline.
134	SH	Northumbria Healthcare NHS Foundation Trust	8	Full	4.2	32	Line 36-38: Very few patients will be excluded from this list. Most patients will require support (which is probably true) but if resources are limited within organisations then they may need to prioritise those patients at greatest risk and/or use of predictive tools e.g. LACE scores to inform targeting.	Thank you for your comment. The GDG concluded that the purpose of the guideline was to set out key principles. Details of the process are for local consideration and determination.
135	SH	Northumbria Healthcare NHS	9	Full	4.2	33	Line 12-13: What does an overseeing role mean? Is this in the context of policy making or in terms	Thank you for your comment. The term 'overseeing role' relates to

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		Foundation Trust					of clinical supervision? This needs clarifying.	overseeing the process. This recommendation has been amended following further discussion by the GDG.
136	SH	Northumbria Healthcare NHS Foundation Trust	10	Full	4.2	33	Starting line 19: Is this an intended deviation from what was recommended in the previous joint NPSA/NICE safety alert where it was very precisely recommended that a pharmacist be involved in the process. Is this just to enable accommodation of one definition which fits for all circumstances? Plus the statement of 48 hours as an acceptable timescale to undertake the process because it 'represented usual practice in many settings' seems an inappropriate judgement for clinical guidelines (ref: section 6.6, p 74). Is this simply for expediency?	Thank you for your comment. This has been amended following further discussion by the GDG.
137	SH	Northumbria Healthcare NHS Foundation Trust	11	Full	7.6	98	States "GDG mentioned that access to and use of summary care records would facilitate medicines reconciliation". This is our very positive experience and we suggest it should be included in the recommendations (along with use of all the other sources of medicines information as stated above).	Thank you for your comment. The purpose of this review question was to look at the clinical effectiveness and economic evidence for medicines reconciliation. The GDG developed recommendations based on key principles of the intervention, rather than looking at particulars of the intervention being reviewed.
138	SH	Northumbria Healthcare NHS Foundation Trust	12	Full	General	General	Necessity for training and competency described through the report but not borne out strongly enough in the recommendations.	Thank you for your comment. The purpose of this review question was to look at the clinical effectiveness and economic evidence of interventions to optimise medicines. The GDG developed recommendations based on key principles of the intervention, rather than looking at particulars of the intervention being

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								reviewed. Training and competencies were considered as part of the intervention in question, however, particular evidence was not looked at in this area, therefore a strong recommendation could not be made.
139	SH	Northumbria Healthcare NHS Foundation Trust	13	Full	General	General	Does NICE take into account the time value of money? If so, then how?	Thank you for your comment. NICE do take into account the time value of money through discounting (see NICE guidelines manual 2012 section 7). In economic review discounting is considered during quality assessment of studies and in de novo modelling discounting is undertaken where the time horizon demands this.
140	SH	The Rotherham NHS Foundation Trust	1	Full	4.1	29 (line 38)	It should be clear what individuals responsibilities are around the monitoring and actions consequent to it eg the monitoring may be either retained by the original care setting or passed onto another	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
141	SH	The Rotherham NHS Foundation Trust	2	Full	4.2.0.17	32 (line 24)	It should be clear what individuals responsibilities are around the monitoring and actions consequent to it eg the monitoring may be either retained by the original care setting or passed onto another	Thank you for your comment. The list in this recommendation is not exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care

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								practitioner to determine.
142	SH	The Rotherham NHS Foundation Trust	3	Full	4.2.0.20	33 (line 1)	While the 24 hours target is aspirational – the reality is that a principle source of the information is GP surgeries – consequently on weekends there may be a delay in their availability (despite improved availability of the record through the SCR system or overlapping clinical systems)	Thank you for your comment. The GDG concluded that the purpose of the guideline was to set out key principles. Details of the process are for local consideration and determination. Other sources to obtain information about a person's medicines can be used, such as a person's own medicines, regular pharmacy, repeat prescription list, discussion with the person, family member or carer.
143	SH	The Rotherham NHS Foundation Trust	4	Full	4.2.0.30	34 (line 34)	Additional point for the conversation with the patient regarding self-management plans. Consider the addition of a point related to monitoring of either the drug or condition and the likely actions should they not comply with those eg stopping the medication	Thank you for your comment. The relevant text has now been amended to reflect this comment.
144	SH	The Rotherham NHS Foundation Trust	5	Full	4.2.0.38	35 (line 42)	Is it intended that a standard set of these patient decision aids is going to be established and form part of the NHS Evidence resources	Thank you for your comment. Patient decision aids may be developed to support the implementation of NICE guideline in line with the implementation needs analysis for each guideline or they may be developed by organisations external to NICE through the NICE endorsement programme.
145	SH	The Rotherham NHS Foundation Trust	6	Full	4.2.0.45	36 (line 47)	Ensuring the reduction of 'alert fatigue' will be difficult to demonstrate. Will there be guidance on methods to achieve this	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention, rather than looking at particulars of the intervention being reviewed.

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146	SH	The Rotherham NHS Foundation Trust	7	Full	4.2.0.49	37 (line 12)	Some clarity on this point would be useful. Is the reference to the care pathway meant to be a general reference to the establishment of the use of medicines an organisational care pathway or is it meant to read at any point in an individual patient's care pathway. If it is the latter the cost and human resource implications will be limiting.	Thank you for your comment. This wording has been amended following further discussion by the GDG
147	SH	The Rotherham NHS Foundation Trust	8	Full	General	General	Was consideration given to the amount of detail related to medicines that nursing care plans should include. There have been inconsistencies between CQC inspections and an agreed standard would be useful.	Thank you for your comment. This is outside the scope of this guideline.
148a	SH	NHS Dorset CCG	1	Full	General	General	We have to commend the team for this piece of work, in particular drawing together the evidence base for medicine optimisation interventions, which means this document will become a very useful and unique reference source. The recommendations are appropriate and what most NHS medicines and pharmacy teams have implemented to some extent. Drawing together the evidence and these robust recommendations will enable this to be further implemented.	Thank you for your comment.
148b	SH	NHS Dorset CCG	1	Full	General	General	Ideally We would prefer a clearer distinction as to what commissioners should do and what providers should do but recognise that the landscape is different in the devolved administrations and such language may not be transferrable. Such distinction however would ensure clear ownership of the recommendations. Perhaps in a similar way to the tools that supported care home medicines document that distinction can be made.	Thank you for your comment. A 'who should take action' section for the recommendations has been included in the guideline. In addition a baseline assessment tool will be developed to support implementation of the guideline. This will allow organisations to identify which recommendations are applicable to them.
149	SH	Care Right Now	1	Full	4.2	31-5	Point 12,13,14,15,16,31 – would it be possible to mention the use of patient held records here? Examples to support this being included:	Thank you for your comment. Your comment will be considered as part of the implementation needs analysis for the guideline.

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							The NIHR My Medication Passport: http://www.clahrc-northwestlondon.nihr.ac.uk/research-projects/bespoke-projects/my-medication-passport Pill Manager: http://www.pharmacyapp.com/ and a project around parent (patient) held medicine's records: https://www.nice.org.uk/savingsAndProductivityAndLocalPracticeResource?ci=http%3a%2f%2fsearch.nice.org.uk%2fusingguidance%2fsharedlearningimplementingniceguidance%2fexamplesofimplementation%2feximpresults.jsp%3fo%3d405	
150	SH	Care Right Now	2	Full	General	General	Our recommendation is the this Guidance is supported by a summary documents (such as NICE bites) including: 1. A summary for patients, families and carers 2. A summary for commissioners	Thank you for your comment. A NICE guideline, full guideline, information for the public and pathway versions will be published. NICE bites are produced by UK medicines information.
151	SH	Department of Health	1	Full	4.1	29	(Rec 24) We suggest adding two further bullets which read *'And has access to the latest evidence based-guidance'* and *'has the relevant access to patient information.'*	Thank you for your comment. The recommendation relates to training and competency of the healthcare professional carrying out medicines reconciliation. The GDG concluded that access to information was not part of this recommendation.
152	SH	Department of Health	2	Full	4.1	29	(Rec 8) We're not clear on what is meant by the use of the word 'identify.' Is the document saying NHS organisations should have processes in place for	Thank you for your comment. Following further discussion with by the GDG, they concluded the wording is consistent with the

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							identifying patient safety incidents?	terminology used by the MHRA.
153	SH	Department of Health	3	Full	4.1	29	(Rec 17) We feel this recommendation could be developed to specify a timescale for this work (i.e. within 24 hours) and a consistent way in which it should be done. Additionally, we suggest adding *'and their pharmacy'* to the end of the first bullet	Thank you for your comment. There is already a recommendation that addresses the timescale of when this should be carried out. Wording and formatting was considered by the NICE publishing team.
154	SH	Department of Health	4	Full	4.2	30	(Recs 1-4) In relation to medicines-related patient safety incidents, can you provide guidance on how to implement appropriate measures and how far these should go?	Thank you for your comment. Your comment will be considered as part of the implementation needs analysis for the guideline.
155	SH	Department of Health	5	Full	4.2	31	(Rec 10) The STOP/START tool is used for very specific prescribing errors. Could the document go further and cover other types of error? I.e. dosage, labels, administration errors	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention, rather than looking at particulars of the intervention being reviewed.
156	SH	Department of Health	6	Full	4.2	31-2	(Recs 11 & 17) Are these recommendations essentially saying the same thing? Could they be amalgamated?	Thank you for your comment. The recommendations are different and following further discussion by the GDG, they agreed that they should not be amalgamated. The wording has been amended to make them clear.
157	SH	Department of Health	7	Full	4.2	32	(Rec 18) Remove the word 'consider'. It should be always done.	Thank you for your comment. The word 'consider' is used to reflect the lack of evidence available to answer this question.' Please see NICE guidelines manual (2012) section 9 which explains how is wording used in recommendations to reflect the evidence base'.
158	SH	Department of Health	8	Full	4.2	32	(Rec 19) At the end of the first sentence, we suggest	Thank you for your comment. Medicines use reviews did not

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							adding *'and their community pharmacists for a medicines use review, where appropriate.'*	form part of the evidence reviewed for this review question about medicines related communication systems. The evidence was searched for under the medication review question, however no evidence was identified.
159	SH	Department of Health	9	Full	4.2	33	(Rec 20) Does the 24 hour timescale conflict with the one in recommendation 15 which is for 48 hours?	Thank you for your comment. This wording has been amended following further discussion by the GDG.
160	SH	Department of Health	10	Full	4.2	33	(Rec 22) The timescale seems unrealistic. The GP might not see the patient for a good while after their discharge from hospital.	Thank you for your comment. This was discussed by the GDG in great depth which is why the GDG agreed to include 'before a prescription or new supply of medicines is issued and no more than 1 week after the GP practice receives the information' to the recommendation.
161	SH	Department of Health	11	Full	4.2	33	(Rec 23) In place of *'a senior responsible pharmacist'* we suggest *'a competent healthcare professional, preferably a pharmacist.'*	Thank you for your comment. This wording has been amended following further discussion by the GDG.
162	SH	Department of Health	12	Full	4.2	33	(Rec 24) Person needs access to and understanding of the patient's clinical condition.	Thank you for your comment. To have clinical and technical knowledge on medicines use, there needs to be some element of understanding of clinical conditions. Furthermore, to address any discrepancies highlighted by the person carrying out the medicines reconciliation the prescriber would be informed to resolve the discrepancy in line with the person's clinical condition.

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163	SH	Department of Health	13	Full	4.2	33	(Rec 25) We agree with the recommendation	Thank you for your comment.
164	SH	Department of Health	14	Full	4.2	34	(Recs 30-1) Carers for patients also need to be involved in discussions on self-management plans. Patients also need to understand the consequences on their condition of not taking their medicines or of missing a dose.	Thank you for your comment. The relevant text has now been added to reflect this comment.
165	SH	Department of Health	15	Full	4.2	35	(Recs 32-3) Can you provide examples of how decision aids are routinely used?	Thank you for your comment. There is currently no consistent approach to the use of patient decision aids in consultations involving medicines. Implementation of the guideline recommendations will help to support this.
166	SH	Department of Health	16	Full	4.2	35	(Rec 35) Patient decision aids – these are not routinely used at present, few healthcare professionals and pharmacists will have any knowledge of what these are and how to use – introducing a new and large area of work?	Thank you for your comment. A key aim of medicines optimisation is to improve patient engagement and involvement in decision-making about medicines There was a large amount of RCT evidence identified for this review question and the GDG was able to develop strong recommendations to optimise medicines use. The recommendations do not advocate 'routine use' of patient decision aids.
167	SH	Department of Health	17	Full	4.2	36	(Rec 42) Shouldn't there be national decision aids developed rather than local.	Thank you for your comment. NICE has produced a patient decision aid on atrial fibrillation and plans to produce others where there is an identified need.
168	SH	Department of	18	Full	4.2	36	(Rec 43)	Thank you for your comment. At

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		Health					We are not clear on what is meant by 'stakeholders.'	NICE, the term 'stakeholder' has an official status. Stakeholders are organisations who are registered with NICE because they have an interest in the topic, or they represent people whose practice or care may be directly affected by the guideline or quality standard.
169	SH	Department of Health	19	Full	4.2	36	(Recs 44-7) We don't feel these recommendations are really relevant to general practice where clinical decision support systems are part and parcel of standard practice software and matters of their quality and updating are addressed by GPSOC. There would be more value in making recommendations to support primary care prescribers when they have to prescribe in environments where they don't have computer access. These recommendations may be more relevant to the hospital sector - if they are about more adoption of e-prescribing in secondary care, can that be made clearer?	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention and the evidence included use of clinical decision support within GP settings. For the purpose of this review question, for clinical decision support to be used access to a computer would be needed and so recommendations could not be made for those who do not have access to a computer.
170	SH	Department of Health	20	Full	4.2	37	(Rec 49) We aren't clear whether this recommendation is really about supporting patients and carers at the point of supply. Pharmaceutical expertise may not always be available 'on tap' for every point in the care pathway but the routes to access that advice should always be clear.	Thank you for your comment. This wording has been amended following further discussion by the GDG.
171	SH	Department of Health	21	Full	4.2.1	37	(Research recommendation) We feel that the major concern should be patients actually taking their medicines. This is a more significant issue that the issues the research recommendations presented.	Thank you for your comment. Medicine adherence is out of scope for this guideline (see Medicines adherence. NICE clinical guideline 76 (2009). The NICE pathway will aim to bring together medicines adherence and medicines optimisation guideline

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								recommendations.
172a	SH	Department of Health	22	General	General	General	The guidance covers the prescribing aspect of medicines optimisation in some detail but more needs to be added in a structured way with regard to all the processes in the chain and how they can support medicine optimisation e.g. prescribing, supply and administration aspects?	Thank you for your comment. The key review questions were identified during scoping. Supply and administration of medicines did not form part of the evidence review for this guideline.
172b	SH	Department of Health	22	General	General	General	We would also like to see more of a focus on the strategic side, particularly the roles that drugs and therapeutics committees should take and how service commissioners can play their part.	Thank you for your comment. The purpose of the review questions was to look at the clinical and economic evidence for interventions that optimise medicines use. The roles of committees for reviewing medicines are not included in the guideline as this is not a specific intervention. However these may be considered as part of the implementation needs analysis. The NICE pathway will aim to bring together NICE guidance on medicines adherence, local formularies and medicines optimisation.
172c	SH	Department of Health	22	General	General	General	The shift from medicines management towards medicine optimisation also needs to be clearly made- so the link that just as much needs to go into ensuring patients are willing and able to take their medicines (by utilising services available such as MURs from GPs and pharmacies and NMS from pharmacies and commissioning new services where needed) as which medicine is prescribed.	Thank you for your comment. The introduction to the guideline explains the difference between medicines management and medicines optimisation. The principles of MUR and NMS may be identified through the implementation needs analysis as being a tool to support some of the recommendations in this guideline.
173a	SH	Faculty of	1	Full	General	General	Our comments are as follows:	Thank you for your comment. The

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		Pharmaceutical Medicine					This subject is of enormous importance both from the evidence of large scale waste totalling billions of pounds per annum to the denying to patient of the benefits of modern medicines. The Medicines Optimisation clinical guideline is disappointing as it contains little data to support the recommendation.The seven identified activities to optimised medicines use are: 1. Identifying, reporting and learning from medicines-related patient safety incidents 2. Medicines-related communication systems when patients move from one care setting to another 3. Medicines reconciliation 4. Self-management plans 5. Patient decision aids in consultations involving medicines 6. Clinical decision support 7. Medicines-related models of organisational and cross-sector working These cover the conventional approaches that have been advocated and the guideline examines the evidence for their use and makes recommendations.The analysis as expected is through and supported by existing guidance documents in related fields.However the most obvious omission is not emphasized namely that there is little evidence to support the recommendations indeed most of the recommendations are a re-iteration of the proposed actions blended with "common sense". It would have been better if the authors had stood back from the above proffered remedies and instead undertaken their own analysis or requested research in the major areas of:	guideline covers the systems and processes for optimising the use of medicines. The key review questions and areas to focus on in the guideline were agreed during the scoping phase of guideline development. Where there was little evidence for the intervention being reviewed, this was reflected in the strength of the recommendation. The scoping phase included an opportunity for stakeholders to be involved in a scoping workshop (to shape the content of the scope) and also opportunity to provide comments on the proposed draft scope, prior to the scope being finalised and development of the guideline starting.

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							Doctor/prescriber/patient interaction Use of the Medicines Information sheet with each therapy The skills necessary to write and to reconcile the medicines prescribed Finally the communication between the different organisations.	
173b	SH	Faculty of Pharmaceutical Medicine	1	Full	General	General	Sadly professional responsibility is not emphasized sufficiently and there is no avocation of simple metrics to follow the use of the medicine in this guidance. Without such a focus on professional accountability the guideline fails to advance the field of Medicines Optimisation	Thank you for your comment. Professional responsibilities or accountabilities of health professionals is not within NICE's remit.
173c	SH	Faculty of Pharmaceutical Medicine	1	Full	General	General	As a simple illustration in a doctor's clinic when a decision to introduce the new medicine is made and a prescription is written the importance of this simple act is as vital as the surgeon making an skin incision. If the prescriber is not held to account for the appropriate use of the medicine how will the use of medicines be optimised.	Thank you for your comment. All health professionals should work and act in accordance to their professional regulations.
173d	SH	Faculty of Pharmaceutical Medicine	1	Full	General	General	However the most worrying aspect of the guideline is the absence of identification of the accountable person who ensures that the medicines are used properly. This individual may differ in the different situations of use of medicines but without the person being held to account little will change.	Thank you for your comment. Professional responsibilities or accountabilities of health professionals is not within NICE's remit.
174	SH	NHS Barking & Dagenham CCG	1	NICE	4.1	29	(Rec 17) After …*reviewed or monitored*, include swallowing difficulties (for oral medicines)	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but

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								includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
175	SH	NHS Barking & Dagenham CCG	2	NICE	4.1	29	(Rec 17) After ….*taking the medicines* add including the use of compliance aids, such as dose reminders for tablets, devices to help with administration of inhalers, eye drops, etc.	Thank you for your comment .The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
176	SH	NHS Barking & Dagenham CCG	3	NICE	4.1	32	(Rec 17) After …*reviewed or monitored*, include swallowing difficulties (for oral medicines)	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
177	SH	NHS Barking & Dagenham CCG	4	NICE	4.1	32	(Rec 17) After ….*taking the medicines* add including the use of compliance aids, such as dose reminders for tablets, devices to help with administration of inhalers, eye drops, etc.	Thank you for your comment. The list in this recommendation not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to

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								determine.
178	SH	Parkinson's UK	1	Full	General	General	**Medication timing** In the current draft guideline, Parkinson's UK does not believe that medication timings is given enough attention. In order to optimise medication in the treatment of Parkinson's and other conditions such as Epilepsy, HIV and Diabetes it is essential medicines are administered on time. We therefore recommend that the guideline makes specific reference to the importance of medication timing under sections 6, 7, 8 and 9. Parkinson's UK runs the Get It On Time campaign which outlines the importance of people getting their Parkinson's medication on time, every time in hospitals and care homes. If people with Parkinson's don't get their medication on time, their ability to manage their symptoms may be lost either temporarily or permanently. For example they may suddenly not be able to move, get out of bed or even walk down a corridor. Such is the importance of medicines timings if these are not adhered to they can have serious long-term implications for someone with Parkinson's. A Newsnight[1] investigation revealed the NHS is wasting millions of pounds every year in England because it is failing to properly care for people with Parkinson's when they are in hospital. This is due to them not being given their medication on time, which makes their condition uncontrolled and permanently worsens their health, meaning they become more reliant on the NHS and the state for care.	Thank you for your comment. This wording has been amended following further discussion by the GDG.

[1] Newsnight, Inadequate care for Parkinson's sufferers: http://www.bbc.co.uk/news/health-24493420, 2013.

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							The Newsnight report revealed a series of systematic failings by the NHS in England when it comes to providing even basic levels of care for people with Parkinson's. More than £20 million was wasted in England in 2012/13 on 128,513 excess bed days for people with Parkinson's as they stayed in hospital longer than they should, due to a lack of staff awareness about the condition and poor medicines management. The report also revealed a person aged over 65 with Parkinson's costs the NHS three and a half times more in unplanned hospital admissions than someone who doesn't have Parkinson's. The report also found that, of the 92,000 people with Parkinson's aged over 65 in England: • 39 per cent went into hospital as an unplanned admission – two and half times more than an over-65 without Parkinson's • Almost half were admitted to hospital more than once in a year – spending, on average, an extra three and a half days longer than expected • This costs the NHS over £177 million each year – 83 per cent of the overall cost of admissions for people with Parkinson's. A recent answer to a parliamentary question revealed that there were 617 safety incidents in hospital involving Parkinson's medication between March and July 2014[2] – 111 of which were said to	

[2] Answer to a Parliamentary Question, 3 September 2014 (Hansard: 206629).

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							have caused a level of harm.[3] This demonstrates that the problem has not been rectified despite the NHS being made aware of it and further underlines the need to draw attention to this area in the medicines optimisation guideline.	
179	SH	Parkinson's UK	2	Full	General	General	**Self-administration** As with medication timings, the right to self-administer medication is not given enough focus in the current guideline. Medication is the main treatment for Parkinson's and as we have demonstrated above, ensuring it is taken on time is absolutely essential for the person to function in their daily life. However, a person with Parkinson's can be taking up to 30 tablets per day at very specific times meaning that it can be difficult for nurses to fit these complex requirements into drug rounds. Therefore, being able to self-administer Parkinson's medication becomes a lifeline for people with the condition allowing them to stay healthy in hospital and leave safely. Ascertaining the ability of a person to self-administer their medication in hospitals and care homes is an essential component of the medicines reconciliation process and should therefore be included in section 7 of the guideline. The NICE Clinical Guideline on Parkinson's[4] includes a specific reference to the importance of getting medication on time and self-medication. The guideline, which is currently under review by NICE, specifically states medication should be	Thank you for your comment. The purpose of this review question was to look at the clinical and economic evidence for interventions that optimise the use of medicines. The GDG developed high level recommendations based on key principles of the intervention, rather than looking at particulars of the intervention being reviewed. The timing of medicines is already included in recommendations where relevant.

[3] Answer to a Parliamentary Question, 13 October (ref: 209177).
[4] NICE: *Parkinson's disease - Diagnosis and management in primary and secondary care*, 2006

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							'given at the appropriate times, which in some cases may mean allowing self-medication.' A 2013 YouGov survey completed by 4,777 people who have either been diagnosed with the condition or are family members or carers of a person with Parkinson's, found that of those having been in hospital or a care home, 30 per cent reported not receiving their medication on time.[5] Furthermore, an online survey of people affected by Parkinson's undertaken in 2012[6] found that only 16% (out of 98 respondents) got their medication on time, every time during their most recent hospital admission. Respondents were also asked about the opportunity to self-administer their own medication (i.e. being able to take responsibility for their Parkinson's medication without direct professional supervision). Only 13% (out of 97 respondents) were able to self-administer their medication every time. 53% reported not being given the opportunity at all. In some cases, this had been deemed inappropriate due to the person's medical status at that time, however quite often the reason given was that this was against hospital policy. In order to gain an insight in to the current practice of self-administration, Parkinson's UK submitted a Freedom of Information request to 181 Trusts and health boards for information on the existence of an organisational self-administration policy and	

[5] Parkinson's UK and YouGov, *Survey of people with Parkinson's and their friends, family and carers*, 2013
[6] Parkinson's UK, *Getting Parkinson's medication on time*, 2012.

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							whether this was being actively utilised. Out of the 88% of trusts and boards that responded, 17% of hospital trusts/boards reported that they did not have a self-administration policy in place. It has been harder to ascertain the level and quality of implementation through the requests. **Case study:** When Phil Walkerdine, 51, went into hospital with pneumonia, the last bit of control he had over his Parkinson's was lost when his medication was locked away. *"Even though I was told I had Parkinson's in 2004, I'm determined to do things the way I did before my diagnosis and, thanks to my medication, I'm normally able to.* *My symptoms include stiffness, balance issues, and freezing and, as long as I take my drugs at set times every day, I can keep them under control. But that all changed for a while when I got taken into hospital.* *I was admitted after developing a rare form of pneumonia. I signed a form when I got there that let me take my own medication but a few hours later they told me this was no longer allowed. My Parkinson's medication was then locked in a container by my bedside cabinet.* *It soon became obvious that getting my medication on time was going to be a problem. On the ward, meds were only given at certain time of day and I often waited an hour past the time my medication was due because the ward was busy.* *I felt myself starting to lose control and struggle with my symptoms – it was bad enough having the pneumonia but when my Parkinson's symptoms got worse it was the last thing I*	

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							needed. *If you haven't got your drugs inside you it's difficult to do even the most basic things and I couldn't even pour myself a glass of water.* *Throughout my stay, I had to keep reminding busy nurses about my medication. I also needed to show them how to use my infusion pump and had to keep doing this whenever I moved to a different ward. I'm thankful for the care I received while I was in hospital, but if I'd been allowed to take my own medication I could have avoided the extra pain and stress, managed my Parkinson's, and saved the nurses time.* *My experience has made me nervous about going into hospital again as I wouldn't be able to go in knowing I'd be looked after properly – I'd have to educate the ward staff all over again, and that does make me worry.* *Every person with Parkinson's is different, with individual medication regimes. Raising awareness among staff and having the right policies on self-administration of medication would help make staying in hospital easier and really put people with Parkinson's back in control."*	
180	SH	Neonatal & Paediatric Pharmacists Group	1	Full	4.2	31	Point 13 – information should be provided to **carers** as well as patients (to cover use in children) and should be in a suitable format for use by parents and carers.	Thank you for your comment. The relevant text has now been amended to reflect this comment.
181	SH	Neonatal & Paediatric Pharmacists Group	2	Full	4.2	32	Point 17 – we agree that the indication for a medicine should be specified however this is not currently always apparent on the discharge prescriptions in use in many NHS organisations.	Thank you for your comment.
182	SH	Neonatal & Paediatric Pharmacists Group	3	Full	4.2	33	Point 21 – we agree that this is a suitable recommendation but question the terminology used. If a patient is transferred between wards, is this a transcription check rather than full	Thank you for your comment, this would depend on the setting of transfer and if there has been a change in the prescription chart.

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							medicines reconciliation?	Medicines reconciliation would still occur, however a transcription check would occur if a new chart is to be written up using the old chart.
183	SH	Neonatal & Paediatric Pharmacists Group	4	Full	4.2	33	Point 22 – this is a laudable aim but would have implications for GP practices.	Thank you for your comment. Your comment will be considered as part of the implementation needs analysis.
184	SH	Neonatal & Paediatric Pharmacists Group	5	Full	4.2	33	Point 23 – does this include Primary Care as well as Secondary Care?	Thank you for your comment. The relevant text has now been added to reflect this comment.
185	SH	Neonatal & Paediatric Pharmacists Group	6	Full	4.2	33	Point 27 – we feel strongly that this should also include children in view of the issues of formulation, unlicensed medicines and changes in dose with age. It would be helpful if bullet points one and two specifically state "including children".	Thank you for your comment. Children could fall under 'people taking multiple medicines (polypharmacy)' or 'people with chronic or long-term conditions'. The term 'people' includes adults and children. The GDG was aware that no evidence was identified in children however the same principles would apply to all. By including reference to children in this specific recommendation the importance would be lost across all recommendations.
186	SH	Neonatal & Paediatric Pharmacists Group	7	Full	4.2	34	Section on Self-Management Plans – this section needs to include reference to parents and carers in order to fully include children in these issues.	Thank you for your comment. The relevant text has now been added to reflect this comment.
187	SH	Neonatal & Paediatric Pharmacists Group	8	Full	4.2	35	Section on Patient Decision Aids – also needs to be more inclusive of parents and carers.	Thank you for your comment. The relevant text has now been added to reflect this comment.
188a	SH	Janssen	1	Full	General	General	Janssen welcomes the development of a clinical guideline for medicines optimisation and the	Thank you for your comment. The Royal Pharmaceutical Society

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							opportunity to comment on it. Janssen is firmly and publically committed to the national medicines optimisation programme and strongly advocate the underpinning principle **that medicines play a crucial role in maintaining health, preventing illness, managing long-term conditions and curing disease. Medicines are a fundamental part of patient management and it is vital that patients get the best quality outcomes from medicines. Medicines optimisation is a holistic patient focused approach to getting the best from investment in and use of medicines.** Medicines optimisation is about ensuring that the right patients get the right choice of medicine at the right time. By focusing on patients and their experiences, the goal is to help patients to improve their outcomes, take their medicines correctly, avoid taking unnecessary medicines, reduce wastage and improve the safe use of medicines. The Royal Pharmaceutical Society published the good practice guide in May 2013 "Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England"* which outlined the guiding principles for Medicines Optimisation across **four** key principles. Each one of these principles - understanding the patient's experience; evidence-based choice of medicines; ensuring medicines areas safe as possible; make medicines optimisation part of routine practice carry equal weight and importance to achieving the aims of medicines optimisation.	guide on Medicines optimisation has been mentioned in the introductory text. The aim of the introduction for this NICE guideline is to introduce the concept of medicines optimisation and highlight areas where work has been carried out for the topic. The document has been hyperlinked for the user to obtain further information. The four key principles as stated in the Royal Pharmaceutical Society guidance Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England*' are included in this guideline.

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188b	SH	Janssen	1	Full	General	General	This document has now become a recognised starting point for national, regional and local medicines optimisation strategic plans and, as such, Janssen would expect the 4 principles set out in this document to have greater emphasis within the NICE guideline. **ABPI believe that it is important to have a balanced and blended approach across all of these principles to ensure the aspirations of Medicines Optimisation are fully achieved.**	Thank you for your comment. The relevant text has been added in to reflect your comment.
188c	SH	Janssen	1	Full	General	General	ABPI has noted that within the document there is a significant emphasis on medicines safety, some regard given to wastage and limited acknowledgement to other principles that recognise the value of medicines to the NHS and patients. Janssen understands that the reason for this is because of the short clinical guideline process adopted by NICE to produce this document. The process relies on appraisal of published evidence according to strict search criteria. It is disappointing that because of the process, the evidence base that has been used is limited in its scope for demonstrating a range of activities already starting to be adopted in pockets within practice that have the potential to achieve improved outcomes for patients. There is little published evidence to support making strong recommendations for a balanced and blended approach across a range of activities which does not align to the 4 principles published last year. In order to overcome this limitation, the ABPI would suggest to NICE that a more balanced approach to medicines optimisation and the 4 principles should be reflected in the introductory pages and in any additional resource materials and implementation activities that NICE may be	Thank you for your comment. The Royal Pharmaceutical Society guide on Medicines optimisation has been mentioned in the introductory text. The aim of the introduction for this NICE guideline is to introduce the concept of medicines optimisation and highlight areas where work has been carried out for the topic. The document has been hyperlinked for the user to obtain further information. The four key principles as stated in the Royal Pharmaceutical Society guidance Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England*' are included in this guideline. Relevant text has been added in to reflect your comment. This comment will be considered in

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							planning (NICE Implementation Team).	the implementation needs analysis.
188c	SH	Janssen	1	Full	General	General	In addition, the difference between medicines management (often focused on process, systems and costs alone) and medicines optimisation need to be recognised and the need to refocus efforts and resource away from medicines management towards medicines optimisation needs to be set out.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
188d	SH	Janssen	1	Full	General	General	Since the central tenant for medicines optimisation is that the patient is key to the decision-making process, the guideline should reflect that appropriate treatment should be provided through open dialogue between the healthcare professional and the patient without compromising clinical freedom. Janssen acknowledges that decision –support tools and resources have their place but should not take precedent over dialogue to understand the needs and experiences of the patients. Reliance on decision-support tools may lead to circumstances where certain treatments are recommended based on criteria which are not aligned to broader NHS principles & policies such as those described within the Innovation, Health and Wealth report [1] & the PPRS agreement [2], which support the uptake of new innovative technologies. [1] Innovation Health and Wealth, accelerating adoption and diffusion in the NHS. [2] The Pharmaceutical Price Regulation Scheme 2014	Thank you for your comment. The evidence for clinical decision support was weak and this is reflected in the strength of the recommendation. Recommendations for clinical decision support state that this should not replace clinical judgement which should be consider for each individual person, their clinical condition and the consultation. If using clinical decision support systems, one that reflects the best available evidence for treatment should be used.
188f	SH	Janssen	1	Full	General	General	Additional points for consideration for inclusion in introductory section:	Thank you for your comment. The aim of the introduction for this NICE guideline is to introduce the

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							1. NICE should acknowledge and support healthcare professionals (HCP) role in understanding adherence and shared decision-making so that the patient gets the maximum value from the medicine and that the NHS obtains the maximum value from the medicine also.	concept of medicines optimisation and highlight the areas where there has been work around the topic. To support healthcare professionals with adherence and shared decision making, NICE has published guidelines on medicines adherence and patient experience in adult NHS services.
188g	SH	Janssen	1	Full	General	General	**Additional points for consideration for inclusion in introductory section:** 1. Although there are a number of references made to home setting in the context of home care throughout the draft consultation document, a more precise definition would be helpful for example to differentiate between patients' home and care homes. This would help further identify specific requirements to enable self-management at home versus care home. Remote monitoring, for example, is likely to play an even greater role in home setting than at care homes.	Thank you for your comment. The relevant wording has been added to reflect your comment.
189a	SH	Janssen	2	Full	3.4.2	26	ABPI have concerns that the economic analysis only being modelled on the Medicines Reconciliation area of the draft guideline is a missed opportunity. There is the potential to demonstrate significant economic benefit in appropriately conducted medication reviews, helping patients to achieve their goals, void complications in the long term and ultimately have a better outcome [Hex et al, *Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs*].	Thank you for your comment. Health economic modelling was not undertaken on medication reviews for the reasons stated in consultation draft guideline, section 8.4 – page 10.9, final paragraph. Hex et al. reported that the majority of costs related to diabetes were as a result of complications. However, we do not have evidence from the clinical review linking a reduction in

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								diabetes related complications to medication reviews neither do we have clinical evidence linking an improvement in quality of life with medication review in patients with diabetes.
189b	SH	Janssen	2	Full	3.4.2	26	We also believe that the guideline could go further in considering how these recommendations might be implemented, for example via commissioned services, and how they are linked to system levers and incentives such as QOF and how the recommendations must be reflected in existing and new quality standards.	Thank you for your comment. This will be considered in the implementation needs analysis.
190	SH	Janssen	3	Full	4.1	29	(Section 4.1 R8 page 29 & section 5.7 pages 59-60) There appears to be no mention of informing manufacturers of adverse events associated with their medicines; Manufacturers need to be kept informed of such matters so they can take appropriate action. Therefore it may worth adding and to make it clear in the text to inform the pharmaceutical company/manufacturer of the incident that occurred?	Thank you for your comment. Following further discussion by the GDG, section 5.6 has been updated. Reporting of adverse drug reactions to the MHRA is outside the scope of this guideline.
191	SH	Janssen	4	Full	4.2.17	32	ABPI would like to draw to the attention of the authors the Commissioning Intentions 2015/16 for Prescribed Specialised Services, Section on Chemotherapy Drugs paragraph 88 refers to the need for all Trusts "to work with Area Teams to maximise opportunities for dose banding and vial sharing where such activity does not exist". ABPI considers it relevant and appropriate for the document to include information, including brand name, on any device or biological medicine that the patient has been given or is using in order to	Thank you for your comment. This list was not intended to be exhaustive with particulars. Where other relevant information including brand name for the medicine or device is required, then this can be included in 'other information' as not every medicine or device will need a brand to be specified. This also applies to signposting to any supporting materials or safety information available.

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							avoiding the patient being inadvertently transferred to a medicine or device with which they are unfamiliar. This is of particular concern where there are several possible medicines and/or devices for administering them for a particular condition. This will also ensure that MHRA guidance is adhered to [http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con207196.pdf] It should also include any supporting materials or safety information available such as the Patient Passport to Safer Use of Insulin [http://www.nrls.npsa.nhs.uk/resources/?EntryId45=130397].	
192	SH	Janssen	5	Full	4.2.29	34	We feel that this recommendation should acknowledge the short- and long-term effects a medicine review can have on a patient's outcome, for example helping to avoid long term complications arising from a poorly controlled long term condition.	Thank you for your comment. The evidence for long-term and short-term effects of medication review was not available for the GDG to consider when developing recommendations.
193	SH	Janssen	6	Full	4.2.30	34	This recommendation could go further and recommend that patients are signposted to and encouraged to engage with appropriate education related to their condition on a systematic basis to improve uptake rates [REF NDA 2014].	Thank you for your comment. The relevant text has now been amended to reflect this comment.
194	SH	Janssen	7	Full	4.2	34	(Rec 30) ABPI would like to draw attention to the lack of clarity on which setting(s) self-management takes place in the first paragraph on self-management plans. There is no mention of home setting at present, which we believe should be included. See general comments on first page.	Thank you for your comment. As stated in the scope and section 2.4, this guideline covers all children, young people and adults groups using medicines in all settings. The relevant text has been added in to reflect your comment.
195	SH	Janssen	8	Full	4.2	34-5	(Rec 31) Janssen suggests inserting the following bullet	Thank you for your comment. The list in recommendation 31 was

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							point: • *Technology available for remote monitoring of patient treatment to support appropriate use of medicines and provide warning of potential side effects.*	agreed by the GDG as the minimum information to include within the self-management plan. Self-management plans should be individualised and tailored to the person's needs, this includes providing any other additional information that meets the person's needs to support self-management. Where such technology for monitoring exists, this would be part of the tailored approach when drawing up the self-management plan with the person. The GDG was aware that not all medicines may have this remote monitoring technology in place.
196	SH	Janssen	9	Full	4.2	35	Janssen would like to suggest strengthening the recommendation for the use of patient decision aids as part of the consultation. Shared decisions relating to medicines will influence whether a patient is more likely to adhere to their chosen care plan [REF: http://www.kingsfund.org.uk/publications/supporting-people-manage-their-health]. The extensive published work of Professor Richard Thomson can provide the evidence for the impact of shared decision making on patient motivation.	Thank you for your comment. The recommendation to 'offer' patients the opportunity to use a patient decision aid is a 'strong' recommendation to reflect the evidence and cannot be strengthened further.
197	SH	Janssen	10	Full	4.2	36	(Rec 41) Janssen would like to suggest the following rewording for this recommendation "*Consider training and education needs,* ***particularly on innovative technologies****, to support health professionals and patients in*	Thank you for your comment. The purpose of this review question was to look at the clinical and economic evidence for patient decision aids. The GDG developed high level recommendations based

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							developing the appropriate skills and expertise to use patient decision aids effectively in consultations about medicines"	on key principles of the intervention found from evidence, rather than looking at particulars of the intervention being reviewed. Training and education to support use of patient decision aids was discussed by the GDG, however the details of what this would involve was not discussed as it is out of scope.
198	SH	Janssen	11	Full	5.7	60	(Rec 3) Janssen very much supports this recommendation. Reporting medicines-related patient safety incidents is critically important and something that the pharmaceutical industry as a whole takes very seriously.	Thank you for your comment.
199	SH	Janssen	12	Full	7.7	99	(Rec 25) A key principle of medicines reconciliation is that it should be patient focussed. We believe that the government's position that there should be "no decision about me without me" is fundamentally right and as such we would strongly support this recommendation.	Thank you for your comment
200	SH	Janssen	13	Full	10.7	163	(Rec 32) Janssen fully supports the patients' involvement in decision making about their medicines and it is important they are encouraged to take an active role in these decisions. However, it should be recognised that some patients are unable, or initially unwilling, to make such decisions for a variety of reasons such as a lack of confidence or belief systems. This should be recognised at the outset and we would like to see this recommendation amended to read; *"Offer the opportunity and encourage all people to be involved in making decisions about their*	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.

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							medicine. Find out what level of involvement in decision-making the person would like and avoid making assumptions about this"	
201	SH	Janssen	14	Full	10.7	163	(Rec 34) Janssen strongly supports an evidence based approach to medication choice. We also recognise that the decision needs to also take into account clinical expertise and the patients' values and preferences. This recommendation should also be included within the medicines reviews section, or at least be made more explicit as a major point throughout the MO guidance.	Thank you for your comment. Shared decision-making and patient experience has been included in the introduction section. We are aware of the overlap of this across some sections and we have cross-referenced where appropriate.
202	SH	Janssen	15	Full	10.7	163	(Rec 35) Janssen supports this recommendation. Additionally cultural and language barriers should be accommodated and patient decision aids should be written in 'plain English' style and translated versions available.	Thank you for your comment
203	SH	Janssen	16	Full	11.7	178	(Rec 44) One of the central tenents of medicines optimisation is that the patient is central to the decision making process. Through an open dialogue between the HCP and patient, the appropriate treatment for them will be prescribed and administered. Whilst this recommendation acknowledges that decision support should never replace clinical judgement, we are concerned that this will begin to erode clinical freedom. It may lead to circumstances where certain treatments are recommended based on criteria which are not aligned to broader NHS principles & policies such as those described within the Innovation, Health and Wealth report [1] & the PPRS agreement [2], which support the uptake of new innovative technologies. We suggest that this point has an	Thank you for your comment. Clinical decision support as a barrier to the uptake of technologies did not form part of the evidence review and so cannot be included within the recommendation.

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							additional sentence which reads "***They should also not act as a barrier to the uptake and access of new technologies***." [1] Innovation Health and Wealth, accelerating adoption and diffusion in the NHS. [2] The Pharmaceutical Price Regulation Scheme 2014	
204	SH	Janssen	17	Full	11.7	178	(Rec 47) The training described within this recommendation appears to cover technical ability in the main, but only a single comment on 'understanding its limitations.' In line with our comment above, we believe this should have additional wording along the lines of '….to ensure that the patient's preferences and circumstances are taken into account and the appropriate medicines offered.'	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
205	SH	Janssen	18	Full	12.7	195	(Rec 49) Janssen supports the recommendation that a pharmacist be involved in medicines discussions during the care pathway. It is, perhaps, more important though to describe the nature of that involvement. It is not just that they bring their clinical knowledge to the discussion, but that they are also able to bring a patient focus and understanding. These skills and attitudes should be emphasised if an effective Medicines Optimisation approach is to be implemented. This should be recognised in the statement such that it reads: *"When medicines are being discussed at any point in the care pathway, involve a pharmacist with relevant clinical knowledge and skills. The skills level should be such that a truly patient focussed and shared decision can be made allied to the evidence base."*	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.

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206	SH	NHS Bedfordshire CCG	1	NICE	8	121	Medicines Use Reviews (MURs and the New Medicines Service (NMS) are both advanced services provided by community pharmacy contractors, commissioned by NHS England within the community pharmacy contractual framework. Each are evidence based interventions, which support medicines optimisation, including the recent NMS evaluation (http://www.nottingham.ac.uk/~pazmjb/nms/). There should be a clear and specific recommendation that patient pathways developed within health economies should include referral into MURs, discharge MURs and NMS (as appropriate). This is particularly important for patients receiving high risk medicines such as anticoagulants, inhalers etc	Thank you for your comment. There was no evidence found for Medicines Use Reviews. The New Medicines Service did not form part of the evidence review. For these reasons they have not been included within the recommendations however their use and support for optimising medicines has been included in the linking evidence to recommendations section and they may also be identified as tools to support implementation of the guideline as part of the implementation needs analysis.
207	SH	NHS Bedfordshire CCG	2	NICE	8	121	There should be a clear and specific recommendation that Support similar to NMS and MURs should be commissioned for patients who cannot access appropriate community pharmacy based services. These might include housebound patients or patients whose condition might require more specialist pharmaceutical support such as complex treatments for mental health conditions.	Thank you for your comment. There was no evidence found for Medicines Use Reviews. The New Medicines Service did not form part of the evidence review. For these reasons they have not been included within the recommendations however their use and support for optimising medicines has been included in the linking evidence to recommendations section and they may also be identified as tools to support implementation of the guideline as part of the implementation needs analysis.
208	SH	NHS Bedfordshire CCG	3	NICE	9	136	There should be a clear and specific recommendation that self-management plans should include reference to patients accessing regular MURs and initially, NMS	Thank you for your comment. There was no evidence found for Medicines Use Reviews. The New Medicines Service did not form

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								part of the evidence review. For these reasons they have not been included within the recommendations however their use and support for optimising medicines has been included in the linking evidence to recommendations section and they may also be identified as tools to support implementation of the guideline as part of the implementation needs analysis.
209	SH	Royal College of Nursing	1	General	General	General	The Royal College of Nursing have no comments to submit to inform on the Medicine's optimisation draft guideline consultation at this time. Thank you for the opportunity to participate.	Thank you for your comment.
210	SH	Royal College of General Practitioners	1	Full	General	General	Medicine optimisation is important to protect patients from harm particularly as they age and to ensure resources are used appropriately with less medicines wastage. **Areas not covered by this guidance include:** Single disease guidance appears to promote polypharmacy particularly in the elderly and those people with multimorbidity where the NNH may greater than the NNTs. The electronic summary care record (SCR) is important to share information between primary secondary care but appears to be only mentioned once. SCRs provide healthcare staff treating patients in an emergency or out-of-hours with faster access to key clinical information. When patients are admitted to hospital most patients have a medicine omitted or a wrong dose recorded. Patients taking several medicines for	Thank you for your comment. There was no evidence found for the use of electronic summary care records as a way to share information. Other areas the comment relates to did not form part of the evidence review.

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							long-term conditions are most likely to have errors Dodds LJ. Unintended discrepancies between pre-admission and admission prescriptions identified by pharmacy-led medicines reconciliation: results of a collaborative service evaluation across East and SE England. IJPP 18 (Supp 2) September 201 pp9-10. The delays in SCR as well as low levels of implementation of electronic discharges and outpatient letters is a significant barrier to safer care. Electronic prescribing systems to transfer the scripts to pharmacists prevent transcription errors and are not mentioned. Viewing the medications in various formats such by BNF group and linkage to problems is available in most GP systems and allows safer medication review. There is poor access in GP and hospital systems to age-specific NNTs for medications in order to prevent the elderly receiving inappropriate medication. The pressures on primary care with recruitment issues is reducing time for full discussions with patients about medication reduction and review. There are transcription errors in hospitals using paper-based drug charts that require rewriting at regular intervals.	
211	SH	Royal College of General Practitioners	2	Full	4.2	30 (line 19)	Ensure that patients and/or their family members or carers understand how to identify and report any medicines-related patient safety incidents	Thank you for your comment. This wording has been amended following further discussion by the

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							This is a comment of no clinical use, more likely to engender fear , anxiety and non adherence than serve any useful purpose.	GDG.
212	SH	Royal College of General Practitioners	3	Full	4.2	32 (line 1)	2 working days is more appropriate	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
213	SH	Royal College of General Practitioners	4	Full	4.2	32 (line 39)	Patients are often discharged from hospital on dangerous or inappropriate medications: this is then corrected or made safe by the GP: this is a process more than reconciliation: e.g. the patient discharged on a combination of aspirin, warfarin and clopidogrel with no gastroprotection	Thank you for your comment. For the purpose of this guideline, evidence was reviewed specifically for medicines reconciliation carried out by health professionals including GPs. The Institute for Healthcare Improvement definition for medicines reconciliation states that this is: 'the process of identifying the most accurate list of a patient's current medicines – including the name, dosage, frequency and route – and comparing them to the current list in use, recognising any discrepancies, and documenting any changes, thus resulting in a complete list of medications, accurately communicated'. This is the definition used in the guideline.
214	SH	Royal College of General Practitioners	5	Full	4.2	33 (line 7)	Vide supra	Thank you for your comment. For the purpose of this guideline, evidence was reviewed specifically for medicines reconciliation carried out by health professionals including GPs. The Institute for Healthcare Improvement definition for medicines reconciliation states that this is: 'the process of

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								identifying the most accurate list of a patient's current medicines – including the name, dosage, frequency and route – and comparing them to the current list in use, recognising any discrepancies, and documenting any changes, thus resulting in a complete list of medications, accurately communicated'. This is the definition used in the guideline.
215	SH	Royal College of General Practitioners	6	Full	4.2	34 (line 17)	Self Management plans in the absence of patient education cause more harm than good. In order to educate patients an educated workforce is needed to be able to perform these activities.	Thank you for your comment. This will be considered as part of the implementation needs analysis.
216	SH	Royal College of General Practitioners	7	Full	4.2	36 (lines 18-45)	Clinical decision support is only as good as the knowledge and skills of the clinician using them. They are not a substitute, but may be helpful. Managers and commissioners seem to treat these as a be all and end all. (DR)	Thank you for your comment.
217	SH	Royal College of General Practitioners	8	Full	4.2	37 (line 15)	Excellent recommendations (DR)	Thank you for your comment.
218	SH	Royal College of General Practitioners	9	Full	4.2	39 (line 16)	Pharmacists are not clinicians (DR)	Thank you for your comment. There is no mention of pharmacists being referred to as a clinician in the page number and line number you are referring to.
219	SH	Royal College of General Practitioners	10	Full	4.2	39 (line 24)	Polypharmacy is in part a result of qof, NICE and other well meaning bodies using disease specific guidelines which do not account for sensible approaches made to prescribing and achieving optimal outcomes in those patients with multiple morbidities. (DR)	Thank you for your comment. NICE is developing a guideline on Multimorbidity: clinical assessment and management to support the assessment, prioritisation and management of care for people with commonly occurring multimorbidities.

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220	SH	Royal College of General Practitioners	11	Full	8.7	121 (lines 27-9)	This research needs to be performed before any well-intentioned recommendations are made; any recommendation must be accompanied by the resource needed to achieve the desired outcome (DR)	Thank you for your comment. The evidence was available for the GDG to consider and use when developing recommendations and so further research was not required for this intervention. The GDG discussed resource implications when developing recommendations for medication review. See section 8.6 of the guideline.
221	SH	Royal College of General Practitioners	12	Full	9.1	122	As usual, patient education is ignored: this is a critical step in achieving self management	Thank you for your comment. Patient education is out of scope for this guideline. For the purpose of this intervention we have emphasised the importance of engagement with the person in the introduction and also recommendations include discussing 'the person's knowledge and skills needed to use the plan' to ensure that this is done.
222	SH	Royal College of General Practitioners	13	Full	General	General	Outcomes in clinical practice are often different from those achieved in clinical trials: this is particularly so with community pharmacists who do not posses the clinical skills to make complex decisions. The use of guided templates is something which is worth considering, but will lengthen consultation time and must be of real and significant benefit otherwise they will be dismissed along with the plethora of alerts which interrupt the smooth flow of a consultation at present. Of greater importance is to re professionalise doctors in particular to make decisions based on individual patient needs and	Thank you for your comment. The use of guided templates did not form part of the evidence review. Professional development of health professionals is not within NICE's remit.

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							to quit slavish adherence to guidelines or having clinical activities driven bt payment vehicles such as qof which have in balance probably more harms than benefits for patient care and are carried out for political and not medical reasons.	
223	SH	Humber NHS Foundation Trust	1	NICE	General	General	Overall looks a really good document and probably fine if the whole document read, however, I know with implementation, services often just look at the recommendations. I have concerns about the section on medication review. I feel the scope used for this part of the document is not wide enough and leads to recommendations that are limited and could be unsafe for patients. I do agree that patients medication should be reviewed and for some patients this is simple, but for patients in the three groups identified in recommendation 27 a medication review is a lot more complex. It should also involve reviewing the patients in context of their current conditions, past history including previous treatments, treatment options (not just medication) and the idiosyncrasies of the individual patient. At best whoever is doing the review should communicate with the patients GP as soon as possible with their findings and recommendations. The GP will often have additional information and knowledge that is essential and, combining this with medication review will inform the best outcome for the patient. If this is what is intended I feel the recommendations should be more explicit.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
224	SH	British Pain Society	1	Full	General	General	The nature and presentation of pain, particularly when chronic, leads to many uncertainties and concerns with prescribing and administering medication for analgesia. Expectations and effects differ widely and contribute to wastage and	Thank you for your comment.

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							potential for adverse effects. There are substantial dangers to life from inappropriate use of analgesics including respiratory depression from opioids and GI haemorrhage from NSAIDs: lack of understanding and communication are often implicated. This review and guideline on medication optimisation is timely and welcomed by the British Pain Society.	
225	SH	Merck Sharp & Dohme UK Ltd	1	General	General	General	MSD appreciates the opportunity to comment on the Medicines Optimisation draft guideline. I can confirm that we have no comments.	Thank you for your comment.
226	SH	Pharmacy Voice	1	Full	General	General	This guideline is extremely informative, however we feel that many busy practitioners may be put off by the size of the document or not have time to read the whole guideline. We suggest section 4 is either published as a standalone section, is repositioned as the first chapter, or otherwise highlighted/signposted to in some way.	Thank you for your comment. A NICE guideline, full guideline, pathway and 'Information for the public' versions will be published.
227	SH	Pharmacy Voice	2	Full	General	General	A diagrammatic version of the recommendations, with links to the relevant area of both section 4.2 and the full guideline, would be useful to enable busy practitioners to find the information they require quickly.	Thank you for your comment. The NICE pathway for medicines optimisation will provide fast and easy access to users of the guidance.
228	SH	Pharmacy Voice	3	Full	General	General	Pharmacists are the health professionals whose specialism is medicines. In addition to a five year masters/preregistration formation programme, many have undertaken further qualifications, and continuing professional development is mandatory. The extent of pharmacists' knowledge is not fully recognised by other health professionals, the public or patients. Given that this specialist expertise put pharmacists at the heart of medicines optimisation, the guideline could recognise the role pharmacists can play more strongly.	Thank you for your comment. This guideline aims to look at the clinical and cost effectiveness of interventions used to optimise medicines. The roles of particular health professionals did not form part of the review. However, where the GDG found evidence for interventions carried out by a particular group of health professionals, this was considered and formed part of the

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								recommendations.
229	SH	Pharmacy Voice	4	Full	4.1	29	Identifying, reporting and learning from medicines related patient safety incidents, Recommendation 8. We consider this recommendation to be aspirational, given the current state of availability/access to information, particularly in primary care, where the professionals involved in care may work in isolation from each other. We support its inclusion in the recommendations, but we believe that a necessary first step in primary care is embedding good practice, so the key priority is recommendation 1.	Thank you for your comment. This recommendation was based on the evidence review where studies included that used several methods to identify medicines-related patient safety incidents. Following further discussion by the GDG, they concluded that ensuring patient safety is important and this recommendation emphasise the need to have systems and processes in place.
230	SH	Pharmacy Voice	5	Full	4.1	29	In Recommendation 17, we believe there is more information which could/should be included in a discharge summary. We would add any end date for an acute course of medication and, where medicines are being supplied direct or via an alternative route such as home care company, a note of those medicines, supplier contact details and supply frequency.	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs. Following further discussion by the GDG, some parts of the recommendation has been amended to reflect your comment.
231	SH	Pharmacy Voice	6	Full	4.1	30	We think recommendation 18 needs to be stronger than "Consider". The evaluation[1] of the Discharge Medicines Service in Wales shows clear benefits and cost savings accruing when pharmacists actively compare discharge summaries with patients' first post-discharge community prescriptions. Earlier research[2] found that providing information to community pharmacists prevents potential adverse events, while a third study[3] found that for every 19 patients discharged, a community pharmacist	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.

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							identified at least one discrepancy, which if gone unnoticed, could have resulted in an adverse outcome for the patient. Given that the recommendation recognises that this may not always be practically possible, we believe it should read: "Send a person's medicines discharge information to their nominated community pharmacy when possible and in agreement with the person" [1]**EVALUATION OF THE DISCHARGE MEDICINES REVIEW SERVICE** **http://www.cpwales.org.uk/Contractors-Area/Pharmacy-Contact---Services/DMR/DMR-Evaluation_Final-Report_13082014.aspx** [2] The Royal Pharmaceutical Society, *Moving patients, Moving Medicines, Moving Safely – Guidance on Discharge and Transfer planning*, 2006 3. Duggan, C et al, *Reducing prescribing discrepancies following hospital discharge: the UK perspective*, Saferhealthcare website, October 2006	
232	SH	Pharmacy Voice	7	Full	4.2	General	A number of useful tools are referred to in this section. It would be helpful to have links to them, using the same method as in Chapter One.	Thank you for your comment. Formatting was considered by the NICE publishing team. Section 4.2 is a summary of all the recommendations and the links are provided in the actual sections.
233	SH	Pharmacy Voice	8	Full	4.2	General	It would seem more logical to rearrange the recommendations so that patient involvement sets the theme for the guideline. We think a better order might be: patient decision aids, medication review, self management plans, medicines reconciliation, followed by communications, medicines related safety incidents and decision aids.	Thank you for your comment. Formatting was considered by the NICE publishing team.

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234	SH	Pharmacy Voice	9	Full	4.2	General	The guidelines are informative, but we are concerned that health professionals and patients may not follow recommendations linearly, or different recommendations may be implemented at different times by different people involved in care. We think a diagrammatic representation of the recommendations with options for next steps and an indication of who might be involved might be helpful.	Thank you for your comment. The NICE pathway for medicines optimisation will provide a visual representation of the recommendations. This will also link with medicines adherence. A 'who should take action' section for the recommendations has been included in the guideline.
235a	SH	Pharmacy Voice	10	Full	4.2	31	Line16; please insert timely (48 hours) after high quality care.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
235b	SH	Pharmacy Voice	10	Full	4.2	31	Recommendation 15 line 2 p32 refers to information being shared in a timely way however this is not reflected in the introduction. For the information to be of use it must be shared in a timely manner, ideally at the time the patient is transferred between settings.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team. The evidence informs the recommendation. The introduction is there to introduce what the intervention is.
236	SH	Pharmacy Voice	11	Full	4.2	31	In recommendation 14, "encouraging" seems a very weak term. GPs particularly - we would add community pharmacists - need to know someone has been in hospital in order to provide appropriate continuing care. Patients should not routinely be relied on to provide information to those involved in their care, although we recognise this may be the only mechanism where, for example, an individual does not have a regular pharmacy.	Thank you for your comment. Following further discussion by the GDG, this recommendation has been taken out.
237	SH	Pharmacy Voice	12	Full	4.2`	32	Please see point 4	Thank you for your comment. This recommendation was based on the evidence review where studies included that used several methods to identify medicines related patient safety incidents.

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								Following further discussion by the GDG, they concluded that ensuring patient safety is important and this recommendation emphasise the need to have systems and processes in place.
238	SH	Pharmacy Voice	13	Full	4.2	32	Recommendation 18 please see point 5	Thank you for your comment. The list in this recommendation not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs. Following further discussion by the GDG, some parts of the recommendation has been amended to reflect your comment.
239	SH	Pharmacy Voice	14	Full	4.2	32	Medicines reconciliation, line 44 states that the reconciliation process will vary between care settings; we can see that documentation may vary, but we are unclear why the process might.	Thank you for your comment. The process may vary depending on the availability of the information, the person carrying out medicines reconciliation, length of stay for example short stay patient (day care) or long stay patient (hospital admission) and transfer from one ward to another.
240	SH	Pharmacy Voice	15	Full	4.2	32	Medicines reconciliation, line 46 states that algorithms have been produced to show the different processes. There is no link to the algorithms or a reference for them.	Thank you for your comment. This has been hyperlinked to reflect your comment.
241	SH	Pharmacy Voice	16	Full	4.2	33	Recommendation 23 states that organisations should identify a senior responsible pharmacist. We wonder about the link to "senior" – a grade concept that does not necessarily translate to the community sector. In addition, "responsible pharmacist" has a legal definition in a registered	Thank you for your comment. This recommendation has been amended following further discussion by the GDG.

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							pharmacy that you might like to avoid in the guideline to avoid confusion.	
242	SH	Pharmacy Voice	17	Full	4.2	35	In line 2 of the second bullet point, this should include suspected interactions as well as adverse reactions.	Thank you for your comment. The relevant text has now been amended to reflect this comment.
243	SH	Pharmacy Voice	18	Full	4.2	35	When discussing the self-management plan a patient's ability to take their medicines should be considered. For example, they may have difficulty swallowing making liquid preparations more appropriate, or they may need a Disability Discrimination Act assessment to be carried out and appropriate measures taken as a result.	Thank you for your comment. Following further discussion by the GDG they concluded that list in this recommendation is not intended to be exhaustive but includes the minimum dataset. Additional information may be needed depending on the person's needs, but this would be for the health professional and this would fall under ''any other instructions the person needs to safely and effectively self-manage their medicines' in the recommendation.
244	SH	Ethical Medicines Industry Group	1	Full	General	General	The Ethical Medicines Industry Group (EMIG) welcomes the development of a guideline for medicines optimisation. Medicines optimisation is central to improving patient outcomes and it is therefore essential all those involved in a patient's care have clear, practical recommendations to follow.	Thank you for your comment.
245	SH	Ethical Medicines Industry Group	2	Full	General	General	Medicines remain the most common therapeutic intervention in healthcare, and those involved in research and development and the broader pharmaceutical industry have placed significant time and investment in developing safe and effective medicines. As such, it is vital we ensure patients, the NHS and the public achieve value for money from this investment. The draft guideline recognises this and is an important tool to ensuring resources are used wisely and	Thank you for your comment.

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							effectively.	
246	SH	Roche Products	1	Full	5.1	38-41	Patient Safety Alert NHS/PSA/D/2014/005 (20Mar14) raised organisational and health care professional awareness of the implications of EU Directive 2010/84/EU1—this will undoubtedly be improved further through the national medication safety network of medication safety officers. It is therefore essential that the terminology used in this section is unambiguous and consistent with that used by other organisations. The guidance appears to have interpreted the term "medication related patient safety incident" differently to NHS England and the MHRA—"medication incidents" include adverse drug reactions not associated with medication errors.	Thank you for your comment. The term medicines-related patient safety incident is defined in the guideline. This terminology has been used for the purpose of this guideline and may differ to the definition used by NHS England and MHRA. The definition used in Directive 2010/84/EU1 is also included in the guideline. Reporting of adverse drug reactions is outside the scope of this guideline.
247	SH	Roche Products	2	Full	5.1	39	*(Re: box at top of page)* The original infographic (NHS/PSA/D/2014/005) included statements which provide clarification of when medication-related patient safety incidents should be reported to the MHRA as opposed to the NRLS and these should be included as they provide important clarification: • when medication was used correctly according to the Product Licence • unlicensed and off-label use • where no medication error has occurred • associated with use and deliberate misuse.	Thank you for your comment. The guideline has been amended to reflect this comment.
248	SH	Roche Products	3	Full	5.3	40 (line 15)	Stating that studies relating to pharmacovigilance were excluded is confusing as the term pharmacovigilance includes the monitoring of any aspect which could impact the safety profile of a medicine—the types of study excluded should be stated in more detail e.g. studies relating to spontaneous reporting of adverse drug reactions (ADRs).	Thank you for your comment. The text has been amended to reflect this comment.
249	SH	Roche Products	4	Full	5.1	38	*(Re: section 5.1 – Definitions & section5.6 – Table*	Thank you for your comment. As

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							12) We note that the Guideline Development Group (GDG) considered the variation in outcome measures across studies and that it was not always clear if medicines-related problems could have been prevented. As this is the case the term "potentially avoidable" should be clarified and not left to local interpretation—for example, if a patient suffers an ADR as a result of insufficient or ineffective support from a healthcare professional (HCP) should this be considered as potentially avoidable?	described, this varied across studies. Details are provided in the Evidence tables – see appendix D.1.1. The example provided would have been included within the definition used for the purpose of this guideline.
250	SH	Roche Products	5	Full	6.1	62	It should be clear that all medicines are in the scope of the guidance, including those administered parenterally in hospital (in-patient, day-case and out-patient settings) and other models such as home care. This would improve consistency with other NHS England guidance e.g. *Service Specification (B15/S/a) Cancer: Chemotherapy (Adult)* and *National Peer Review Programme Manual for Cancer Services Chemotherapy Measures* which include measures relating to information to be shared across organisational boundaries.	Thank you for your comment. The definition of 'medicine' is covered in the guideline introduction and states: 'the term 'medicines' covers all healthcare treatments, such as oral medicines, topical medicines, inhaled products, injections, wound care products, appliances and vaccines.
251	SH	Roche Products	6	Full	6.1	62	The GDG acknowledge the development of standards for homecare services by the Royal Pharmaceutical Society— such important resources, developed following publication of the Hackett Report, should be clearly signposted in the introduction to this section so that organisations apply NICE guidance in all sectors where medicines are used.	Thank you for your comment. Medicines-related communication systems involves the transfer of medicines information when the person moves from one care setting to another. Homecare services do not involve the person being transferred from one care setting to another but involves medicines being provided to

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								people direct from the manufacturer.
252	SH	Roche Products	7	Full	6.7	77	*(Re: point 17)* The MHRA, British National Formulary and Royal Pharmaceutical Society all recommend that, where relevant, medicines should be identified by generic name and brand–the recommendation should be amended to state this.	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health professional to determine. Where other relevant information including brand name for the medicine is required, then this can be included in 'other information' as not every medicine will need a brand to be specified.
253	SH	Roche Products	8	Full	8.1	100	It should be clear that all medicines are in the scope of the guidance, not only those "taken or used by the patient", for example those administered parenterally in hospital on a recurring basis (in-patient, day-case and out-patient settings) and other models such as home care.	Thank you for your comment. The definition of 'medicine' is covered in the guideline introduction and states: 'the term 'medicines' covers all healthcare treatments, such as oral medicines, topical medicines, inhaled products, injections, wound care products, appliances and vaccines.
254	SH	Roche Products	9	Full	8.7	121	*(Re: point 29)* Recommendation 29 should be re-worded to include "all prescribed, over-the-counter and complementary medicines that the person is taking, using or receiving, and what these are for"	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
255	SH	Roche Products	10	Full	12.1	183	The GDG acknowledge the role of NHS and commercial companies in home care and joint-working projects although no published studies were identified that demonstrate improved patient outcomes.	Thank you for your comment.

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							NICE have previously referenced the outputs of joint working projects in its own advice e.g. *Commissioning for Quality in Rheumatoid Arthritis (CQRA): patient metric data collection form for recent onset rheumatoid arthritis* is referenced in *Quality Standard 33* [Roche provided project management and facilitation support in this joint working project].	
256	SH	Roche Products	11	Full	12.7.1	195	Joint working with the pharmaceutical industry and other commercial organisations is not reflected in the research recommendation— this omission should be rectified. If the GDG believe research in such joint working is less likely to improve patient outcomes than research into joint working between NHS organisations – this should be justified.	Thank you for your comment. This wording has been amended following further discussion by the GDG.
257	SH	Gloucestershire Hospitals NHS Foundation Trust	1	Full	General	General	Will any recognition/support be given to ensure organisations plan/deliver adequate resources to ensure the guidelines can be implemented effectively? Without adequate resources my concern would be that the undoubted benefits of the various interventions will not be deliverable, patient care and safety will be compromised and 'blame' for failures is likely to land on Chief pharmacists' within the hospital setting.	Thank you for your comment. This may be considered as part of the implementation needs analysis.
258a	SH	Gloucestershire Hospitals NHS Foundation Trust	2	Full	4.2	30	Recommendation 1, 7 and 8 – We suggest that there should be a link here to the MHRA document on medicines safety officers. This role is likely to pull all these recommendations together and allow them to be actioned. Support for this role within the guidelines would give prominence to the position as well as facilitating the implementation of the recommendations.	Thank you for your comment. There is a link to this document in section 5.1. Following further discussion by the GDG, the medicines safety officer role has been highlighted in the relevant recommendation.
258b	SH	Gloucestershire Hospitals NHS Foundation	2	Full	4.2	30	Recommendation 4 - discusses having "no blame culture"- we believe this should actually be a 'fair blame culture' as some people are negligent and	Thank you for your comment. The wording has been amended to reflect your comment following

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		Trust					even criminal (Beverly Allot etc).- reference NPSA towards and open and fair culture in the NHS to move from just to reporting to learning culture.	further discussion by the GDG.
259a	SH	Gloucestershire Hospitals NHS Foundation Trust	3	Full	4.2	31	Line 18- We strongly support the recommendation around availability of information when patients are admitted to hospital. Recommendation 11- There should be a recommendation that information about a patient's medicines prescribed by their GP should be readily accessible in an electronic format to all healthcare professionals involved in medicines reconciliation etc. This may be in the form of the summary care record or another similar system. The main issues are accessibility and accuracy of such systems. This issue seriously compromises the safe prescribing of medicines when patients are admitted to hospital	Thank you for your comment. Methods used to access information did not form part of the evidence review and so a recommendation cannot be made.
259b	SH	Gloucestershire Hospitals NHS Foundation Trust	3	Full	4.2	31	Recommendation 13- should the list given to patients include changes made to **pre-admission** medicines? A patient's drug therapy may have many changes during the course of the admission which will not be necessary to communicate. However what is valuable are changes to existing treatment to avoid inadvertent medication errors when the patient goes home.	Thank you for your comment. The GDG concluded that the purpose of the guideline was to set out key principles. Details of the process are for local consideration and determination.
259c	SH	Gloucestershire Hospitals NHS Foundation Trust	3	Full	4.2	31	Recommendation 14- is it appropriate to expect patients to tell the GP what the actual changes are or should we be encouraging patients to tell the GPs that changes have been made and the discharge summary should be the vehicle for communicating the changes?	Thank you for your comment. Following further discussion by the GDG, this recommendation has been removed.
260a	SH	Gloucestershire Hospitals NHS Foundation Trust	4	Full	4.2	32	Recommendation 15 - The recommendation of within 48hours is reasonable for patients discharged, but transfer of care also covers on admission. Additional recommendations/guidance	Thank you for your comment. Following further discussion by the GDG, this recommendation has been amended to 'ideally within 24

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							may be required to ensure this happens.	hours'. However, the GDG recognised that this may not be appropriate or achievable in all settings. See section 6.6 for further details.
260b	SH	Gloucestershire Hospitals NHS Foundation Trust	4	Full	4.2	32	Recommendation 17- this is not about transfer of care it is solely relating to discharge information. To prevent a misunderstanding of what transfer of care means, this recommendation should be reworded as' upon discharge' rather than transfers from one care setting to another.	Thank you for your comment. The wording has been amended to reflect your comment following further discussion by the GDG.
260c	SH	Gloucestershire Hospitals NHS Foundation Trust	4	Full	4.2	32	Recommendation 17- It is impractical to expect the discharge summary to contain information on allergies as most of these will be historical and hence the hospital team will not have any knowledge of the allergy other than the patient stating they are allergic to a medicine. Also, the number of patients that report being allergic to medicines without knowing what the allergy was, is alarmingly high. We suggest this be details of allergic reactions that occurred during the admission!	Thank you for your comment. NICE have published a guideline on drug allergy, see Drug Allergy NICE clinical guideline 183.This guideline is consistent with CG183 and we have hyperlinked to it where appropriate.
260d	SH	Gloucestershire Hospitals NHS Foundation Trust	4	Full	4.2	32	Recommendation 17 – Again, it may not be possible for the discharge letter to have the indication for all medicines to be documented as a number of these will have been started by the GP and it may be difficult to determine the actual indication. We suggest that all medication summaries provided on admission also detail the indication for each medicine, and the indication be for those medicines newly initiated on that admission!	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
260f	SH	Gloucestershire Hospitals NHS Foundation Trust	4	Full	4.2	32	Medicines reconciliation definition (line 40) - this was taken form IHI definition but surely it should contain something around correcting any unintentional discrepancies otherwise what is the	Thank you for your comment. This wording has been amended following further discussion by the GDG.

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							point of the whole process? Medicines reconciliation only works if staff can get the information. Summary Care records help but they can show medicines that have been stopped. It is not just the resource of manpower (which is desperate in some NHS Trusts) and skill mix within pharmacy but also the IT behind it.	
261	SH	Gloucestershire Hospitals NHS Foundation Trust	5	Full	4.2	33	Recommendation 20 - as a point of clarification, the compilation of the accurate list is not medicines reconciliation. It is part of that process, but medicines reconciliation also covers other aspects as previously outlined in the section. Is the goal of medicines reconciliation to prepare the accurate list within 24 hours of admission or to actually do something about the discrepancies that are found? We would question the value of any accurate list if the discrepancies are not acted upon and the patient comes to harm as a consequence. One of the difficulties here is a lack of clarity as to what we are calling medicines reconciliation and within what timeframe it should be started (as in the 'Medicines Safety Thermometer'), partially completed (as is the case here) or fully completed, including the correction of any discrepancies (which is what really counts if you are looking at patient safety and prevention of harm).	Thank you for your comment. This recommendation has been reworded following further discussion by the GDG.
262	SH	Gloucestershire Hospitals NHS Foundation Trust	6	Full	4.2	35	Recommendation 35 - For patient decision aids to be useful, they must be quick and easy to use. The NICE AF aid is a good case in point. Whilst it may be thorough it is not really user friendly within the confines of a standard patient consultation therefore its true value is unlikely to be realised.	Thank you for your comment. This has been forwarded onto the team who developed the NICE patient decision aid. Please also see http://www.nice.org.uk/guidance/cg180/resources/cg180-atrial-fibrillation-update-decision-support-tool-.
263	SH	Gloucestershire	7	Full	4.2	36	There should be a comment in within this	Thank you for your comment. The

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		Hospitals NHS Foundation Trust					statement on where to warn about the risks associated with 'warning fatigue'? It is well recognised within electronic systems that this potentially is an issue that can compromise the value of any such warnings. This is particularly true if the warnings appear frequently without just cause.	GDG developed recommendations based on key principles of the intervention from the evidence found. The specifics of 'warning fatigue' did not form part of the evidence review.
264	SH	Gloucestershire Hospitals NHS Foundation Trust	8	Full	4.2	37	We fully support this statement	Thank you for your comment.
265	SH	Keele Centre for Medicines Optimisation	1	Full	General	General	General comments: • We welcome this guidance and the extremely thorough review of the evidence that informs how best to optimise medicines for patients. Strikingly, it highlights the relative lack of good quality research in this area and we would welcome further suggestions for recommended research to help inform the research agenda. We make some specific suggestions in the sections below. • The recommendations for education and development of pharmacy staff around shared decision making is very much at the heart of Keele School of Pharmacy's philosophy for the education of future and current pharmacists • As with all NICE guidance, the key to affecting clinical practice is in the implementation of the guidance. **We would welcome the opportunity to be involved in the implementation support for this guidance**	Thank you for your comment.
266a	SH	Keele Centre for Medicines Optimisation	2	Full	10.6	163	(Page 163) We welcome the recommendation that organisations should select high quality patient decision aids. We would go further and suggest	Thank you for your comment. Patient decision aids may be developed to support the implementation of NICE guideline

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							that the guidance calls for **a central repository of NICE endorsed implementation tools** are stored and can be accessed as a national resource. This is particularly needed for patient decision aids. Keele would welcome the opportunity to host such a repository should it be receommended.	in line with the implementation needs analysis for each guideline or they may be developed by organisations external to NICE through the NICE endorsement programme.
266b	SH	Keele Centre for Medicines Optimisation	2	Full	10.6	163	(Page 159) We acknowledge the GDG observation about the need for more time to use a PDA in a consultation. There is a particular need to use patient decision aids that can actually be delivered during a standard 10 minute consultation. **We would welcome a recommendation based on the evidence to support this.**	Thank you for your comment. This evidence was not identified within the evidence review. The GDG did not agree that the 10-minute consultation should act as a barrier and recognised that more than one consultation may be needed.
266c	SH	Keele Centre for Medicines Optimisation	2	Full	10.6	163	(Page 161) We disagree with the GDG's opinion that paper-based PDAs are more cost-effective than computer-based systems. This was based on evidence from 2001 and 2002 and electronic delivery systems have improved considerably since then. Rather there is an urgent need for good quality research in this area. Specifically, initial pilot work using a computerised version of the current paper-based NICE AF patient decision aid indicates that the ease of use increases utility and facilitates implementation particularly with the regard to the natural flow of a consultation and less time spent navigating the aid. **We would welcome a specific research recommendation to be added to this section**.	Thank you for your comment. The available evidence included in the cost effectiveness review showed cost effectiveness for paper based PDAs and not for computer based PDAs. The GDG discussed that other factors may have influenced the cost effectiveness, including the patient population that the PDA was used in. The recommendation does not state that either type of PDA should be used over the other. The GDG can only make research recommendations based on areas where there is no evidence available when it has been searched for.
266d	SH	Keele Centre for Medicines Optimisation	2	Full	10.6	163	Whilst there is a responsibility for education institutions to introduce decision making, decision support and decision aids into the undergraduate syllabus, there is also a need to engage the	Thank you for your comment. This may be considered in the implementation needs analysis.

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							hearts and minds of practicing clinicians to increase the uptake of the use of such tools. This requires work to influence qualified clinicians as well as undergraduates and use of change agents to embed these principles within the overall MO agenda. **To this end, we would welcome a clear delineation of research recommendations in Section 10**	
267	SH	Keele Centre for Medicines Optimisation	3	Full	General	General	The guideline is quite rightly focussed towards working on MO with the individual patient. There is perhaps a broader issue to be considered that is for an individual practitioner or practice to understand, on the basis of public health need where the MO challenges lie within their own practice. Greater use should be made of triangulation of hospital admissions, prescribing data (such as PACT), and public health datasets to identify "hotspots" where MO support could best be focussed. We would suggest the guidance would benefit from a health economic analysis of the best methods for stratifying a health economy and identifying the optimum areas for the interventions suggested in this guideline. **This is another area where a specific research recommendation would be welcome or a recommendation for a further iteration of the guidance to address this question.**	Thank you for your comment. The GDG can only make research recommendations based on areas where there is no evidence available when it has been searched for.
268a	SH	Keele Centre for Medicines Optimisation	4	Full	12.7	195	CCGs have limited resource to support MO activity. We would suggest that such resource as is available would be best focussed on working with individual practitioners and practices to produce the desired changes outlined within this guidance. Greater efficiencies could be made by a consortia approach to data analysis and	Thank you for your comment. This may be considered as part of the implementation needs analysis.

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							evidence based implementation freeing up MO teams as change agents.	
268b	SH	Keele Centre for Medicines Optimisation	4	Full	12.7	195	Although the evidence from PINCER and STOP-START is robust, dissemination is still very heterogeneous possibly due to less attention being paid to both influencing and training clinicians and healthcare teams on the use of these tools.	Thank you for your comment. This may be considered as part of the implementation needs analysis.
268c	SH	Keele Centre for Medicines Optimisation	4	Full	12.7	195	Change does not make itself. The principles of academic detailing have been proved and established since Avorn's work in the 1980's. **We therefore ask why the evidence to support academic detailing as an intervention does not seem to have been considered by the guidance?**	Thank you for your comment. Education and training of health and social care practitioners are outside of scope.
268d	SH	Keele Centre for Medicines Optimisation	4	Full	12.7	195	All the principles espoused therein have still not been used on a widespread basis to produce effective change. Engaging practitioners, building a trusting relationship and providing the support for them to implement the guidance contained herein is as important as the tools themselves. Unless health care professionals are convinced of the value of these tools they will not recognise the value of them. **A review of the evidence for educational outreach and academic detailing as a specific delivery tool to facilitate change in medicines optimisation and/or a good practice recommendation along these lines would be welcomed.**	Thank you for your comment. Education and training of health and social care practitioners is outside of scope.
269	SH	Keele Centre for Medicines Optimisation	5	Full	6.7	77	ESCAs (Effective Shared Care Agreements) and electronic ESCAs are a key part of the communication between secondary and primary care. Enabling discussion between GP, specialist and the patient about the medication to be taken, monitoring, adverse events. Referral criteria	Thank you for your comment. Shared care was out of scope and for this reason a recommendation or research recommendation cannot be considered for this guideline as it did not form part of

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							when a patient should be returned back to secondary care Experience from MTRAC of using shared care agreements. There is an electronic ESCA library available at Keele. While we recognise that specific shared care arrangements were excluded from the scope, there is the need for a research recommendation here: ESCAs have been used effectively, but no formal evaluation has been undertaken. Although ESCAs can be resource intensive to produce a repository of Electronic ESCA templates has been started and may be of use nationally and implementation would be facilitated by a recommendation within the guidance.	the evidence review.
270	SH	Keele Centre for Medicines Optimisation	6	Full	11	General	(Re: section 11 and then apply to 10) We note from the excluded trials list in Appendix 1: Kawamoto K, Houlihan CA, Balas EA, et al. (2005) Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. BMJ 330(7494): 765 Reason for exclusion: Systematic review, not all studies relevant. Relevant studies extracted and included in analysis While we understand the reasons for exclusion, the 4 keys points for success of clinical decision support (CDS) should be part of the guidance: • The CDS is integrated into the clinical work flow rather than as separate login or screen • The CDSS is electronic rather than paper	Thank you for your comment. The GDG can only make research recommendations based on areas where there is no evidence available when it has been searched for.

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							based • The CDS provides decision support at the point of care rather than before or after the patient encounter • The CDS provides 'active voice' recommendations for care rather that assessments We would suggest the same principles apply to the use of patient decision aids and that issues such as integration into the clinical work flow, availability online at the point of care etc., are critical to the successful implementation and should be fully accounted for in any issues relating the cost effectiveness. **This could be included as a research recommendation.**	
271	SH	Keele Centre for Medicines Optimisation	7	Full	11	166	There is no mention of the principles of what a good clinical decision support (CDS) system should look like. This may benefit from a research recommendation, although there is a qualitative study from Canada that informs practice in this area: Adoption needs to be actively fostered through a bottom up clinical needs first approach. Ref: 16 rozenblum. A qualitative study of Canadas experience of the implementation of an electronic health information technology Can Med Assoc J 281-288 Summary: service orientated architecture has been proposed as a way to assess barriers to CDS such as feasibility (cost), usability /integration, clinician non-acceptance, alert desensitisation.	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. The recommendations suggest what health professionals should consider when using a clinical decision support system. The details of what a good clinical decision support system should look like did not form part of the evidence review and so the GDG are unable to develop a research recommendation for this. The reference you have cited did not come up in the literature search and therefore was not included in the review.

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							We appreciate that this is not within a UK setting but could not find a reason why this study was excluded and would appreciate you considering it for inclusion.	
272	SH	Keele Centre for Medicines Optimisation	8	Full	10	137	We would welcome a recommendation on the use of simulation technology for the education of undergraduate, postgraduate, CPD of healthcare professionals and patients, particularly for consultation skills to facilitate shared decision making. This paper informs the evidence base: Bracegirdle L Chapman S R programmable Patients: simulation of consultation Skills in a Virtual environment. Bio –Algorithms and Med-Systems 2010 Vol ^ (no 11) pp 111-115	Thank you for your comment. Education and training of health and social care practitioners is out of scope.
273	SH	Keele Centre for Medicines Optimisation	9	Full	11	165	The point about CDSS's being kept up-to-date is well made. However, there is no acknowledgement that the updating and (most importantly, widespread dissemination) of more up-to-date information is in practice easier with web-based/computer technology than print technology. (Re-prints, distribution, assimilation, etc). The notion of being kept-up-to-date is as relevant to the BNF, NICE guidelines, formularies, etc., as it is to CDSS.	Thank you for your comment. This is outside the scope of this guideline. Methods of keeping up-to-date did not form part of the evidence review.
274	SH	Keele Centre for Medicines Optimisation	10	Full	General	General	*(General point but also relates to sections 5 and 12)* Although the evidence from PINCER and STOP-START is robust, dissemination is still very heterogeneous possibly due to less attention being paid to both influencing and training clinicians and healthcare teams on the use of these tools. Change does not make itself. The principles of academic detailing have been proved and established since Avorn's work in the 1980's.	Thank you for your comment. Education and training of health and social care practitioners is outside the scope of this guideline.

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							We therefore ask why the evidence to support academic detailing as an intervention does not seem to have been considered by the guidance? All the principles espoused therein have still not been used on a widespread basis to produce effective change. Engaging practitioners, building a trusting relationship and providing the support for them to implement the guidance contained herein is as important as the tools themselves. Unless health care professionals are convinced of the value of these tools they will not recognise the value of them.	
275a	SH	Merck Serono	1	Full	General	General	Merck Serono welcomes the development of a clinical guideline for medicines optimisation and the opportunity to comment on it. We support the consultation response submitted by the ABPI and have added to their comments in the areas of medicines optimisation we have added observations that are particularly pertinent to Merck Serono. We fully support the NHS' vision for medicines optimisation. Medicines optimisation is about ensuring that the right patients get the right choice of medicine at the right time. By focusing on patients and their experiences, the goal is to help patients to improve their outcomes, take their medicines correctly, avoid taking unnecessary medicines, reduce wastage and improve the safe use of medicines. Medicines optimisation is a holistic patient focused approach to getting the best from investment in and use of medicines. *The Royal Pharmaceutical Society published the good practice guide in May 2013 "Medicines Optimisation: Helping patients to make the most*	Thank you for your comment. The four key principles as stated in the Royal Pharmaceutical Society guidance Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England*' are included in this guideline.

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							of medicines Good practice guidance for healthcare professionals in England" which outlined the guiding principles for Medicines Optimisation across four key principles. Each one of these principles - understanding the patient's experience; evidence-based choice of medicines; ensuring medicines areas safe as possible; make medicines optimisation part of routine practice carry equal weight and importance to achieving the aims of medicines optimisation. This document has now become a recognised starting point for national, regional and local medicines optimisation strategic plans and, as such, Merck Serono would expect the 4 principles set out in this document to have greater emphasis within the NICE guideline. We believe that it is important to have a balanced and blended approach across all of these principles to ensure the aspirations of Medicines Optimisation are fully achieved.	
275b	SH	Merck Serono	1	Full	General	General	We do have concerns that the balance within the guideline is skewed by the availability of evidence that meets NICE criteria. There is, understandably, a significant emphasis on medicines safety and some regard given to wastage, but there is only limited acknowledgement of the other principles that recognise the value of medicines to the NHS and patients. We believe that this is due to the short clinical guideline process adopted by NICE in producing this document. It relies heavily on appraisal of published evidence according to strict search criteria. It is disappointing that because of the review process, the evidence base that has been used is limited in its scope for demonstrating a range of activities already initiated within certain areas. These practices have the potential to	Thank you for your comment. The four key principles as stated in the Royal Pharmaceutical Society guidance Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England*' are included in this guideline. The aim of the introduction for this NICE guideline is to introduce the concept of medicines optimisation and highlight areas where work has been carried out for the topic. This comment may be considered in the implementation needs

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							achieve improved outcomes for patients. There is little published evidence to support making strong recommendations for a balanced and blended approach across a range of activities which does not align to the 4 principles published last year. In order to overcome this limitation, Merck Serono, in line with the ABPI, would like to suggest to NICE that a more balanced approach to medicines optimisation and the 4 principles should be reflected in the introductory pages, in any additional resource materials and within planned implementation activities (NICE Implementation Team).	analysis.
275c	SH	Merck Serono	1	Full	General	General	In addition, the difference between medicines management (often focused on process, systems and costs alone) and medicines optimisation needs to be recognised. The necessity to refocus efforts and resource away from medicines management towards medicines optimisation needs to be outlined clearly.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team and this is included in the scope and the introduction.
276a	SH	Merck Serono	2	Full	3.4.2	26	276 a) Merck Serono supports the point made by the ABPI in its response, ie: "The ABPI have concerns that the economic analysis only being modelled on the Medicines Reconciliation area of the draft guideline is a missed opportunity. There is the potential to demonstrate significant economic benefit in appropriately conducted medication reviews, helping patients to achieve their goals, avoid complications in the long term and ultimately have a better outcome [Hex et al, Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs].	Thank you for your comment. Health economic modelling was not undertaken on medication reviews for the reasons stated in Section 8.4 – page 10.9, final paragraph. Hex et al. reported that the majority of costs related to diabetes were as a result of complications. However, we do not have evidence from the clinical review linking a reduction in diabetes related complications to medication reviews, neither do we have clinical evidence linking an improvement in quality of life with medication review in patients with

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								diabetes.
276b	SH	Merck Serono	2	Full	3.4.2	26	We also believe that the guideline could go further in considering how these recommendations might be implemented. An example of this could be via commissioned services, their link to system levers and incentives such as QOF and how the recommendations must be reflected in existing or new quality standards."	Thank you for your comment. This may be considered as part of the implementation needs analysis.
277	SH	Merck Serono	3	Full	4.1	29	*(Sections 4.1 (R8) and also 5.7, pages 29 and 59-60)* Merck Serono strongly supports the point raised by the ABPI on this section of the Guideline, ie: "There appears to be no mention of informing manufacturers of adverse events associated with their medicines; Manufacturers need to be kept informed of such matters so they can take appropriate action. Therefore it may worth adding and to make it clear in the text to inform the pharmaceutical company/manufacturer of the incident that occurred?"	Thank you for your comment. Following further discussion by the GDG, section 5.6 has been updated. Reporting of adverse drug reactions to the MHRA is outside the scope of this guideline.
278	SH	Merck Serono	4	Full	4.2.17	32	Merck Serono supports the point raised by the ABPI in their submission in relation to ensuring all relevant documentation facilitates accurate identification of products given / supplied to patients through use of the brand name in documentation: "ABPI would like to draw to the attention of the authors the Commissioning Intentions 2015/16 for Prescribed Specialised Services, Section on Chemotherapy Drugs paragraph 88 refers to the need for all Trusts "to work with Area Teams to maximise opportunities for dose banding and vial sharing where such activity does not exist".	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health professional to determine. Where other relevant information including brand name for the medicine or device is required, then this can be included in 'other information' as not every medicine or device will

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							ABPI considers it relevant and appropriate for the document to include information, including brand name, on any device or biological medicine that the patient has been given or is using in order to avoiding the patient being inadvertently transferred to a medicine or device with which they are unfamiliar. This is of particular concern where there are several possible medicines and/or devices for administering them for a particular condition. This will also ensure that MHRA guidance is adhered to [http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con207196.pdf]"	need a brand to be specified.
279	SH	Merck Serono	5	Full	4.2	34-5	*Section 4.2 (31)* Merck Serono supports the insertion of the following bullet point as suggested by the ABPI as it acknowledges how advances in technology are creating innovative ways to support patient's adherence and persistence in medicines use and the outcomes they are getting from their medicines. "ABPI suggests inserting the following bullet point: • *Technology available for remote monitoring of patient treatment to support appropriate use of medicines and provide warning of potential side effects."*	Thank you for your comment. The list in recommendation 31 was agreed by the GDG as the minimum information to include within the self-management plan. Self-management plans should be individualised and tailored to the person's needs, this includes providing any other additional information that meets the person's needs to support self-management. Where such technology for monitoring exists, this would be part of the tailored approach when drawing up the self-management plan with the person. The GDG was aware that not all medicines may have this remote monitoring technology in place.
280	SH	Merck Serono	6	Full	4.2	36	*Section 4.2 (41)* In line with the comment immediately above we	Thank you for your comment. The purpose of this review question

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							think that the addition of the ABPI's suggested wording would facilitate the uptake of innovative technologies that support patients to gain better outcomes from their use of medicines. "ABPI would like to suggest the following rewording for this recommendation "*Consider training and education needs, **particularly on innovative technologies**, to support health professionals and patients in developing the appropriate skills and expertise to use patient decision aids effectively in consultations about medicines" "*	was to look at the clinical and economic evidence for patient decision aids. The GDG developed high level recommendations based on key principles of the intervention found from evidence, rather than looking at particulars of the intervention being reviewed. Training and education to support use of patient decision aids was discussed by the GDG, however the details of what this would involve was not discussed as it is out of scope.
281	SH	Merck Serono	7	Full	5.7	60	(Re: recommendation number 3) Merck Serono strongly supports this recommendation. Reporting medicines-related patient safety incidents is a corner-stone of the infra-structure that supports the safe use of medicines.	Thank you for your comment
282	SH	Merck Serono	8	Full	11.7	178	(Re: recommendation number 47) The training described within this recommendation appears to cover technical ability in the main, but only a single comment on 'understanding its limitations.' In line with our comment above, we believe this should have additional wording along the lines of '….to ensure that the patient's preferences and circumstances are taken into account and the appropriate medicines offered.'	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
283	SH	Alder Hey Children's NHS Foundation Trust	1	Full	General	General	A clear guideline which consolidates the role of the Pharmacist in delivering frontline patient care. I am pleased to see a paediatric pharmacist included as a member of the guideline development group. The recommendations are consistent with the 4 principles of optimisation described by the Royal Pharmaceutical Society in	Thank you for your comment.

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							2013, but now need to be reviewed and aligned to the 5 year NHS forward plan, particularly in relation to adverse reactions (rather than just medication errors) and medicines waste.	
284								Line entered in error
285								Line entered in error
286								Line entered in error
287								Line entered in error
288	SH	NHS England	5	Full	1.1	8-11	There is no mention of the risks of addiction to medicines both in the community and in secure environments. This is a recently prioritised area for PHE and NHS England (Health and Justice) based on published documents 2013: https://www.gov.uk/government/news/new-commissioning-guidance-for-addiction-to-medicines . In the health and justice healthcare setting there is a substantial risk from harm due to diversion and abuse of prescribed medicines and specific guidance has been published to support prescribers in formulary choices to support medicines optimisation in prisons: http://www.rcgp.org.uk/clinical-and-research/clinical-resources/~/media/106D28C849364D4CB2CB5A75A4E0849F.ashx	Thank you for your comment. The risks of addiction to medicines, diversion and abuse of prescribed medicines was not considered during the scoping phase of the guideline. The aim of the introduction for this NICE guideline is to introduce the concept of medicines optimisation and highlight the areas where there has been work around the topic.
289	SH	NHS England	6	Full	2.6.2	16	There are two NICE guidelines under development that will have medicines-related aspects that should be considered for inclusion: Mental healthcare in prison https://www.nice.org.uk/guidance/indevelopment/GID-CGWAVE0726 ; Physical healthcare in prison: https://www.nice.org.uk/guidance/indevelopment/GID-CGWAVE0729	Thank you for your comment. The list of related guidelines provided in section 2.6.2 was not intended to be exhaustive as majority of NICE guidelines have some medicines-related aspects included in them.
290	SH	NHS England	7	Full	5.6	58	The table states: The GDG agreed that patients and/or their family	Thank you for your comment. The term 'carer' is used throughout

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							members or carers have an important role in identifying and reporting of medicines-related patient safety incidents. The consensus of the GDG was that health and social care practitioners should ensure that patients and/or their carers understand how to identify and report medicines-related patient safety incidents and are encouraged and supported to do so. This is reflected in recommendation 2 on page 60. Our comment is that it would be helpful if the term "carer" could be defined or the recommendation re-phrased in a way that includes custodial staff who are responsible for the person on a routine basis in secure environments. These would include prison officers and police custody staff. Incident reporting and communication of these between healthcare and security is a key recommendation in the 2012 McFeeley review into deaths in Custody *(link)*. Current operational barriers exist in improving communication of security incidents relating to medicines. Inclusion of custodial workforce in the recommendation or narrative would provide a clear mandate for these barriers to be justifiably removed and will improve medication incident reporting and handling in secure environments.	NICE guidelines and is defined as 'someone who looks after family, partners or friends in need of help because they are ill, frail or have a disability'. The text has been amended to reflect this comment.
291	SH	NHS England	8	Full	6.7	76	We recognise that the evidence base and deliberations around transfer of care and discharge focusses on hospital settings. The GDG acknowledged that the principles of transfer and discharge apply to all transfers of care between any setting. However this is not fully reflected in the opening paragraph in section 6.7. In secure environment transfers most of the	Thank you for your comment.. Organisations can include secure environments. The scope details the settings to which the guideline applies to and includes all settings for all groups of people using medicines. The text has been amended to include secure

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							recommendations will apply when people are admitted to or released from custody or transferred between custodial settings. In order to ensure that healthcare providers in secure environments interpret these recommendations as being inclusive to the care of people in these settings, please could you consider adding a sentence to the introductory paragraph in section 6.7. stating that although some of these recommendations explicitly mention hospital transfers and discharge, that organisations such as secure environments should consider these for patient transfer and release and implement them in a way that reflects transfer of care for their setting.	environments for clarity.
292	SH	NHS England	9	Full	7.1	79	Medicines reconciliation is equally important on admission, transfer between and release from secure environments. This is not included in the list of examples shown as bullet points. Please could "when a patient moves into or is transferred between secure environments" be considered for inclusion in the list?	Thank you for your comment. The relevant text has now been added to reflect this comment.
293	SH	NHS England	10	Full	7.1	79-80	Please could you consider adjusting the text to clarify inclusivity for **all** care setting transfers/releases for example: "However, it is widely acknowledged that the medicines reconciliation process should also happen when the patient is discharged from hospital or moves into or between any other care setting. In a hospital setting, medicines reconciliation may involve a process to ensure that the medicines prescribed in hospital reflect what the patient was taking before admission or it may be used identify what the patient was taking on another ward. In a primary care setting, medicines reconciliation involves a process to ensure that the medicines	Thank you for your comment. The relevant text has now been added to reflect this comment.

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							prescribed by the GP (or other prescriber) reflect what the patient was taking after discharge from any care setting.	
294	SH	NHS England	11	Full	7.7	98	Please consider adding the word "and other care setting" for recommendation 22. This is because people may be discharged home from temporary care home stays (where other clinicians may have altered therapy) or from secure environments. Otherwise the MR process is to narrowly focused on hospital stays.	Thank you for your comment. This recommendation has been amended following further discussion by the GDG.
295	SH	North West Commissioning Support Unit	1	Full	General	General	It is a positive step that NICE has produced guidelines as Medicines Optimisation covers such a wide range of issues which can impact many aspects of patient care. We do understand the evidence for large sections is of low to moderate quality so will have limited some of the guidance. Some recommendations lack specificity especially in relation to primary care and many seem to be more likely to be achievable in secondary care.	Thank you for your comment. A 'who should take action' section for the recommendations has been included in the guideline.
296	SH	North West Commissioning Support Unit	2	Full	General	General	Many sections appear to focus more on secondary care settings, rather than on what and how primary care could deliver. All care wrapped around the patient should be involved in medicines optimisation, but the guidance contains little that is specific to community services, care homes and social services.	Thank you for your comment. We have used terms such as 'organisation' 'providers' and 'commissioners' in the recommendations which could include community services, care homes and social services.
297	SH	North West Commissioning Support Unit	3	Full	General	General	We wondered if there funding available to implement the recommendations fully, bearing in mind current financial problems. We would certainly need more pharmacists and pharmacy technicians in primary care.	Thank you for your comment. The GDG discussed resource implications during their deliberations when developing the recommendations. Funding of services would be determined locally.
298	SH	North West Commissioning Support Unit	4	Full	General	General	We are concerned about how achievable the recommendations are.	Thank you for your comment. Your comment may be considered as part of the implementation of the

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								guideline process.
299	SH	North West Commissioning Support Unit	5	Full	2.5	13	Line 2 is superfluous to the document and doesn't fit in with the heading.	Thank you for your comment. The relevant text has now been taken out to reflect this comment.
300	SH	North West Commissioning Support Unit	6	Full	2.5	13	Line 10 - Patient education programmes such as Dafne and Patient Experts can have an impact on individual's understanding of the reasons for taking their medications which can lead to better medicine optimisation and hence medical outcomes for the individual. We feel education should be integral to medicine optimisation programmes.	Thank you for your comment. We agree that patient education is important for the medicines optimisation agenda, however, for this short clinical guideline, interventions that specifically patient education was out of scope. This was agreed during the scoping phase.
301	SH	North West Commissioning Support Unit	7	Full	3.3.1	20	The guideline development group doesn't have any representation from community pharmacy.	Thank you for your comment. Members of the GDG were selected from various backgrounds to provide expert knowledge of different settings and practice.
302	SH	North West Commissioning Support Unit	8	Full	4.2.9	30	Not all primary care providers can currently facilitate MDT reviews and do not have dedicated pharmacist support.	Thank you for your comment. The GDG concluded that the purpose of the guideline was to set out key principles. Resources required are for local consideration and determination.
303	SH	North West Commissioning Support Unit	9	Full	4.2.12	31	With consent, it would also be useful to consider other recipients for information e.g. carers (formal and informal) as care homes are often out of the loop; community services, social services, community pharmacists.	Thank you for your comment. This has been amended to reflect your comment following further discussion by the GDG. The person to share the information with would depend on the care setting.
304	SH	North West Commissioning Support Unit	10	Full	4.2.23	33	Does this recommendation also apply to primary care? It appears to reflect secondary care ways of working.	Thank you for your comment. This has been amended to reflect your comment following further discussion by the GDG.
305	SH	North West	11	Full	4.2.25	33	This point lacks clarity regarding patient ability	Thank you for your comment. This

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		Commissioning Support Unit					and consent to involve family/carer.	has been reworded following further discussion by the GDG.
306	SH	North West Commissioning Support Unit	12	Full	4.2.29	34	Should this also include an assessment of whether the patient requires adjustments or additional support to be able to take medicines effectively e.g. large print labels	Thank you for your comment. The relevant text has now been amended to reflect this comment.
307	SH	North West Commissioning Support Unit	13	Full	5.1	39	Lines 16 & 17 – Is there likely to be investment by primary care to assist GP practices to implement this?	Thank you for your comment. The GDG concluded that the purpose of the guideline was to set out key principles. Resources required are for local consideration and determination.
308	SH	North West Commissioning Support Unit	14	Full	8	114	(Table 23) Costings for medication review do not include primary care pharmacists, which may be the preferred route for GP practices or care homes.	Thank you for your comment. As stated in Appendix F.1 (page 423), a unit cost for primary care pharmacists could not be identified, however the GDG recognised that medication reviews are undertaken by this group. Due to the lack of unit cost for primary care pharmacists they were not included within the costings in Table 23.
309	SH	North West Commissioning Support Unit	15	Full	8.6	120	Extra bullet point – nothing listed next to it.	Thank you for your comment. This has been amended to reflect your comment.
310	SH	North West Commissioning Support Unit	16	Full	9.6	135	Extra bullet point toward end of table 27 – nothing listed next to it.	Thank you for your comment. This has been amended to reflect your comment.
311a	SH	Department of Health, Social Services and Public Safety Northern Ireland	1	Full	General	General	Comments regarding Integrated Medicines Management: Were the following references considered: - Scullin et al. An Innovative approach to integrated medicines management. Journal of evaluation in clinical practice. Vol 13, issue 5. Oct	Thank you for your comment. The first reference listed, Scullin et al, was not identified in the searches and so was not considered. The second reference listed, Burnett et al, was considered during the initial sift of the literature review,

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							2007: 781-788. - Burnett et al. Effects of an integrated medicines management programme on medication appropriateness in hospitalised patients. American journal of health-system pharmacy. May 1 2009 vol 66, no.9: 854-859	however the reference did not meet the criteria set out in the review protocol for medicines review and so it was not included for evidence review.
311b	SH	Department of Health, Social Services and Public Safety Northern Ireland	1	Full	General	General	In Northern Ireland, an Integrated Medicines Management Service (IMM) has strategically re-engineered clinical pharmacy services in Health and Social Care Trusts. By targeting the work of pharmacists and pharmacy technicians on admission carrying out medicines reconciliation, pharmacy input during the patient's inpatient journey and full medicines reconciliation at discharge, the service has demonstrated significant improvements in patient care validated by the two randomised controlled trials above. These included reduced length of stay, lower re-admission rates, reduced medication errors and increased medicines appropriateness and revealed that each £1 invested equated to £5-8 in non cash-releasing efficiencies.	Thank you for your comment. The systematic literature reviews were undertaken by guidance information specialists. Please see appendix C of the full guideline for details of the search strategies used. Recommendations for medicines reconciliation were based on the evidence found from randomised controlled trials.
312	SH	Department of Health, Social Services and Public Safety Northern Ireland	2	Full	4.1	31	*(Sections 4.1, 4.2 and 7.7 / pages 31, 34 and 101)* Comments regarding medicines reconciliation: 1. This should state accurate and timely 2. A pharmacist should ideally undertake medicines reconciliation. When this is not immediately possible for all patients, a pharmacist should verify medicine history taken by another healthcare professional (trained accredited pharmacy technician/doctor/nurse). A pharmacist should then use the drug history to undertake medicines reconciliation.	Thank you for your comment. The recommendation relating to who the most appropriate person would be to carry out the medicines reconciliation was discussed by the GDG who concluded that ideally it should be a pharmacist, however, during out of hours, this may not be possible and so other trained a competent healthcare professionals can carry it out to prevent delay in care.
313	SH	Department of Health, Social	3	Full	7.7	35	*(Pages 35 and 101)* The medicines reconciliation should actually be	Thank you for your comment. The recommendation relating to who

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		Services and Public Safety Northern Ireland					carried out by a pharmacist	the most appropriate person would be to carry out the medicines reconciliation was discussed by the GDG who concluded that ideally it should be a pharmacist, however, during out of hours, this may not be possible and so other trained a competent healthcare professionals can carry it out to prevent delay in care.
314	SH	Department of Health, Social Services and Public Safety Northern Ireland	4	Full	General	General	Was the following reference considered: Bradley et al. Potentially inappropriate prescribing among older people in the United Kingdom. BMC Geriatrics 2014 It is stated that 'there is a need for targeted interventions to reduce PIP across all regions but especially in NI and ROI. Targeted interventions focus on specific instances of PIP. The UK has, in the past, successfully introduced incentives to reduce inappropriate prescribing of particular drug groups such as benzodiazepines and these appear to have been successful in reducing the overall burden of PIP. They state that polypharmacy appears to be a major influence on PIP, although attempts to reduce polypharmacy may prove challenging due to the current emphasis on chronic disease management in primary care'.	Thank you for your comment. The reference you have listed, Bradley et al. was not identified in the searches and therefore was not considered. Also, with the study being a retrospective cross-sectional study it would not have formed part of the evidence review, which was mainly based on randomised controlled trials.
315	SH	Department of Health, Social Services and Public Safety Northern Ireland	5	Full	8.7	123	Under the point regarding consider review for some groups of patients, what about the use of risk prediction tools for example Scottish Patients At Risk of Admission and Readmission (SPARRA)?	Thank you for your comment. The use of risk prediction tools did not form part of the evidence review.
316	SH	Department of	6	Full	8.7	123	Under determine locally the most appropriate	Thank you for your comment. The

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		Health, Social Services and Public Safety Northern Ireland					health professional to carry out a medication review, should this not be a defined role for clinical pharmacists in community and hospital?	GDG was aware that the many of the Randomised controlled trials included in the review involved either a pharmacist carrying out the review or the pharmacist was part a multidisciplinary team carrying out the medication review. However, the clinical outcomes were mixed either being clinically effective or being no different to routine care. The GDG also considered resource use and the economic impact and they concluded that the most appropriate health professional to carry out a medication review should be determined locally based on their knowledge and skills.
317	SH	Department of Health, Social Services and Public Safety Northern Ireland	7	Full	12.7	197	Pharmacists should have a defined role regarding medicines optimisation within the patient's care pathway	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. Roles of health professionals involved did not form part of the evidence review.
318	SH	Department of Health, Social Services and Public Safety Northern Ireland	8	Full	4.1	32	Under recommendation 18: 'Consider sending a person's medicines discharge information to their nominated community pharmacy, when possible and in agreement with the person' - **this should read 'a person's medicines discharge information should be sent to their nominated community pharmacy, when possible and in agreement with the person'**	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.

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319	SH	Boehringer Ingelheim	1	Full	General	General	Boehringer Ingelheim welcomes the opportunity to comment on the NICE clinical guideline for Medicines Optimisation. Boehringer Ingelheim believes that medicines play a vital role in improving patients' lives and strongly supports the need to drive a change in practice and culture to ensure medicines are used more effectively, that the right patient gets the right medicine at the right time, and we improve patient outcomes. This approach is focused on two main areas: • optimising existing medicine use • accelerate uptake of innovative clinical and cost effective medicines In order for this approach to be effective it needs to be implemented through the 4 principles of medicines optimisation, as defined in the Royal Pharmaceutical Society publication in May 2013, "Medicines Optimisation: Helping patients to make the most of medicines. Good practice guidance for healthcare professionals in England". However, this guideline concentrates mainly on the safety aspects of medicines optimisation and less so on the other principles. We feel a more balanced approach needs to be set out at least in the introduction and with any resource materials and implementation activities in order to realise the full potential of medicines optimisation.	Thank you for your comment. The four key principles as stated in the Royal Pharmaceutical Society guidance Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England*' are included in this guideline.
320	SH	Boehringer Ingelheim	2	Full	4.1	29	We would support medication review as a priority area for implementation, as in our view this forms a central pillar of any strategy to ensure the quality and effectiveness of prescribing in line with	Thank you for your comment. This may be considered as part of the implementation needs analysis.

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							NICE guidance, in particular for patients with multiple long term conditions and polypharmacy.	
321	SH	Boehringer Ingelheim	3	Full	4.2	30	Some patient groups are more vulnerable to medicine related safety incidents, for example renal impairment where doses are dependent on renal function. This should be highlighted.	Thank you for your comment. The linking to evidence to recommendation (LETR) table captured the discussions by the GDG relating to the evidence presented. Specific examples, such as the potential harm of medicines-related patient safety incidents in people with impaired renal function were not discussed by the GDG. Therefore, this was not included in the LETR table.
322	SH	Boehringer Ingelheim	4	Full	4.2	31	(R9&10) Other medication safety tools exist e.g. PRIMIS Warfarin patient safety audit; Asthma audit tool; GRASP AF; GRASP COPD; Diabetes audit tool – which all are free for general practice use, they include important aspects of patient safety and are designed to optimise medicines use.	Thank you for your comment. These recommendations have been based on evidence found for these tools. The tools you have listed were not identified during the evidence review.
323	SH	Boehringer Ingelheim	5	Full	5.7	60	Although this guideline does not cover specific medicines it would seem sensible to highlight those that are most known to cause preventable adverse events, for example warfarin. Ref: Pirmohamed M et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ 2004; 329; 15-19	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. Medicines that cause adverse events did not form part of the evidence review.
324	SH	Boehringer Ingelheim	6	Full	General	General	It is important to provide patients with accurate information that is of good quality. We would suggest acknowledging the importance of The Information Standard (TIS) which is a certification programme for all organisations producing evidence-based health and care information for the public. Any organisation achieving The Information Standard has undergone a rigorous	Thank you for your comment. The introduction includes the Patient experience in adult NHS services guideline link which has recommendations about providing patients information.

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							assessment to check that the information they produce is clear, accurate, balanced, evidence-based and up-to-date. TIS is now hosted by NHS England.	
325	SH	Boehringer Ingelheim	7	Full	10.7	163	(R34) Patient choice of medicine should be made more explicit here.	Thank you for your comment. Wording was considered by the NICE Publishing team, and is consistent with the NICE guideline on Patient experience in adult NHS services. Patient's values and preferences reflect patient choice.
326	SH	Boehringer Ingelheim	8	Full	9	123-6	The National Review of Asthma Deaths report is not cited. One of the key recommendations is for every patient to have a Personal Asthma Action Plan. Personal asthma action plans (PAAPs), acknowledged to improve asthma care, were known to be provided to only 44 (23%) of the 195 people who died from asthma. All people with asthma should be provided with written guidance in the form of a personal asthma action plan (PAAP) that details their own triggers and current treatment, and specifies how to prevent relapse and when and how to seek help in an emergency. It also suggests an assessment of inhaler technique to ensure effectiveness should be routinely undertaken and formally documented at annual review, and also checked by the pharmacist when a new device is dispensed.	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. Management of specific conditions did not form part of the evidence review as it was out of scope. NICE guidelines exist for specific conditions. Where we have mentioned some conditions, they have been used as examples as part of the introductory text.
327	SH	Boehringer Ingelheim	9	Full	General	General	The document uses the term 'medicines' throughout but we feel it must stress the importance of using this term explicitly in all care settings, as opposed to "tablets" which is commonly used. For example, when patients are	Thank you for your comment. The term 'medicines' has been defined in the guideline: 'medicines' covers all healthcare treatments, such as oral medicines, topical medicines,

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							admitted to hospital and asked what 'tablets' they are on – it can lead to inhaled medicines being overlooked and not restarted.	inhaled products, injections, wound care products, appliances and vaccines.
328	SH	Boehringer Ingelheim	10	Full	7.4	88	With regard to the economic evaluation of medicines reconciliation, Boehringer Ingelheim suggests further research is carried out to identify more robust estimates of the proportion of preventable adverse drug events (pADEs). The current estimates are based upon US inpatients and the applicability of this data source to the UK population is unclear. As a minimum, expert opinion should be sought from an advisory board of UK key opinion leaders to validate the assumptions used within the model.	Thank you for your comment. Targeted literature searching identified no UK data reporting the proportion of preventable adverse drug events (pADE) being significant, serious or severe. The use of US data within the model is a limitation of the analysis. During the model development expert advice on all model inputs and assumptions was sought from experts on the GDG. Threshold analysis provided in Appendix F.2 shows medicine reconciliation remains cost effective where the proportion of significant or serious pADE is at 0. Medicine reconciliation is cost-effective at a threshold of £20,000 providing the proportion of pADE is above 10.5%. The GDG discussed whether proportions of pADE were likely to differ substantially between the UK NHS and US and validated the use of US data in the absence of UK specific data.
329	SH	Boehringer Ingelheim	11	Full	7.4	90	Boehringer Ingelheim takes issue with the presentation of the base case results from the economic evaluation of medicines reconciliation; specifically the omission of results per prescription or per patient year. Boehringer Ingelheim suggests further consideration is given to the	Thank you for your comment. The guideline has been updated to included results per prescription order.

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							presentation of the cost-effectiveness results to aid interpretation by decision makers.	
330	SH	Crohn's and Colitis UK	1	Full	1.1	8	The website link to HSCIC statistics does not send the reader directly to the statistics but to the main website.	Thank you for your comment. Hyperlinks were considered by the NICE publishing team.
331	SH	Crohn's and Colitis UK	2	Full	1.1	8	"Medicines optimisation aims to ensure a person-centred approach to safe and effective medicines use, enabling people to obtain the best possible outcomes from their medicines". Insert '*and enable the patient to exercise choice'.* Important that we are moving from a point of informed consent to that of 'informed choice'. The overall goal must be to "involve patients in decisions so that they are educated about their options, confident in the plan, adherent to chosen therapy and ultimately have a better quality of life" (http://gut.bmj.com/content/61/3/459.full?sid=b05355c0-840c-4f25-ac11-74f429d70c4a). The IBD standards relating to provision of information state that all patients should be offered appropriate information about their care and treatment options at all stages of their illness. This should be delivered by an identified member of the IBD team. Improvement is needed in this area; 22% of adults and 15% of paediatric admissions reported that they were not given enough information about their condition or treatment. The recent audit of IBD services also found that	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.

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							nearly a quarter of patients (23%) of patients are not actively involved in management decisions about care, with a clear structured pathway for the patient to discuss his or her treatment with the multi-disciplinary team. https://www.rcplondon.ac.uk/sites/default/files/national_ibd_organisational_audit_adult_report_final_web.pdf page 30	
332	SH	Crohn's and Colitis UK	3	Full	1.2	11	"If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment." It is vital that patients, especially those under the age of 16, are given information that is appropriate to their age and level of understanding. A recent audit of IBD services in the UK found that 54% of IBD sites provided age-appropriate written and verbal advice on day to day management of symptoms and treatment. Patients would also like greater education on their condition. This should include: disease education, treatment options and self-management strategies. Services are good at providing patients with written information about their condition, with 88% (153/173) of services reporting that they provide educational material for all newly diagnosed patients, but the provision of formal education sessions remains low, with only 42% (72/173) of services reporting that they provide regular education opportunities for patients and their families.	Thank you for your comment. Section 1.2 has provided a link to the Department of Health's Transition: getting it right for young people publication for further information. This would also be part of the health and social care practitioner's role to provide information that is appropriate to the child's age.

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							Clear written information about IBD should be provided in outpatient clinics, wards, endoscopy and day care areas. Information should be available in languages other than English where the catchment population requires this. It should also be available in a variety of format including written, DVD and web based where appropriate. https://www.rcplondon.ac.uk/sites/default/files/national_ibd_organisational_audit_adult_report_final_web.pdf page 44	
333	SH	Crohn's and Colitis UK	4	Full	4.1.14	29	Insert *with experience of using decision making tools/aids* Clinicians will require training to use decision making aids effectively.	Thank you for your comment. Decision making tools would not routinely be used during medicines reconciliation.
334	SH	Crohn's and Colitis UK	5	Full	4.1.19	29	The IBD Standards 2013 recommend that participation in the IBD Biologics Audit should be mandatory for all units prescribing biologics. We would like to see national clinical audits, such as the IBD audit, included in the final guidance for medicines optimisation. www.ibdstandards.org.uk The audit measures the efficacy, safety and appropriate use of biological therapies (such as infliximab and adalimumab) in patients with inflammatory bowel disease in the UK. https://www.ibdbiologicsaudit.org/WebPages/Login/frmLogin.aspx Currently 45% of IBD sites report that patients on	Thank you for your comment. Audits for specific groups of medicines did not form part of the evidence review.

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							both immunomodulator and biological therapy are subject to regular audit for outcome monitoring. https://www.rcplondon.ac.uk/sites/default/files/national_ibd_organisational_audit_adult_report_final_web.pdf page 31	
335	SH	Crohn's and Colitis UK	6	Full	4.1.26	29	As well as their GP, patients with IBD may want their IBD Consultant or IBD Nurse specialist contacted. Their GP may not be the clinician that the patient with IBD has the most contact with/or is most involved with decisions about their care.	Thank you for your comment. The first bullet point in the recommendation relates to having the patients GP contact details to obtain any information if required about all medicines, not all patients will have a specialist. Where there is a specialist involved in caring for a particular condition, then this will fall under 'other information, including when the medicines should be reviewed or monitored, and any support the person needs to carry on taking the medicines'.
336	SH	Crohn's and Colitis UK	7	Full	4.2	38	We would like to see the guidance strengthened with reference to the information provided to patients and carers. In particular, improvements are needed in the provision of information about potential drug side effects and the warning signs of which to be aware after discharge. The 2014 IBD patent experience audit found that for most UC admissions patients reported a positive experience of pre-discharge information, but a significant proportion stated that they were not told about medication side effects (35% of adult respondents; 11% of paediatric respondents) or danger signals (33% of adult respondents; 20% of paediatric respondents) of	Thank you for your comment. Section 1.2 provides a link to the Patient experience in adult NHS services guideline that provides recommendations on providing information to patients.

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							which to be aware after going home. https://www.rcplondon.ac.uk/sites/default/files/ibd_inpatient_experience_web.pdf page 8. The survey also reported that: Under half (47%) of adults and 65% of paediatric admissions felt they received enough information from the hospital on how to manage their condition after discharge. A quarter (25%) of adults and 6% of paediatric admissions felt that the doctors and nurses did not give family or someone close to them the information they needed to help care for them. 15% of adult admissions said hospital staff did not take their family or home situation into account when planning their discharge. Just over half (53%) of adult admissions felt they were definitely involved in decisions about their discharge, but 8% felt that they were not involved at all. Although just under three-quarters (74%) of adult admissions said they were given clear, written or printed information about their medicines and 68% said a member of staff explained the purpose of their medicine clearly, one-third of adult patients reported that they were not told about medication side effects or danger signals to watch out for when they went home, more than triple the proportion of paediatric admissions (11%).	

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							There has been an increase in the number of adult admissions receiving copies of letters between hospital doctors and GPs, although 30% of adult admissions and 18% of paediatric admissions still reported not receiving these. https://www.rcplondon.ac.uk/sites/default/files/ibd_inpatient_experience_web.pdf page 19.	
337	SH	Crohn's and Colitis UK	8	Full	4.1.41	29	Insert *Signpost to the relevant patient organisation*	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
338	SH	Crohn's and Colitis UK	9	Full	4.2.28	32	Insert *information about how to manage their condition and medications either at work or at school* One-fifth (20%, 16/82) of adolescent admissions reported that they wanted advice about how to manage their IBD either at work or at school after they left hospital but this was not given.	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
339	SH	Crohn's and Colitis UK	10	Full	4.1.14	29	Suggested area for further exploration: What considerations might be made in the guidance for those medications that are administered as a day patient? For example medications administered by a specialist nurse in the form of infusions? Or, for example, those medications that might not be prescribed by a	Thank you for your comment. The purpose of this review question was to look at the clinical and economic evidence for medicines reconciliation. The GDG developed recommendations based on key principles of the intervention, rather than looking at particulars of

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							community pharmacist but delivered directly to a patient's home/dwelling, such as a self-administered injection.	the intervention being reviewed. Administration of medicines did not form part of the evidence review for this intervention.
340	SH	Crohn's and Colitis UK	11	Full	4.1.38	29	Communications should clearly state not just when and how regularly medicine should be monitored, but who will be responsible for monitoring the medicine on an on-going basis. The 2012 IBD audit found that only one-third of services report having a protocol in place with GPs for the shared outpatient management of IBD patients. In addition, only 66% of these services shared this practice with the patient, and most often, only verbally (62%). [i] In 2014, 22% of IBD sites reported that there was no clear written guidance on action if (i) white cell counts are low and (ii) a named individual who acts on abnormal results and (iii) communicates with GPs and patients if appropriate. Therefore we would like to see the guidance strengthened: "they should clearly define organisational and individual roles and responsibilities and regularly review and monitor the effectiveness of local processes". Patients should have written information explaining clearly what arrangements have agreed with them for their care. https://www.rcplondon.ac.uk/sites/default/files/national_ibd_organisational_audit_adult_report_final_web.pdf%20page%20 The IBD Standards 2013 state that:	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.

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							A system for sharing of information about test results or treatment changes should be place through the use of IT (for example, through patient management systems), written communication between the GP and hospital, also provided to the patient or a patient held record. Shared care protocols should be developed to support ongoing prescribing and monitoring of these drugs in general practice. Arrangements should always be made in discussion with the patient. www.ibdstandards.org.uk	
341	SH	Crohn's and Colitis UK	12	Full	4.2.20	30	Verbally and in writing	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. The methods used to ensure how patients report and identify medicines-related incidents within the organisation would be determined locally.
342	SH	Crohn's and Colitis UK	13	Full	4.2.37	30	Insert *Use of the IBD biological therapies audit.* The audit measures the efficacy, safety and appropriate use of biologics therapies (such as infliximab and adalimumab) in patients with inflammatory bowel disease in the UK. https://www.ibdbiologicsaudit.org/WebPages/Login/frmLogin.aspx	Thank you for your comment. Recommendations are based on evidence reviewed. The IBD biological therapies audit was not identified during the evidence review.

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							The IBD Standards 2013, Standards for the Healthcare of People who have inflammatory Bowel Disease recommends that participation in the National Biologics Audit should be mandatory for all units prescribing biologics. Outcomes of biological therapy and the patients receiving biological therapy should be reviewed regularly. Local practice and immunomulator and biological therapy should be audited. http://www.ibdstandards.org.uk/uploaded_files/IBDstandards.pdf Page 16.	
343	SH	Crohn's and Colitis UK	14	Full	4.2. 34	32	Insert *Provide details of an emergency contact or 24 hour helpline or answer phone service to deal with concerns or potential emergencies regarding medicines.* Some IBD services run helplines that deal with patient's enquiries/concerns, including potential adverse drug reactions.	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. The recommendation relates to evidence-based interventions used to improve medicines-related communication between the service providers and the patient.
344	SH	Crohn's and Colitis UK	15	Full	4.2.36	33	It is important that discussions between a patient and their clinician include a conversation about how the medicine option/different option(s) might best suit an individual's lifestyle/particular life stage. For example, a patient may prefer to receive a drug by infusion as a day patient rather than a drug that is given by self-administered injection (and vice versa).	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. Another recommendation takes into consideration of patients views of their medicines.

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							A number of factors may be considered in their decision such as convenience, taking time out from work, family life, parental responsibilities, caring responsibilities to attend outpatient appointments etc.	
345	SH	Crohn's and Colitis UK	16	Full	4.2.25	33	Insert *with experience of using decision making tools/aids*	Thank you for your comment. Medicines reconciliation may not involve decision making depending on which health professional is carrying out the process.
346	SH	Crohn's and Colitis UK	17	Full	4.2.25	32	In the case of people with IBD using drugs such as azathioprine that will require monthly/quarterly monitoring via a blood test. A system for sharing information about test results or treatment changes should be in place through the use of IT, written communication between the GP and hospital or a patient held record.	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. IT systems for sharing information about test results or treatment changes did not form part of the evidence review.
347	SH	Crohn's and Colitis UK	18	Full	4.2.16	34	Some patients with IBD are prescribed steroids as part of their treatment. The side effects can include the thinning of the bones, muscles and skin. When prescribing drugs such as steroids, patients must be advised about and prescribed corresponding medicines that can protect them from the side effects, such as bone protecting medication or supplements. The most recent audit of IBD services found that • 26% are not prescribing bone protection medication for the prevention of osteoporosis • Preventative anticoagulants are given to 90% of adult patients (an increase from 70%).	Thank you for your comment. Side effects of medicines would be captured when discussing how safe the medicines are; this is one of the points to take into account when carrying out a medication review.

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							https://www.rcplondon.ac.uk/sites/default/files/national_ibd_organisational_audit_adult_report_final_web.pdf	
348	SH	Crohn's and Colitis UK	19	Full	4.2.9	35	The discussion should also made reference to the person's lifestyle, current circumstances and future goals, employment status, relationships and any future plans to have a family. We would want the final medicine optimisation guidance to reference this. The plan should be written up and disseminated to all relevant clinicians involved in that person's care.	Thank you for your comment. Following further discussion by the GDG they concluded that list in this recommendation is not intended to be exhaustive but includes the minimum dataset. Additional information may be needed depending on the person's needs, but this would be for the health professional and this would fall under ''any other instructions the person needs to safely and effectively self-manage their medicines' in the recommendation. Sharing of the self-management plan with other health and social care practitioners would be determined by the person (family member or carer where appropriate).
349	SH	Crohn's and Colitis UK	20	Full	4.1.41	29	Insert *Explain how a patient can access a second opinion.* A recent audit found that half of services (49% (84/173)) routinely provide patients with information about how they can obtain a second opinion on their care.	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine. This is outside of the scope of the guideline.
350	SH	Crohn's and Colitis UK	21	Full	4.2.9	37	We would want this recommendation to be stronger that a consideration but a requisite part	Thank you for your comment. The strength of recommendations are

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							of patient care. A recent audit of IBD services found that: IBD multi-disciplinary team meetings have established their pivotal role in the management of complex IBD cases, but now require a final footing to ensure that occur regularly and with appropriate structure and resource. Effective multidisciplinary care can offset relapse, prolong remission, treat complications and improve quality of life. 91% (157/173) of services now hold some form of IBD multidisciplinary team (MDT) meeting, where complex IBD cases are discussed. However, only 40% (70/173) of services reach the IBD Standards' requirement for the MDT to meet at least fortnightly and to be regularly attended by medical, nursing and surgical staff, to be minuted and to have an attendance register. https://www.rcplondon.ac.uk/sites/default/files/national_ibd_organisational_audit_adult_report_final_web.pdf page 9	based on the quality of evidence, clinical and cost effectiveness of the intervention. The GDG are unable to make a recommendation stronger without sufficient evidence to base it on. The recommendation that your comment is relating to is not supported by strong evidence and can therefore not be strengthened.
351	SH	Crohn's and Colitis UK	22	Full	5.7.2	60	Verbally and in writing	Thank you for your comment. The GDG concluded that the purpose of the guideline was to set out key principles. Details of the process are for local consideration and determination
352	SH	Crohn's and Colitis UK	23	Full	General	General	The IBD Standards 2013, Standards for the Healthcare of People who have inflammatory Bowel Disease state that: Patients should be offered choice between their	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional

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							treatments, after receiving the necessary support and information. For example this might include the choice between drug treatments and dietary therapy for Crohn's disease. Patients should be supported in their choice of follow up care such as self-management. Patients should have written information explaining what arrangements have been agreed with them for their care. http://www.ibdstandards.org.uk/uploaded_files/IBDstandards.pdf Page 19.	information may be needed depending on the person's needs, but this would be for the health professional to determine.
353	SH	Crohn's and Colitis UK	24	Full	9.7	135	When discussing medicines with people who have chronic or long-term conditions, consider using an individualised self-management plan to support those who want to be involved in managing their medicines. Insert *'use' instead of 'consider using'*	Thank you for your comment. Wording and formatting was considered by the NICE publishing team. In addition the strength of recommendations are based on the quality of evidence, clinical and cost effectiveness of the intervention.
354	SH	Crohn's and Colitis UK	25	Full	9.7	135	Insert: *Include input from the multi-disciplinary team members; such as dieticians* The IBD Standards 2013, Standards for the Healthcare of People who have inflammatory Bowel Disease state that: Patients should be offered choice between their treatments, after receiving the necessary support and information. For example this might include the choice between drug treatments and dietary therapy for Crohn's disease.	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. The key health and social care practitioners involved in the multidisciplinary team may vary depending on the needs of the person, therefore examples have not been provided in the recommendation.

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							Those patients with complex nutritional needs, which may include enteral and parental feeding, must be able to access a full multidisciplinary nutritional support team for comprehensive assessment, management and advice to the IBD team. Often this choice is under recognised and underutilised. http://www.ibdstandards.org.uk/uploaded_files/IBDstandards.pdf Page 19.	
355	SH	Crohn's and Colitis UK	26	Full	4.2.4	34	We believe that pharmacists should be linked to IBD multi-disciplinary teams. The 2014 IBD audit found that 41% of IBD sites are not routinely supported by a named pharmacist with a specialist interest in IBD or gastroenterology. Just 25% of IBD sites reported that clinicians involved in the management of patients on immunosuppressants have access to a pharmacist with specialist knowledge /interest. https://www.rcplondon.ac.uk/sites/default/files/national_ibd_organisational_audit_adult_report_final_web.pdf page 37	Thank you for your comment. The guideline did not look at any specific condition, however the section that looks at medicines-related models of organisational and cross-sector working has a recommendation that says to involve a pharmacist Involve a pharmacist when making strategic decisions about medicines use or when developing care pathways that involve medicines use.
356	SH	Crohn's and Colitis UK	27	Full	4.9.1	34	Insert below *How their self-management plan might reflect the fluctuating nature of the condition.* It will be important that clinicians address with the patient how their self-management plan might fit with someone with a fluctuating condition which follows an unpredictable relapsing and remitting course, with significant variation in the pattern and	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health professional to determine.

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							complexity of the symptoms both between patient and in the individual patient at different times in his or her life.	
357	SH	Crohn's and Colitis UK	28	Full	General	General	Further reading: Shared decision making in inflammatory bowel disease: helping patients understand the tradeoffs between treatment options Corey A Siegel http://gut.bmj.com/content/61/3/459.full?sid=b05355c0-840c-4f25-ac11-74f429d70c4a	Thank you for your comment.
358	SH	Crohn's and Colitis UK	29	Full	4.2.15	32	Side effects such as fatigue for example, should be taken into consideration as well as adverse events.	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG when transferring medicines-related information to another care setting. Additional information may be needed depending on the person's needs, but this would be for the health professional to determine.
359	SH	Crohn's and Colitis UK	30	Full	4.2.2	35	Side effects such as fatigue for example, should be taken into consideration as well as adverse events.	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health professional to determine.
360	SH	Crohn's and Colitis UK	31	Full	4.2.38	34	Insert: *self-care plan is reviewed following the patient's*	Thank you for your comment. Wording and formatting was considered by the NICE publishing

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							annual review.	team.
361	SH	Crohn's and Colitis UK	32	Full	General	General	We are disappointed that this consultation does not take into consideration the impact of charging for prescriptions on medicine optimisation. Research and individual experiences collected by the Prescription Charges Coalition have found that many people with long-term conditions are not collecting their medication or are rationing it because of the cost and are experiencing worse health and, in some cases, hospitalisation as a result. http://www.prescriptionchargescoalition.org.uk/campaign-blog We would urge NICE to look at the charging issue alongside medicine optimisation.	Thank you for your comment. This is outside the scope of this guideline. Prescription charging is not within NICE's remit.
362	SH	Crohn's and Colitis UK	33	Full	General	General	Information about prescription charge entitlements should be provided to people with diagnosis and when medicines are dispenses and reviewed. In section 4.2.27 page 32 Insert: *Information on prescription charge entitlements*	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health professional to determine.
363	SH	Biogen Idec	General	General	General	General	We have looked at both the model and the guideline and have decided not to comment on this occasion. This is principally because the guideline relates mainly to primary care situations and the transfer of care between secondary or tertiary care and primary care. As our activities relate mainly to the treatment of MS, where care is retained by specialist services	Thank you for your comment.

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							and there is little or no primary care input to the use of disease modifying therapy (as opposed to symptomatic treatment) we feel comments from us would make a limited contribution to the guideline process.	
364a	SH	Pfizer	1	Full	General	General	Medicines play a crucial role in maintaining health, preventing illness, managing long-term conditions and curing disease. They are a fundamental part of patient management to help improve outcomes. Medicines are a significant investment for the NHS and accordingly, to get the most value from them, their use must be optimal. We believe that Medicines Optimisation can help to deliver this aspiration. Medicines optimisation is about ensuring that the right patients get the right choice of medicine at the right time. By focusing on patients and their experiences, the goal is to help patients to improve their outcomes, take their medicines correctly, avoid taking unnecessary medicines, reduce wastage and improve the safe use of medicines. The Royal Pharmaceutical Society published its good practice guide last year [1] which outlined four guiding principles for Medicines Optimisation across four key principles. We believe that it is important to have a **balanced approach across each of these principles to ensure the aspirations of Medicines Optimisation are achieved** and that this should be captured in the narrative within the guideline.	Thank you for your comment. The Royal Pharmaceutical Society guide on Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England*' has been mentioned in the introductory text. The four key principles as stated in the guidance are included in this guideline. The aim of the introduction for this NICE guideline is to introduce the concept of medicines optimisation and highlight areas where work has been carried out for the topic. The document has been hyperlinked for the user to obtain further information. Relevant text has been added in to reflect your comment.
364b	SH	Pfizer	1	Full	General	General	To ensure MO becomes part of everyday and sustained practice there needs to be a real change in behaviors and culture within the NHS.The guideline needs to support a behavioural and cultural shift away from	Thank you for your comment. Your comment may be considered as part of the implementation of the guideline process.

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							medicines management thinking to a more patient centric and outcomes focussed one where the true value of medicines are realised.	
364c	SH	Pfizer	1	Full	General	General	The NHS aims to be amongst the best healthcare systems in the world and ensuring patients are able to access the latest innovative medicines is fundamental to achieving this aspiration. In addition, one of the key elements of the Pharmaceutical Price Regulation Scheme (PPRS), agreed by government and the industry, is to "*Improve outcomes for patients by improving access to and appropriate use of clinically and cost-effective medicines and, in England, encourage the NHS to promote the rapid adoption and diffusion of innovative medicines and treatments recommended by NICE commensurate to the outcomes they offer patients*." [2] It states that prescribers and commissioners should continue improving uptake of NICE technology appraisals. It goes on to say that the focus should shift from cost-saving onto securing better patient outcomes and value through medicines optimisation and commissioners should disengage from cost-containment measures that will not ensure value for money or patient benefit for the system as a whole [3]. **Pfizer would like to see this principle to use innovative medicines explicitly recognised in the clinical guideline and that Medicines Optimisation can and should be a vehicle to facilitate this aspiration.** **We do not believe this guide makes the link strongly enough and should include a statement to this effect.**	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. Innovative medicines use did not form part of the evidence review.

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							[1] Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England.* May 2013 [2] The Pharmaceutical Price Regulation Scheme 2014 [3] Question and Answer document for the NHS on the Pharmaceutical Price Regulation Scheme (PPRS) Publications Gateway Reference 01604	
365	SH	Pfizer	2	Full	4.2	32	Certain medicines should be prescribed by brand. This is of particular concern where there are several forms of the same medicine or device and, for reasons of efficacy, safety or adherence, the brand should be prescribed by name. This may be the case for medicines such as certain epilepsy drugs, lithium preparations or biologics for example, which may have the same international non-proprietary name but cannot be presumed to be identical. Pfizer believes the guideline should contain an additional recommendation outlining this.	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. For the recommendations that include information about medicines, 'other information' included in the recommendation would take into account medicines that need to be prescribed by brand where appropriate. Not all medicines are required to be prescribed by brand.
366	SH	Pfizer	3	Full	5.7	60	There are some medicines that are known to be associated with preventable adverse events more than others. The National Prescribing Centre published a document entitled Ten Top Tips for GPs, Strategies for Safer Prescribing, in which it listed medicines commonly associated with harm in general practice. Early in the document it states the following: **"***It is worth noting that just four classes of drug are associated with around half of preventable medication related hospital admissions. These are antithrombotics (such as aspirin), anticoagulants, NSAIDs and diuretics,"*	Thank you for your comment. The purpose of this review question was to look at the clinical and economic evidence for the intervention. The GDG developed recommendations based on key principles of the intervention, rather than looking at particulars of the intervention being reviewed. Specific medicines causing harm did not form part of the evidence review. Reference to high risk

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							and goes on to name warfarin, methotrexate and digoxin. **We believe that this point should be made, and reference to those medicines which are responsible for a majority of safety incidents should be referenced within this document as an additional bullet.** [1] Ten Top Tips for GPs, Strategies for Safer Prescribing http://www.npc.nhs.uk/evidence/resources/10_top_tips_for_gps.pdf	medicines had been added into the introduction of section 5 of the guideline.
367	SH	Pfizer	4	Full	6.7	76	Pfizer agree with the recommendations outlined in this section and support active patient involvement in their treatment and care received from healthcare professionals. Ensuring the patient is actively involved in the decisions about their medicines and conditions should ensure they get the medicine which is right for them. This in turn should mean they are more likely to comply, less likely to experience side effects and medication errors, and the true value which medicines provide is more likely to be realised.	Thank you for your comment.
368	SH	Pfizer	5	Full	7.7	98	(Rec 21) It is sensible to recognise that medicines might need to be reconciled at different stages of a hospital stay. Where the stay is long and involves several moves this is even more important. However, probably the most important time is upon discharge to ensure the best possible handover to the GP. This adds further support to recommendation 22 that medicines are reconciled as soon as possible in primary care after discharge.	Thank you for your comment.
369	SH	Pfizer	6	Full	8.7	121	Pfizer support the recommendations outlined in this section, however the increased opportunity for pharmacists to carry out medication reviews is not highlighted or recognised. Pharmacists are ideally	Thank you for your comment. During the GDG discussions, the members took into consideration the evidence and resource use to

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							placed as healthcare professionals to conduct medication reviews, which is recognised through the New Medicines Service and Medicines use Reviews. **We believe that pharmacists should be highlighted as a named group within this.**	carry out medication reviews. Pharmacists may not be available in all healthcare settings to carry out medication reviews and while the GDG acknowledge that pharmacists carry out a new medicines service and medicines use reviews, they concluded that this would need to be determined locally based on resources.
370	SH	Pfizer	7	Full	10.7	163	(Rec 32) Pfizer fully supports the patients' involvement in decision making about their medicines and it is important they are encouraged to take an active role in these decisions. However, it should be recognised that some patients are unable, or initially unwilling, to make such decisions for a variety of reasons such as a lack of confidence or belief systems. This should be recognised at the outset and we would like to see this recommendation amended to read; *"**Offer the opportunity and encourage all people to be involved in making decisions about their medicine.*** ***Find out what level of involvement in decision-making the person would like and avoid making assumptions about this**"*	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
371	SH	Pfizer	8	Full	11.7	178	(Rec 44) One of the central tenets of medicines optimisation is that the patient is central to the decision making process. Through an open dialogue between the healthcare professional and patient, the appropriate treatment for them will be prescribed and administered. Whilst this recommendation acknowledges that decision support should never replace clinical judgement,	Thank you for your comment. Clinical decision support as a barrier to the uptake of technologies did not form part of the evidence review and so cannot be included within the recommendation.

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							we are concerned that this will begin to erode clinical freedom. It may lead to circumstances where certain treatments are recommended based on criteria which are not aligned to broader NHS principles & policies such as those described within the Innovation, Health and Wealth report [1] & the PPRS agreement [2], which support the uptake of new innovative technologies. We suggest that this point has an additional sentence which reads "***They should also not act as a barrier to the uptake and access of new technologies***." [1] Innovation Health and Wealth, accelerating adoption and diffusion in the NHS. [2] The Pharmaceutical Price Regulation Scheme 2014	
372	SH	Pfizer	9	Full	11.7	178	(Rec 47) The training described within this recommendation appears to cover technical ability in the main, but only a single comment on 'understanding its limitations.' In line with our comment above, we believe this should have additional wording along the lines of **'….to ensure that the patient's preferences and circumstances are taken into account and the appropriate medicines offered.**'	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
373	SH	Pfizer	10	Full	12.7	195	(Rec 49) Pfizer supports the recommendation that a pharmacist be involved in discussions about a patient's medicines during the care pathway. It is, perhaps, more important though to describe the nature of that involvement. It is not just that they bring their clinical knowledge to the discussion, but that they are also able to bring a patient centred focus and understanding. **We believe**	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. The nature of pharmacist involvement would depend on the circumstances and the needs of the person.

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							that these skills and attitudes should be emphasised within this chapter if an effective Medicines Optimisation approach is to be implemented.	
374	SH	NHS Cambridgeshire and Peterborough CCG	1	Full	4.2	30	Consider including recommendation that learning from medicines-related patient safety incidents should be shared across local healthcare economy, e.g. Provider Trusts, Primary Care, CCGs within one geographical area.	Thank you for your comment. This has been added following further discussion by the GDG.
375	SH	NHS Cambridgeshire and Peterborough CCG	2	Full	4.2	32-3	Care homes could also be included as an example of a care setting where medicines reconciliation takes place. This is usually undertaken by a pharmacist.	Thank you for your comment. This has already been addressed in Managing medicines in care home. NICE social care guideline 1 (2014).
376	SH	NHS Cambridgeshire and Peterborough CCG	3	Full	4.2	32	Consider also making reference to hospital patient medicines helplines for discharged patients.	Thank you for your comment. The recommendation was based on evidence found for the interventions. There were no studies found that used hospital patient medicines helplines as an intervention.
377	SH	NHS Cambridgeshire and Peterborough CCG	4	Full	4.2	36	Consider making reference for the need to involve pharmacists/pharmacy technicians in the development/maintenance of content for clinical decision support systems.	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. Health professionals involved in the development and maintenance of the content for clinical decision support systems did not form part of the evidence review and therefore cannot be included within a recommendation.
378	SH	British Medical Association	1	Full	4.1	29	With regards to communications between different care settings - there are continuing problems with hospital discharge letters, especially when patients move from the wards back into a nursing	Thank you for your comment. This may be considered as part of the implementation needs analysis.

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							home or to their own residence. Drugs are often stopped or changed with no reason being given for the altered medication. The changes in medication need to be clear and the reasons for the change explained.	
379	SH	British Medical Association	2	Full	4.2.14	31	Responsibility should not rest with the patient to inform the GP of medication changes. but should be achieved by robust written timely communication between the clinician responsible for the change and the GP	Thank you for your comment. Following further discussion by the GDG, this recommendation has been taken out.
380	SH	British Medical Association	3	Full	4.2.17	31	Again, the reasons for the change in medication should be clearly documented.	Thank you for your comment. This is included in the bulleted list of the recommendation in question.
381	SH	British Medical Association	4	Full	5.1	38	Reporting to the MHRA via the Yellow Card system should be encouraged. It would be useful if a trigger reminder to report was incorporated into IT prescribing systems once side effects were entered as a code, and the form auto-populated from the clinical software. There is occasionally some disparity between what GPs experience, in for instance muscle aches with statins, and the reported incidence of such side effects in trials.	Thank you for your comment. Health professionals as part of their professional practice should report any suspected adverse drug reaction to the MHRA. Reporting via the yellow card scheme falls within the remit of the MHRA. Section 5.1 includes methods of reporting.
382	SH	British Medical Association	5	Full	5.7	59	A 'no blame' culture' should be encouraged.	Thank you for your comment. This wording has been amended following further discussion by the GDG.
383	SH	British Medical Association	6	Full	General	General	Many of the studies referenced are from the US, Canada and Australia. These do not fit easily into the NHS.	Thank you for your comment. The GDG was aware of this and discussed the applicability of the evidence to the UK health and social care system. The discussions of this can be found in each section where there was no UK based studies found for the intervention in question.

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384a	SH	European Medicines Group	1	Full	General	General	The European Medicines Group (EMG) welcomes the opportunity to comment on the clinical guideline for medicines optimisation. Firstly we support the detailed comments made by the ABPI on the content.	Thank you for your comment.
384b	SH	European Medicines Group	1	Full	General	General	Within the tight limitations of its scope, and its narrow context, this draft guideline provides a detailed review of the published evidence leading to practical recommendations that could be implemented into practice.	Thank you for your comment.
384c	SH	European Medicines Group	1	Full	General	General	However, at the heart of emerging policy on Medicines Optimisation is a desire to change the culture and practice of medicine to ensure that the greatest overall value to patients and the NHS can be gained from investment in and use of medicines. Medicines Optimisation is about ensuring that the right patients get the right choice of medicine at the right time. By focusing on patients and their experiences, the goal is to help patients to improve their outcomes, take their medicines correctly, avoid taking unnecessary medicines, reduce wastage and improve their safe use. This aspirations for Medicines Optimisation, for example as laid out by the CPO Dr Keith Ridge is a 'big vision' – ambitious, expansive and forward looking. These ambitious are wholeheartedly supported by EMG member companies. With the very best will, any document based on historical evidence will fail to put this goal at its heart as it is inevitably backward looking. The nature of an evidence based review and the limitations of NICE methodology, including the reliance on published evidence (which is a	Thank you for your comment. The guideline development has followed the NICE accredited process for 'clinical guidelines'. Full details of the development process can be found here. The aim of this guideline was to look to the evidence for interventions that can be used to optimise the use of medicines and to develop recommendations to move the medicines optimisation agenda forward. Methods used by NICE for this guideline have been included in section 3 of the guideline. Limitations and applicability of the studies have been further discussed by the GDG and this is also included within the linking evidence to recommendations (LETR) table in each section.

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							judgement on past practices set in the context of the time the data was collected), limit the guideline to a narrow focus in the context of the broader policy ambition. We believe this limitation should be discussed in greater detail in the introductory sections in order to better convey the forward looking aspirations for medicines optimisation in the NHS and encourage a continuation of the innovative approaches that are beginning to be adopted in some localities which seek to improve patient outcomes through optimal use of medicines. If this is not emphasised then a significant opportunity has been lost to develop a broader understanding of the promise of Medicines Optimisation.	
384d	SH	European Medicines Group	1	Full	General	General	EMG fully supports ABPI in its call that the four guiding principles of Medicines Optimisation, as laid out by the Royal Pharmaceutical Society *(Royal Pharmaceutical Society. 2013. Medicines Optimisation: Helping Patients to Make the Most of Medicines)* need to be given more equal weight in the document. As currently written, medicines waste and the very important issue of safety dominate. We accept this might reflect the methodology of development of a short clinical guideline, however, this limitation of process should be fully acknowledged within the document.	Thank you for your comment. The four key principles as stated in the Royal Pharmaceutical Society guidance Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England*' are included in this guideline. Medicines waste was out of scope for the guideline. Section 5 of the guideline focuses on the safety issues of medicines use and this is mentioned throughout the guideline.
384f	SH	European Medicines Group	1	Full	General	General	As a general observation throughout the guideline is the need to make clear that all medicines are in the scope of the guidance, including those	Thank you for your comment. The relevant text has been added to define the term 'medicines' in the

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							administered parenterally in hospital (in-patient, day-case and out-patient settings) and other models such as home care. Currently much of the text refers to the medicines that 'patients take'.	guideline: 'medicines' covers all healthcare treatments, such as oral medicines, topical medicines, inhaled products, injections, wound care products, appliances and vaccines. The interventions that have been reviewed for this guideline involve the patient taking medicines. The interventions look at: how the patient can be supported with taking their medicines; safe medicines use; and what organisations, health and social care practitioners can do to further support patients.
385	SH	European Medicines Group	2	Full	5.7	59-60	Despite the strong focus on safer use of medicines we are disappointed at the exclusion of company pharmacovigilance activities from the discussion in the document. Manufacturers have a major role to play in ensuring the safe use of the medicines they carefully develop and research. This omission leaves a sizable gap in the armoury of safety support addressed in this draft guideline and at worst reads as if there is no legitimate role for industry in the safe use of medicines within a Medicines Optimisation context. EMG believes that the general intention is for the opposite to be true and comprehensive reporting of incidents leading to licence updates is one of the corner stones of the 'safety' system. Manufacturers routinely inform the relevant authorities about patient safety incidents, we	Thank you for your comment. Pharmacovigilance falls within the remit of the MHRA which we have referenced to in the introduction of section 5. Recommendations are based on evidence and pharmacovigilance did not form part of the evidence review. Following further discussion by the GDG, we have amended section 5.6 to reflect your comment.

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							consider this guideline should make that process explicit. Manufacturers of medicines should also be routinely informed by healthcare professionals about patient safety incidents and adverse events associated with their medicines in order that appropriate action can be taken as necessary. Again this should be made clear in the guideline, specifically in this section.	
386	SH	European Medicines Group	3	Full	4.2.1	37	Joint working with the pharmaceutical industry and other commercial organisations is not reflected in research recommendation 2 — this omission should be rectified.	Thank you for your comment. This wording has been amended following further discussion by the GDG.
387a	SH	AstraZeneca	1	Full	General	General	AstraZeneca welcomes the development of a clinical guideline for Medicines Optimisation and trusts that NICE will work closely with NHS England and Dr. Keith Ridge, the Chief Pharmaceutical Officer, on the development of this guideline, as well as with patients and industry to ensure alignment	Thank you for your comment.
387b	SH	AstraZeneca	1	Full	General	General	AstraZeneca supports the introductory narrative that describes the importance of involving the patient and patient safety when making the most of medicines. However, we would strongly encourage a more balanced view on all the principles of Medicines Optimisation in the introductory text so that it recognises and reflects the broader value of medicines.	Thank you for your comment. The four key principles as stated in the Royal Pharmaceutical Society guidance Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England*' are included in this guideline. The aim of the introduction for this NICE guideline is to introduce the concept of medicines optimisation and highlight areas where work has been carried out for the topic.
388	SH	AstraZeneca	2	Full	1.1	8	AstraZeneca would like to suggest the following	Thank you for your comment.

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							wording for inclusion in the introductory pages; "**Medicines Optimisation should recognise and communicate the value of medicines to the NHS, patients and the wider UK economy. It is important that the value of medicines is understood in broader terms than acquisition cost alone so the impact that appropriate medicines use can have on improving patient outcomes, system wide and societal benefits is acknowledged. Taken correctly, medicines can make a real difference to the health and wellbeing of patients. They can provide cost savings for the National Health Service (NHS) by reducing the need for longer term, more expensive treatment, and help to move care from hospitals into the community, all elements that support the agenda of a sustainable NHS**."	Wording and formatting was considered by the NICE publishing team.
389	SH	AstraZeneca	3	Full	1.1	10	AstraZeneca suggest that the difference between Medicines Management, which is often focused on processes, systems and costs alone, and Medicines Optimisation needs to be recognised. We suggest that there should be reference to the need to refocus efforts and resource away from Medicines Management towards Medicines Optimisation and there should be an inclusion in the introductory narrative that describes the shift from medicines being seen as just an acquisition cost to the opportunity medicines can provide to drive improved` patient outcomes and the positive impact the use of better medicines can have on the cost to the healthcare system.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
390	SH	AstraZeneca	4	Full	1.1	11	AstraZeneca welcomes the inclusion of the definition of Medicines Optimisation, in particular the use of the Medicines Optimisation dashboard	Thank you for your comment. Your comment may be considered as part of the implementation needs

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							to encourage [Clinical Commissioning Groups] CCGs and trusts to think more about how well their patients are supported to use medicines and less about focusing on cost and volume of drugs. We would welcome an addition to this that would recognise that this work will also be important in developing a joint approach to working in partnership with the pharmaceutical industry, giving us a set of common goals and will also inform how schemes such as the Pharmaceutical Pricing Regulation Scheme are implemented. We believe that an understanding of the opportunity PPRS can offer in providing better access to innovative medicines, whilst supporting the NHS with stability on the medicines bill.	analysis.
391	SH	AstraZeneca	5	Full	4.1	31	Whilst AstraZeneca supports the key priorities for implementation, we would recommend that additional priorities are included to ensure that all the principles of Medicines Optimisation are reflected to provide a more balanced view of Medicines Optimisation and not weighted heavily to safety	Thank you for your comment. Your comment may be considered as part of the implementation needs analysis.
392	SH	AstraZeneca	6	Full	4.2	32	AstraZeneca supports the recommendation to identify, report and learn from medicines-related patient safety incidents and would encourage the inclusion of reporting adverse events to the relevant pharmaceutical company.	Thank you for your comment. This has been added following further discussion by the GDG.
393	SH	AstraZeneca	7	Full	4.2	36	AstraZeneca supports the recommendation on Self Management plans	Thank you for your comment
394	SH	AstraZeneca	8	Full	4.2	37	AstraZeneca supports the recommendation on patient decision aids used in consultations involving medicines. We welcome the recommendation to apply the principles of evidence-based medicine when discussing the available treatment options with a person in a consultation about medicines and using the best	Thank you for your comment

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							available evidence carefully when making decisions with or for individual patients, together with clinical expertise and the patients' values and preferences	
395	SH	AstraZeneca	9	Full	4.2	39	AstraZeneca supports the recommendation on medicines-related models of organisational and cross-sector working	Thank you for your comment
396	SH	AstraZeneca	10	Full	12.7.1	197	Whilst AstraZeneca recognises that there are no RCTs or observational studies, as per the criteria set out to evaluate the evidence in this guideline, to evaluate the cost and clinical effectiveness for models of cross-organisational working between health and social care and the pharmaceutical industry in relation to medicines optimisation, we would like to note that there are a number of evaluations of cross-organisational working that have demonstrated an improvement in patient reported outcomes, clinical effectiveness of medicines for patients, cost effectiveness of models used to reduce suboptimal use of medicines to inform commissioning of services and that this should be noted for consideration. We are happy to provide further information on the outcomes of JW projects on request	Thank you for your comment
397	SH	Croydon Clinical Commissioning Group	1	Full	4.1	29-30	Whilst we agree that the key recommendations chosen are all important it is a shame that the opportunity has not been taken to include some of the recommendations that reflect the ethos of medicines optimisation ie person-centred/shared decisions. We would have liked to see something from medication review and/or self-management plans, which are not purely focused on transfer of care and on everyday care. 3 of the 4 key priorities are all linked to transfer of care and, although this is an important area where often something goes wrong, none of them address the	Thank you for your comment. Your comment may be considered as part of the implementation needs analysis.

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							overall aim of getting the most from medicines for both patients and the NHS.	
398	SH	Croydon Clinical Commissioning Group	2	Full	4.2	37	In addition to involving a pharmacist with relevant clinical knowledge and skills when medicines are being discussed we feel that another point should be added about ensuring that care pathways involving medicines should consider the role of the community pharmacist.	Thank you for your comment. Following further discussion by the GDG, the recommendation has been amended.
399	SH	International Glaucoma Association	1	Full	General	General	The International Glaucoma Association (IGA) is disappointed to note there is very little reference to eye drops, if any, and the 'special problems' that surround this route of administration. The IGA carried out a glaucoma patient survey in January 2014 involving 966 patients and the results were a little disappointing: 1. 45% of patients had not been instructed on how to use their eye drops. 2. 91% had not been physically assessed on their ability to use eye drops. 3. 50% were not aware they should practice punctual occlusion. 4. Just 9% had been given any information on compliance aids to assist with their drops. 5. 31% of patients said they had not been given enough information to understand their condition. All of these points are recommendations in the NICE Glaucoma Quality Standards (QS7) published in March 2011. All of these points will lead to poor outcomes with patient's defaulting from treatment, increased consultations and increased wastage of medicines and associated costs.	Thank you for your comment. The guideline did not include specific methods of delivery for administration of medicines. The term 'medicines' covers all healthcare treatments, such as oral medicines, topical medicines, inhaled products, injections, wound care products, appliances and vaccines.
400	SH	International Glaucoma	2	Full	4.1		(Rec 24) Eye Clinic Liaison Officers (ECLO's) are not	Thank you for your comment. The health professionals mentioned in

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		Association					mentioned.	this recommendation are based on evidence and on expert knowledge of the GDG but it is not limited to other trained and competent health professionals.
401	SH	International Glaucoma Association	3	Full	4.1		(Rec 17) Compliance aids for eye drops are not mentioned.	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
402	NON REG	Spectrum Community Health (NHS Wakefield)	1	General	General	General	GDG members-no representation from prison. Important to be mindful of holistic approach	Thank you for your comment. Members of the guideline development group were selected from various backgrounds to provide expert knowledge of different settings and practice. The Chair of the GDG is the chief pharmacist of an NHS foundation trust that provides health care services to prisons.
403	NON REG	Spectrum Community Health (NHS Wakefield)	2	General	General	General	Reference to the NHS MEDICINES OPTIMISATION DASHBOARD NHS England – prisons/other secure environments not included in these figures	Thank you for your comment. Section 5.1 includes a hyperlink to the dashboard for further information as this guideline can be applicable to other settings.
404	NON REG	Spectrum Community Health (NHS Wakefield)	3	General	General	General	No reference to any research on medication errors occurring within the secure environment	Thank you for your comment. No evidence was found in this setting that met the criteria outlined in the review protocol.
405	NON REG	Spectrum Community	4	General	4	General	4.Guideline summary Recommendation 17 reference to medicines	Thank you for your comment. The relevant text has been added to

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		Health (NHS Wakefield)					the patient is taking bullet point 4…clarify that this includes OTC medicines.	reflect your comment.
406	NON REG	Spectrum Community Health (NHS Wakefield)	5	General	6.3	General	6.3 evidence review Reference to medicines related discharge planning interventions…No consideration included of the occurences of immediate transfer/discharge due to security needs and the often very little time for discharge planning within the secure setting.	Thank you for your comment. The literature search aimed to identify evidence when patients move from one care setting to another, in all settings as outlined in the guideline. Evidence was not identifies in the secure setting. However, the GDG agreed that the principles would apply to other health and social care settings.
407	NON REG	Spectrum Community Health (NHS Wakefield)	6	General	6.7	General	6.7 should ALL settings have a common framework and then place local policy around it	Thank you for your comment. The GDG concluded that the purpose of the guideline was to set out key principles. Details of the process are for local consideration and determination.
408	NON REG	Spectrum Community Health (NHS Wakefield)	7	General	7.1	General	7.1 The purpose of medicines reconciliation is to: Important to be mindful of holistic approach	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
409	SH	Royal Pharmaceutical Society	1	Full	General	General	We are pleased to see that the Principles of Medicines Optimisation are mentioned in the guidance. We believe that the principles of medicines optimisation should be integral to this guidance and referenced at appropriate stages of the guidance and this is not currently reflected in this draft document. These principles are now being used to develop national strategy on medicines optimisation by the jointly chaired ABPI and NHS England PPRS and medicines optimisation steering group so are being used at strategic levels within the NHS.	Thank you for your comment.
410	SH	Royal Pharmaceutical	2	Full	General	General	The document needs to be contextualised into the real world setting if we are to realise the full	Thank you for your comment. The guideline development has

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		Society					potential of the evidence review. In our opinion the guidance document needs to be more comprehensive in this respect. We do not believe that there is currently anything within the guidance that will ensure practice is changed at a local level within the current economic climate.	followed the NICE accredited process for 'clinical guidelines'. Your comment may be considered as part of the implementation needs analysis.
411	SH	Royal Pharmaceutical Society	3	Full	General	General	In general we are pleased to see the guidance place pharmacists at the centre of the delivery of MO whilst recognising that all professionals have a role to play in the delivery of MO.	Thank you for your comment.
412a	SH	Royal Pharmaceutical Society	4	Full	General	General	Although this guidance states that it is being developed for use in the NHS in England, Wales and Northern Ireland it does not seem to be reflective of this within the guidance. In Wales the principles of Medicines Optimisation are being addressed under the banner of prudent healthcare and prudent prescribing. The three key principles of prudent healthcare aim to address a number of issues which resonate with the aims of medicines optimisation. Those principles are – 1. Minimizing avoidable harm 2. Carry out the minimum appropriate intervention 3. Promote equity between the people who provide and use the service. Prudent healthcare aims to ensure that the patient is at the heart of their care and can access effective treatment in a timely manner.	Thank you for your comment. The way NICE was established in legislation means that our guidance is officially England-only. Therefore, NICE guidelines are written in the context of health and social care in England.
412b	SH	Royal Pharmaceutical Society	4	Full	General	General	In Wales the Discharge Medicines Review (DMR) service was developed to improve the management of medicines following the discharge of a patient from a care setting. This service which is now fully endorsed by the Welsh Government and it is a good example of prudent healthcare in action and the evaluation highlights that from the 14,649 DMRs processed, 19,878 discrepancies	Thank you for your comment. The way NICE was established in legislation means that our guidance is officially England-only. Therefore, NICE guidelines are written in the context of health and social care in England.

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							were uncovered. It is stated in the evaluation document that; 'In the sample reviewed in detail as part of the economic evaluation, of the 252 DMRs reviewed, 82 unintended discrepancies were found. Of these, 21 were assessed by the expert panel as being 'significant', 22 as 'serious', and 8 were 'life-threatening'. Of the last group, five involved aspirin or anti-coagulant drugs. Of this detailed sample, it was estimated that 32 patients would have been admitted to a hospital Emergency Department' The DMR service provides a good example which NICE may wish to reference in their MO document.	Discharge medicines use reviews did not form part of the evidence review.
413	SH	Royal Pharmaceutical Society	5	Full	General	General	In the guidance proposal the term patient centred care is used and this does not reflect the more appropriate term 'person-centred care' as described in the introduction.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team. For the purpose of this guideline, the term 'person' or 'patient' was used interchangeably depending on the context of use.
414	SH	Royal Pharmaceutical Society	6	Full	General	General	We strongly believe that it is not possible to separate medicines optimisation and medicines adherence. The ultimate goal of medicines optimisation is to ensure better adherence to medicines with the aim of getting the best outcomes for patients from their medicines. Medicines optimisation without medicines adherence is pointless. We believe that it is contradictory and inconsequential to consider medicines optimisation and medicines adherence as separate topics. In our view, the entire aim of medicines optimisation is to maximise medicines adherence with the aim of getting optimal outcomes for patients. The two are inseparable, in	Thank you for your comment. Medicine adherence is out of scope for this guideline (see Medicines adherence. NICE clinical guideline 76 (2009). Medicines adherence was used as an outcome measure when looking at the clinical effectiveness of the intervention and this has been included within the relevant sections. The NICE pathway will aim to bring together medicines adherence and medicines optimisation guideline

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							our opinion as even if you prescribe the right medicines for the right patient at the right time, if the patient is not supported to take that medicine through a shared decision making process then they are unlikely to achieve the best outcomes possible. There is an option that patients could choose to stop or avoid taking a particular medicine as part of an informed joint-decision making process. Although the NICE adherence guidance will be signposted as an additional resource, it will be one among many and we believe that medicines adherence needs to be integral to the MO guidance and given greater prominence. There should be references made, and support of, evidence based interventions on medicines adherence.	recommendations.
415	SH	Royal Pharmaceutical Society	7	Full	4.2	30	We agree with all of the elements of outlined in the full list of recommendations, however, it would be useful to show how each of these elements relates to the four principles of Medicines Optimisation.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team. Your comment may be considered as part of the implementation needs analysis.
416	SH	Royal Pharmaceutical Society	8	Full	4.1	29	NICE have picked three of the priorities for implementation. We do not believe the priorities should be separated out and any one of them given a higher ranking than the others as we believe they are all key elements of MO and actually, those centred on the person should be where the focus is, for example a medication review with the patient.	Thank you for your comment. The 'key priorities for implementation' section has been removed from the full guideline.
417	SH	Royal Pharmaceutical Society	9	Full	8.1	101	The latest research into the value of NMS is not included	Thank you for your comment. NMS did not form part of the evidence review and so was not included within a recommendation. The service has been mentioned in section 8 of the guideline and this

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								may be considered as part of the implementation needs analysis.
418	SH	Royal Pharmaceutical Society	10	Full	8.4	109	The RPS believes that more research is needed into the growing evidence base around the benefits of pharmacist medication reviews. There is much activity around improving patient care, outcomes and safety in the UK with over 100 examples in the 'Now or Never: Shaping Pharmacy for the Future' report most of which deliver improved patient care and outcomes through integration of pharmacists into primary and secondary care teams. The evidence review conclusion that medication review is not cost effective does not align with current practice and the RPS would like to see much wider adoption of the Medicines Optimisation Principles which put patient experience at the heart of MO with pharmacists having an active role in contributing their expertise in medicines and patient support.	Thank you for your comment. There was a high number of RCTs looking at pharmacist medication reviews, mainly carried out by hospital and community pharmacists. Further research is required for primary care pharmacists to carry out medication reviews and this has been discussed further by the GDG which has included an additional research recommendation.
419	SH	Royal Pharmaceutical Society	11	Full	8.5	116 / 117	The evidence review conclusions about medication review show that pharmacist contribution is not cost effective which is at odds with the CDGs comments about the benefits.	Thank you for your comments. The GDG was aware of the mixed clinical and economic evidence for medication reviews. However, there were a number of limitations to the economic evidence and the GDG agreed that focused medication reviews in some patient groups (i.e. those at higher risk of medication errors) are more likely to be cost-effective as these patients have a greater scope for benefit.
420	SH	East & South East England Specialist	1	Full	4.1	29	Please consider clarifying where medicines reconciliation should take place - at all transfers of care to include both arriving in a new care	Thank you for your comment. Following further discussion by the GDG the text has been amended.

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		Pharmacy Service					setting and leaving this setting for the next care setting (eg admission and discharge in hospital)	
421	SH	East & South East England Specialist Pharmacy Service	2	Full	General	General	I think that voluntary reporting via the NRLS should be mentioned in the summary	Thank you for your comment. Section 5.2 signposts users to the NRLS and other relevant information through hyperlinks.
422	SH	East & South East England Specialist Pharmacy Service	3	Full	4.1	29	Include promotion of patient –reported safety incidents	Thank you for your comment. This may be considered as part of the implementation needs analysis.
423	SH	East & South East England Specialist Pharmacy Service	4	Full	4.2	30	(Item 4) Consideration should be given to using the term 'just culture' as that takes in to account that there cannot be entirely 'no blame'	Thank you for your comment. The relevant text has now been amended to reflect this comment.
424	SH	East & South East England Specialist Pharmacy Service	5	Full	4.2	30	(Rec 8 item 3 / also on page 60) There should be some emphasis on the reports being complete and understandable since currently many are neither.	Thank you for your comment. This recommendation is aimed at interventions used to identify medicines-related patient safety incidents. Other recommendations take into account the processes required by the organisation for identifying, reporting, prioritising, investigating and learning from medicines-related patient safety incidents, in line with national patient safety reporting systems.
425	SH	East & South East England Specialist Pharmacy Service	6	Full	4.2	37	(Number 48) There is a lot of good work around virtual wards in the community and integrated care organisations promoting cross sector multidisciplinary working. Work on preventable medicines related admission both from the hospital and community sides are in place in some localities using tools to target	Thank you for your comment. This may be considered as part of the implementation needs analysis.

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							patients in this risk category. It may be worth highlighting that while there is a paucity of published data at present, this is an emerging area of work	
426	SH	East & South East England Specialist Pharmacy Service	7	Full	General	General	This is a comprehensive document with clear recommendations for practice. While some perhaps relevant studies have been excluded due to the process of selection this does not detract from the overall usefulness of the document	Thank you for your comment.
427	SH	East & South East England Specialist Pharmacy Service	8	Full	8	General	This section includes some reviews that do not reflect current practice (eg Holland et al) but the recommendations remain clear and useful	Thank you for your comment.
428	SH	East & South East England Specialist Pharmacy Service	9	Full	12.7	195	While the recommendations reflect the paucity of good evidence, there are a number of local practices that are currently being undertaken which look promising around cross sector referrals for medicines related care which include multidisciplinary teams (similar to 4.2). It would be worth highlighting the benefit of networking to raise awareness of current good practice	Thank you for your comment. This may be considered as part of the implementation needs analysis.
429	SH	East & South East England Specialist Pharmacy Service	10	Full	1.1	8-11	There is no mention of the risks of addiction to medicines both in the community and in secure environments. This is a recently prioritised area for PHE and NHS England (Health and Justice) based on published documents 2013: https://www.gov.uk/government/news/new-commissioning-guidance-for-addiction-to-medicines . In the health and justice healthcare setting there is a substantial risk from harm due to diversion and abuse of prescribed medicines and specific guidance has been published to support prescribers in formulary choices to support medicines optimisation in prisons: http://www.rcgp.org.uk/clinical-and-	Thank you for your comment. The risks of addiction to medicines and the diversion and abuse of prescribed medicines was not considered during the scoping phase of the guideline. The aim of the introduction for this NICE guideline is to introduce the concept of medicines optimisation and highlight the areas where there has been work around the topic.

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							research/clinical-resources/~/media/106D28C849364D4CB2CB5A75A4E0849F.ashx	
430	SH	East & South East England Specialist Pharmacy Service	11	Full	2.6.2	16	There are two NICE guidelines under development that will have medicines-related aspects that should be considered for inclusion: Mental healthcare in prison https://www.nice.org.uk/guidance/indevelopment/GID-CGWAVE0726 ; Physical healthcare in prison: https://www.nice.org.uk/guidance/indevelopment/GID-CGWAVE0729	Thank you for your comment. The list of related guidelines provided in section 2.6.2 is not intended to be exhaustive as majority of NICE guidelines have medicines included in them.
431	SH	East & South East England Specialist Pharmacy Service	12	Full	5.6	58	The table states: The GDG agreed that patients and/or their family members or carers have an important role in identifying and reporting of medicines-related patient safety incidents. The consensus of the GDG was that health and social care practitioners should ensure that patients and/or their carers understand how to identify and report medicines-related patient safety incidents and are encouraged and supported to do so. This is reflected in recommendation 2 on page 60. Our comment is that it would be helpful if the term "carer" could be defined or the recommendation re-phrased in a way that includes custodial staff who are responsible for the person on a routine basis in secure environments. These would include prison officers and police custody staff. Incident reporting and communication of these between healthcare and security is a key recommendation in the 2012 McFeeley review into deaths in Custody *(link)*. Current operational barriers exist in improving communication of	Thank you for your comment. The term 'carer' is used throughout NICE guidelines and is defined as 'someone who looks after family, partners or friends in need of help because they are ill, frail or have a disability'. The text has been amended to reflect this comment.

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							security incidents relating to medicines. Inclusion of custodial workforce in the recommendation or narrative would provide a clear mandate for these barriers to be justifiably removed and will improve medication incident reporting and handling in secure environments.	
432	SH	East & South East England Specialist Pharmacy Service	13	Full	6.7	76	We recognise that the evidence base and deliberations around transfer of care and discharge focusses on hospital settings. The GDG acknowledged that the principles of transfer and discharge apply to all transfers of care between any setting. However this is not fully reflected in the opening paragraph in section 6.7. In secure environment transfers most of the recommendations will apply when people are admitted to or released from custody or transferred between custodial settings. In order to ensure that healthcare providers in secure environments interpret these recommendations as being inclusive to the care of people in these settings, please could you consider adding a sentence to the introductory paragraph in section 6.7. stating that although some of these recommendations explicitly mention hospital transfers and discharge, that organisations such as secure environments should consider these for patient transfer and release and implement them in a way that reflects transfer of care for their setting.	Thank you for your comment. The text has been amended to reflect this comment.
433	SH	East & South East England Specialist Pharmacy Service	14	Full	7.1	79	Medicines reconciliation is equally important on admission, transfer between and release from secure environments. This is not included in the list of examples shown as bullet points. Please could "when a patient moves into or is transferred between secure environments" be considered for inclusion in the list?	Thank you for your comment. The relevant text has now been added to reflect this comment.

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434	SH	East & South East England Specialist Pharmacy Service	15	Full	7.1	79-80	Please could you consider adjusting the text to clarify inclusivity for **all** care setting transfers/releases for example: "However, it is widely acknowledged that the medicines reconciliation process should also happen when the patient is discharged from hospital or moves into or between any other care setting. In a hospital setting, medicines reconciliation may involve a process to ensure that the medicines prescribed in hospital reflect what the patient was taking before admission or it may be used identify what the patient was taking on another ward. In a primary care setting, medicines reconciliation involves a process to ensure that the medicines prescribed by the GP (or other prescriber) reflect what the patient was taking after discharge from any care setting.	Thank you for your comment. The relevant text has now been added to reflect this comment.
435	SH	East & South East England Specialist Pharmacy Service	16	Full	7.7	98	Please consider adding the word "and other care setting" for recommendation 22. This is because people may be discharged home from temporary care home stays (where other clinicians may have altered therapy) or from secure environments. Otherwise the MR process is to narrowly focused on hospital stays.	Thank you for your comment. This recommendation has been amended following further discussion by the GDG.
436	SH	East & South East England Specialist Pharmacy Service	17	Full	4.1	30	(Rec 18) Consider sending a person's medicines discharge information to their nominated community pharmacy, when possible and in agreement with the person. This recommendation needs to be strengthened. "The GDG concluded that there is a significant risk to patient safety if there is no, or ineffective, communication about medicines when a patient transfers from 1 care provider to another". The Community Pharmacist is a provider of care (pharmaceutical care) who needs this information	Thank you for your comment. The strength of recommendations are based on the quality of evidence, clinical and cost effectiveness of the intervention. The GDG are unable to make a recommendation stronger without sufficient evidence to base it on. The recommendation that your comment is relating to is not supported by strong evidence and can therefore not be strengthened.

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							to provide a safe service.	
437	SH	Asthma UK	1	Full	General	General	We very much welcome this guideline overall, and are delighted to see the focus placed on asthma. This is especially timely following the National Review of Asthma Deaths (2014) which outlined key concerns related to prescribing errors, patient education and self-management. Most of the £1billion spent on asthma each year is spent on asthma drugs, and we know that medicines optimisations can both improve outcomes for people with asthma and ensure that the money spent on asthma is spent more effectively.	Thank you for your comment.
438	SH	Asthma UK	2	Full	General	General	We are content that the different sections cover medicines optimisation comprehensively.	Thank you for your comment.
439	SH	Asthma UK	3	Full	General	General	(General / section 9.7) The focus on a person-centred approach is excellent, especially in the section focussing on self-management. It fully takes into account personal knowledge, values and skills in order to evaluate their risk which is very important in managing asthma.	Thank you for your comment.
440	SH	Asthma UK	4	Full	General	General	Overall, we are keen to see the term 'written' used for self-management plans as evidence for asthma suggests that plans must be written for them to be most effective.	Thank you for your comment.
441	SH	Asthma UK	5	Full	General	General	Overall, we would like to see a stronger focus on reducing or increasing dosage as an aspect of medicines optimisation (this is often referred to as stepping up or stepping down for asthma). This is a very important part of optimising medicines to ensure that patients are only on the exact level of medication they need at any given point, and is also an opportunity to identify issues with poor adherence or technique problems. If patients remain at the wrong level they may experience unnecessary burden from drugs and may also be	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. Specific dose changes did not form part of the evidence review. The interventions such as medication reviews would take dose changes and other issues about medicines into account.

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							taking highly expensive medication without due course (for example, if they remain on asthma Step 3 when they could in fact be on Step 2). We were surprised by how little this was referred to.	
442	SH	Asthma UK	6	Full	8.1	101	Please remove the reference to asthma in the Box 1 - we are uncomfortable with its use here because it could be misleading (asthma medication reviews could in theory come in the form of most of the levels depending on the situation, so it is misleading to associate asthma with only one).	Thank you for your comment. This is used an example and was considered by the NICE publishing team.
443	SH	Asthma UK	7	Full	8.7	121	Recommendation 27 should include reference to clinical guidelines. For example, "Consider carrying out a medication review for some patient groups when a clear purpose for the review has been identified, in line with condition-specific national clinical guidelines". Without this, there is risk that practice could occur contrary to existing clinical guidance. For example, medication reviews should occur for all people with asthma.	Thank you for your comment. Condition specific guidelines do not always state the type of medication review, for example it may be a full structured medication review or a routine review of medicines. Wording and formatting was considered by the NICE publishing team.
444	SH	Asthma UK	8	Full	8.7	121	Recommendation 28 should include reference to clinical guidelines. For example, "**In line with condition-specific national clinical guidelines**, determine locally the most appropriate health professional to carry out a medication review, based on their knowledge and skills, including all of the following". Without this, there is risk that practice could occur contrary to existing clinical guidance. Some clinical guidelines may explicitly state which specific health care professionals should conduct medications reviews so it is important that this guidance is not contradictory.	Thank you for your comment. Condition specific guidelines do not always state the type of medication review, for example it may be a full structured medication review or a routine review of medicines. Wording and formatting was considered by the NICE publishing team.

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445	SH	Asthma UK	9	Full	8.7	121	Recommendation 29, bullet point four, should include an understanding of how to use the medications effectively.	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be taken into account depending on the person's needs, but this would be for the healthcare professional to determine.
446	SH	Asthma UK	10	Full	9.5	130	Reference to asthma self-management plans should include the term 'written self-management plans'.	Thank you for your comment. Following further discussion with the GDG, they agreed that the term 'self-management plan' captures both written and electronic plans.
447	SH	Asthma UK	11	Full	9.1	122	We would like to see asthma used as an example here. NICE Quality standard for asthma (Quality Statement 3) states how written asthma action plans improve outcomes, as does the BTS/SIGN Guideline on the Management of Asthma. We understand that the COPD self-management guidance is proceeding despite a lack of clinical consensus amongst primary care professionals while the equivalent for asthma has much better evidence.	Thank you for your comment. This was an example for the introduction and was considered by the NICE publishing team.
448a	SH	Asthma UK	12	Full	9.7	135	Recommendation 30 should include reference to clinical guidelines. "When discussing medicines with people who have chronic or long-term conditions, **written** self-management plans should be used where they are recommended by condition-specific national clinical guidelines; **use** an individualised **written** self-management plan to support people who want to be involved in managing their medicines where clinical guidelines are not available."	Thank you for your comment. Following further discussion with the GDG, they agreed that the term 'self-management plan' captures both written and electronic plans.

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							Without this, there is risk that practice could occur contrary to existing clinical guidance. Also, add the term 'written' as without this, it will be hard to record compliance and may not be auditable. This is also recommended in the asthma guideline.	
448b	SH	Asthma UK	12	Full	9.7	135	The term 'consider using' should instead be stronger. Suggest 'use'.	Thank you for your comment. The strength of recommendations are based on the quality of evidence, clinical and cost effectiveness of the intervention. The GDG are unable to make a recommendation stronger without sufficient evidence to base it on. The recommendation that your comment is relating to is not supported by strong evidence and can therefore not be strengthened by replacing 'consider' with 'use'.
448c	SH	Asthma UK	12	Full	9.7	135	This section could also be expanded to include reference to written self-management plans assisting with recognition of when symptoms are getting worse.	Thank you for your comment. Following further discussion by the GDG, they agreed that assisting with recognition of when symptoms are getting worse would come under 'any other instructions the person needs to safely and effectively self-manage their medicines' in the recommendation. .
449	SH	Asthma UK	13	Full	9.7	136	Should read "Record the discussion in the person's medical notes and retain a copy of the self-management plan".	Thank you for your comment. Following further discussion, the GDG agreed that this would be part of standard professional practice to make contemporaneous records during consultation.

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450	SH	Asthma UK	14	Full	9.7	136	Recommendation 31, bullet point seven should read "[… a health professional and how to do so".	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
451	SH	Asthma UK	15	Full	11.1	165	Should the final paragraph also include Northern Ireland in discussing the variable uptake?	Thank you for your comment. Evidence from another NICE guideline only suggests this for England and Wales. The way NICE was established in legislation means that our guidance is officially England-only. However, we have agreements to provide certain NICE products and services to Wales, Scotland and Northern Ireland. Decisions on how our guidance applies in these countries are made by the devolved administrations, who are often involved and consulted with in the development of NICE guidance.
452	SH	Guild of Healthcare Pharmacists	1	Full	General	General	Will any recognition/support be given to ensure organisations plan/deliver adequate resources to ensure the guidelines can be implemented effectively? Without adequate resources my concern would be that the undoubted benefits of the various interventions will not be deliverable, patient care and safety will be compromised and 'blame' for failures is likely to land on Chief pharmacists' within the hospital setting.	Thank you for your comment. Your comment may be considered as part of the implementation needs analysis.
453	SH	Guild of Healthcare Pharmacists	2	Full	4.2	30	Recommendation 1, 7 and 8 – We suggest that there should be a link here to the MHRA document on medicines safety officers. This role is likely to pull all these recommendations together and allow them to be actioned. Support for this role within the guidelines would give	Thank you for your comment. Following further discussion by the GDG, the medicines safety officer role has been highlighted within the relevant recommendation.

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							prominence to the position as well as facilitating the implementation of the recommendations.	
453	SH	Guild of Healthcare Pharmacists	2	Full	4.2	30	Recommendation 4 - discusses having "no blame culture"- we believe this should actually be a 'fair blame culture' as some people are negligent and even criminal (Beverly Allot etc).- reference NPSA towards and open and fair culture in the NHS to move from just to reporting to learning culture.	Thank you for your comment. The wording has been amended to reflect your comment following further discussion by the GDG.
454a	SH	Guild of Healthcare Pharmacists	3	Full	4.2	31	Line 18- We strongly support the recommendation around availability of information when patients are admitted to hospital. Recommendation 11- There should be a recommendation that information about a patient's medicines prescribed by their GP should be readily accessible in an electronic format to all healthcare professionals involved in medicines reconciliation etc. This may be in the form of the summary care record or another similar system. The main issues are accessibility and accuracy of such systems. This issue seriously compromises the safe prescribing of medicines when patients are admitted to hospital	Thank you for your comment Methods used to access information did not form part of the evidence review and so a recommendation cannot be made.
454b	SH	Guild of Healthcare Pharmacists	3	Full	4.2	31	Recommendation 13- should the list given to patients include changes made to **pre-admission** medicines? A patient's drug therapy may have many changes during the course of the admission which will not be necessary to communicate. However what is valuable are changes to existing treatment to avoid inadvertent medication errors when the patient goes home	Thank you for your comment. The GDG concluded that the purpose of the guideline was to set out key principles. Details of the process are for local consideration and determination.
454c	SH	Guild of Healthcare Pharmacists	3	Full	4.2	31	Recommendation 14- is it appropriate to expect patients to tell the GP what the actual changes are or should we be encouraging patients to tell the GPs that changes have been made and the discharge summary should be the vehicle for communicating the changes?	Thank you for your comment. Following further discussion by the GDG, this recommendation has been taken out.

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455a	SH	Guild of Healthcare Pharmacists	4	Full	4.2	32	Recommendation 15 - The recommendation of within 48hours is reasonable for patients discharged, but transfer of care also covers on admission. Additional recommendations/guidance may be required to ensure this happens.	Thank you for your comment. Following further discussion by the GDG, this recommendation has been amended and will be considered as part of the implementation of the guideline process.
455b	SH	Guild of Healthcare Pharmacists	4	Full	4.2	32	Recommendation 17- this is not about transfer of care it is solely relating to discharge information. To prevent a misunderstanding of what transfer of care means, this recommendation should be reworded as' upon discharge' rather than transfers from one care setting to another.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
455c	SH	Guild of Healthcare Pharmacists	4	Full	4.2	32	Recommendation 17- It is impractical to expect the discharge summary to contain information on allergies as most of these will be historical and hence the hospital team will not have any knowledge of the allergy other than the patient stating they are allergic to a medicine. Also, the number of patients that report being allergic to medicines without knowing what the allergy was, is alarmingly high. We suggest this be details of allergic reactions that occurred during the admission!	Thank you for your comment. Wording and formatting was considered by the NICE publishing team. NICE have published a guideline on drug allergy, see Drug Allergy NICE clinical guideline 183 that we have hyperlinked to where appropriate.
455d	SH	Guild of Healthcare Pharmacists	4	Full	4.2	32	Recommendation 17 – Again, it may not be possible for the discharge letter to have the indication for all medicines to be documented as a number of these will have been started by the GP and it may be difficult to determine the actual indication. We suggest that all medication summaries provided on admission also detail the indication for each medicine, and the indication be for those medicines newly initiated on that admission!	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
455f	SH	Guild of Healthcare	4	Full	4.2	32	Medicines reconciliation definition (line 40) - this was taken form IHI definition but surely it should	Thank you for your comment. This wording has been amended

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		Pharmacists					contain something around correcting any unintentional discrepancies otherwise what is the point of the whole process? Medicines reconciliation only works if staff can get the information. Summary Care records help but they can show medicines that have been stopped. It is not just the resource of manpower (which is desperate in some NHS Trusts) and skill mix within pharmacy but also the IT behind it.	following further discussion by the GDG.
456	SH	Guild of Healthcare Pharmacists	5	Full	4.2	33	Recommendation 20 - as a point of clarification, the compilation of the accurate list is not medicines reconciliation. It is part of that process, but medicines reconciliation also covers other aspects as previously outlined in the section. Is the goal of medicines reconciliation to prepare the accurate list within 24 hours of admission or to actually do something about the discrepancies that are found? We would question the value of any accurate list if the discrepancies are not acted upon and the patient comes to harm as a consequence. One of the difficulties here is a lack of clarity as to what we are calling medicines reconciliation and within what timeframe it should be started (as in the 'Medicines Safety Thermometer'), partially completed (as is the case here) or fully completed, including the correction of any discrepancies (which is what really counts if you are looking at patient safety and prevention of harm).	Thank you for your comment. This recommendation has been reworded following further discussion by the GDG.
457	SH	Guild of Healthcare Pharmacists	6	Full	4.2	35	Recommendation 35 - For patient decision aids to be useful, they must be quick and easy to use. The NICE AF aid is a good case in point. Whilst it may be thorough it is not really user friendly within the confines of a standard patient consultation therefore its true value is unlikely to be realised.	Thank you for your comment. This has been forwarded onto the team who developed the NICE patient decision aid.
458	SH	Guild of	7	Full	4.2	36	There should be a comment in within this	Thank you for your comment. The

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		Healthcare Pharmacists					statement on where to warn about the risks associated with 'warning fatigue'? It is well recognised within electronic systems that this potentially is an issue that can compromise the value of any such warnings. This is particularly true if the warnings appear frequently without just cause.	GDG developed recommendations based on key principles of the intervention from the evidence found. The specifics of 'warning fatigue' did not form part of the evidence review.
459	SH	Guild of Healthcare Pharmacists	8	Full	4.2	37	We fully support this statement	Thank you for your comment.
460	SH	UK Medicines Information	1	Full	General	General	UKMi welcomes the publication of the draft guidelines as a means to ensuring the best possible outcomes for patients and best value for the NHS as a whole from the use of medicines.	Thank you for your comment.
461	SH	UK Medicines Information	2	Full	General	General	Whilst understanding the desire to focus on a small number of areas for prioritisation, consideration could also be given to allowing organisations to focus on areas where most gain could be made locally rather than a national set of four key priorities or where it could be demonstrated that the organisation has already met the recommendation. This approach is reflected in the recently reported proposals for CCGs to adopt locally negotiated quality programmes in place of QOF It also assumes that all organisations are starting from zero. Many organisations have optimised medicines reconciliation and so the guidance might usefully prioritise all its recommendations.	Thank you for your comment. The 'key priorities for implementation' section has been removed from the full guideline. Your comment may be considered as part of the implementation needs analysis.
462	SH	UK Medicines Information	3	Full	4.2	30	**Identifying reporting and learning from medicines related patient safety incidents** Recommendation 1: It would be helpful if organisations were to ensure reporting of safety issues at Board Level. For real change to happen there will need to be ownership and recommendations to ensure transparency and	Thank you for your comment. The GDG concluded that the purpose of the guideline was to set out key principles. Details of the process are for local consideration and determination

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							robustness of processes which may need a Board level champion to oversee change with appropriate minutes available as evidence. This principle would also apply to recommendations 3,4,5,7.	
463	SH	UK Medicines Information	4	Full	4.2	30	**Identifying reporting and learning from medicines related patient safety incidents** Recommendation 2: a suggested standard mechanism for demonstrating this recommendation has been met would be useful as a benchmark.	Thank you for your comment. Your comment may be considered as part of the implementation needs analysis or in the development of the NICE quality standard on medicines optimisation.
464	SH	UK Medicines Information	5	Full	4.2	30	**Identifying reporting and learning from medicines related patient safety incidents** Recommendation 6: unsure whether the CPD recommendation applies to individuals or to the wider organisation.	Thank you for your comment. This has been amended following further discussion by the GDG.
465	SH	UK Medicines Information	6	Full	4.2	30	**Identifying reporting and learning from medicines related patient safety incidents** Recommendation 9: there is a risk that increased and consistent reporting as in recommendations 3, 4 and 5 will override the important work suggested in recommendation 9 with organisations appearing to 'fail' to implement good practice.	Thank you for your comment. Your comment may be considered as part of the implementation needs analysis.
466	SH	UK Medicines Information	7	Full	4.2	30	**Identifying reporting and learning from medicines related patient safety incidents** The recently established Medication Safety Officers and associated network would be key to the success of these recommendations so a general comment in the introduction reminding organisations of their importance and evidence based approach would be helpful.	Thank you for your comment. This has been added following further discussion by the GDG. The recommendation now highlights the role of the medicines safety officer.
467	SH	UK Medicines Information	8	Full	4.2	31	**Medicines-related communication systems when patients move from one care setting to another** Recommendation 11: The emphasis on review and monitoring of effectiveness is	Thank you for your comment. Your comment may be considered as part of the implementation needs analysis.

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							welcomed. To avoid duplication of effort some best practice models could be suggested for adoption as part of any implementation support package.	
468	SH	UK Medicines Information	9	Full	4.2	32	**Medicines-related communication systems when patients move from one care setting to another** Recommendation 15 - share with whom? Suggest GP, nominated community pharmacist and "hospital"	Thank you for your comment. This has been amended to reflect your comment following further discussion by the GDG. The person to share the information with would depend on the care setting.
469	SH	UK Medicines Information	10	Full	4.2	32	**Medicines-related communication systems when patients move from one care setting to another** Recommendation 19: The promotion of quality based Medicines Information Patient Helplines would be another mechanism for supporting patients and carers as care is moved back to the place of residence. This may extend to nursing and residential home settings. Provision of such expert support for community pharmacists could also be explored to strengthen outcomes from recommendation 18 as part of any implementation support package.	Thank you for your comment. The examples listed in this recommendation reflect the evidence identified and presented to the GDG. Other interventions that provide additional support for patients at the time of hospital discharge, such as a medicines information patient helpline, would need to be considered and determined locally.
470	SH	UK Medicines Information	11	Full	4.2	33	**Medicines reconciliation** Recommendation 23: a key issue is to integrate this role with that of the medication safety lead to allow a further route for reporting patient safety issues identified during the reconciliation process.	Thank you for your comment. The GDG concluded that reporting of medicines-related patient safety incidents would apply to all interventions reviewed in the guideline and not just medicines reconciliation. The process of reporting would need to be determined locally.
471	SH	UK Medicines Information	12	Full	4.2	34	**Medication Review** Recommendation 29: Could this be strengthened to suggest that it is critical that the patient and/or carers are involved in a bona fide medication review (particularly in the	Thank you for your comment. The recommendations for medication review make it clear that the person should be involved if they

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							community setting) in order to optimise medicines use so as to distinguish from the 'medication reviews' authorising the issue of repeat prescriptions.	wish to be.
472	SH	UK Medicines Information	13	Full	4.2	35	**Self Management Plans** Recommendation 31: signposting to a suitable patient helpline could also be considered.	Thank you for your comment. The relevant text has now been amended to reflect this comment.
473	SH	UK Medicines Information	14	Full	4.2	36	**Patient Decision Aids** Recommendation 42: We welcome the evidence based approach to the provision of decision aids and would further suggest that patient information to take away from the consultation should be provided as well as signposting other sources of information e.g. patient helplines and appropriately supported community pharmacists. Given the amount of work to develop these, the NHS should have a system for sharing validated PDAs. The development of PDAs in a range of languages and styles to suit BME groups is also an area that needs addressing	Thank you for your comment. This will be considered in the implementation needs analysis.
474a	SH	UK Medicines Information	15	Full	4.2	36	**Clinical Decision Support** Recommendation 44. We would encourage the use of the term 'evidence based clinical decision support' throughout this section to ensure consistency of approach across differing systems.	Thank you for your comment. This has been reworded following further discussion by the GDG.
474b	SH	UK Medicines Information	15	Full	4.2	36	**Clinical Decision Support** Recommendation 45: a reference to reporting of patient safety issues through such software not just identification would link up the different strands of recommendations.	Thank you for your comment. Clinical decision support is used to support prescribers with decision-making. We did not look at clinical decision support systems as an intervention to report patient safety issues as this was already covered in section 5 of the guideline.
475	SH	UK Medicines Information	16	Full	4.2	37	**Medicines-related models of organisational and cross-sector working** Recommendation 46: We agree that it is vital that health and social care	Thank you for your comment. Your comment may be considered as part of the implementation

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							work together to optimise medicines use across a health-economy however experience suggests that public health / social care representation on Area Prescribing Committees is patchy at best. Capacity to input at a MDT level for individual patients may be impossible to achieve but best practice examples where this has been possible could help spread of adoption.	needs analysis.
476	SH	UK Medicines Information	17	Full	14	210	**Glossary:** Complimentary Medicine should read Complementary Medicine	Thank you for your comment. The relevant text has now been amended to reflect this comment.
477a	SH	Association of the British Pharmaceutical Industry	1	Full	General	General	ABPI welcomes the development of a clinical guideline for medicines optimisation and the opportunity to comment on it.	Thank you for your comment.
477b	SH	Association of the British Pharmaceutical Industry	1	Full	General	General	ABPI are firmly and publically committed to the national medicines optimisation programme and strongly advocate the underpinning principle that medicines play a crucial role in maintaining health, preventing illness, managing long-term conditions and curing disease. Medicines are a fundamental part of patient management and it is vital that patients get the best quality outcomes from medicines. Medicines optimisation is a holistic patient focused approach to getting the best from investment in and use of medicines. Medicines optimisation is about ensuring that the right patients get the right choice of medicine at the right time. By focusing on patients and their experiences, the goal is to help patients to improve their outcomes, take their medicines correctly, avoid taking unnecessary medicines, reduce wastage and improve the safe use of medicines.	Thank you for your comment.
477c	SH	Association of the British	1	Full	General	General	The Royal Pharmaceutical Society published the good practice guide in May 2013 "Medicines	Thank you for your comment. The four key principles as stated in the

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		Pharmaceutical Industry					Optimisation: Helping patients to make the most of medicines Good practice guidance for healthcare professionals in England" which outlined the guiding principles for Medicines Optimisation across four key principles. Each one of these principles - understanding the patient's experience; evidence-based choice of medicines; ensuring medicines are as safe as possible; and making medicines optimisation part of routine practice carry equal weight, and importance to achieving the aims of medicines optimisation. This document has now become a recognised starting point for national, regional and local medicines optimisation strategic plans and, as such, ABPI would recommend that the four principles set out in this document to have greater emphasis within the NICE guideline. ABPI believe that it is important to have a balanced and blended approach across all of these principles to ensure the aspirations of Medicines Optimisation are fully achieved.	Royal Pharmaceutical Society guidance Medicines Optimisation: Helping patients to make the most of medicines *Good practice guidance for healthcare professionals in England*' are included in this guideline in the introductory text. The aim of the introduction for this NICE guideline is to introduce the concept of medicines optimisation and highlight areas where work has been carried out for the topic. The RPS guidance has been hyperlinked in the NICE guideline for the user to obtain further information if needed.
477d	SH	Association of the British Pharmaceutical Industry	1	Full	General	General	In July 2014, the Ministerial Industry Strategy Group (MISG 14(05)) endorsed the development of the NHS England and ABPI joint commitment to maximise the benefits of the nationally agreed Pharmaceutical Price Regulation Scheme 2014 (PPRS) through a programme of action to create clinical pull in order to accelerate uptake of innovative, clinically effective and cost effective medicines. Ensuring medicines are used and adopted effectively is a key policy for this joint committee and as such the four principles developed through the RPS are an essential framework for implementation and communication of messages to the NHS. A PPRS Medicines Optimisation Steering Group	Thank you for your comment. This is outside the scope of the guideline.

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							has been established to oversee and ensure the delivery of this programme of action to improve patient outcomes, quality and value of care from medicines use. The 'Engaging Hearts and Minds section of this programme outlines the ABPI and NHSE commitment to strategically align the work of ABPI's Therapy Groups and National Clinical Directors(NCDs) during 2015. ABPI would suggest that this guideline should be more aligned to national work programmes and ministerial policy direction. Such as that outlined above.	
477f	SH	Association of the British Pharmaceutical Industry	1	Full	General	General	In addition, the difference between medicines management (often focused on process, systems and costs alone) and medicines optimisation need to be recognised and the need to refocus efforts and resource away from medicines management towards medicines optimisation needs to be set out more clearly.	Thank you for your comment. The introduction to the guideline explains the difference between medicines management and medicines optimisation. In addition, wording and formatting was considered by the NICE publishing team.
477g	SH	Association of the British Pharmaceutical Industry	1	Full	General	General	ABPI would suggest that this guidance alone is limited in supporting the changes in thinking, behaviours and culture that are needed to embed effective use of medicines within a complex system. To overcome this limitation ABPI would suggest that an additional Good Practice Guide be produced to support implementation of medicines optimisation principles and practice. Since the central tenant for medicines optimisation is that the patient is key to the decision-making process, the guideline should reflect that the most appropriate treatment for a patient should be agreed upon through open dialogue between the healthcare professional and the patient. ABPI acknowledges that decision – support tools and resources have their place but	Thank you for your comment. This may be considered in the implementation need assessment. The evidence for clinical decision support was weak and this is reflected in the strength of the recommendation. Recommendations for clinical decision support state that this should not replace clinical judgement which should be consider for each individual person, their clinical condition and the consultation. If using clinical decision support systems, one that

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							should not take precedent over dialogue to understand the needs and experiences of patients. Reliance on decision-support tools may lead to circumstances where certain treatments are recommended based on criteria which are not aligned to broader NHS principles & policies such as those described within the Innovation, Health and Wealth report [2] & the PPRS Agreement , which support the uptake of new innovative technologies. [2] Innovation Health and Wealth, accelerating adoption and diffusion in the NHS.	reflects the best available evidence for treatment should be used.
477h	SH	Association of the British Pharmaceutical Industry	1	Full	General	General	Whilst ABPI recognises that there are no RCTs or observational studies, as per the criteria set out to evaluate the evidence in this guideline, to evaluate the cost and clinical effectiveness of models for cross-organisational working between health and social care and the pharmaceutical industry in relation to medicines optimisation, we would like to note that there are a number of evaluations of such collaborations that have demonstrated an improvement in patient reported outcomes. The guideline process used has been unable to identify examples of practice that can demonstrate clinical effectiveness of medicines for patients, cost effectiveness of models used to reduce suboptimal use of medicines to inform commissioning of services and that this limitation should be noted for further research or additional resource. Similarly, ABPI also notes that although there is a recognised body of evidence underpinning clinical decision-making behaviour change principles, the database searches used for this guideline didn't include the journals that would include relevant	Thank you for your comment. The methods used to develop this guideline are included in the NICE guidelines manual (2012).

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							literature to support these principles. ABPI would suggest that further research is considered in this area.	
477i	SH	Association of the British Pharmaceutical Industry	1	Full	General	General	Additional points for consideration for inclusion in introductory section: 3. NICE should acknowledge and support healthcare professionals (HCP) role in understanding adherence and shared decision-making so that the patient gets the maximum value from the medicine and that the NHS obtains the maximum value from the medicine also.	Thank you for your comment. The aim of the introduction for this NICE guideline is to introduce the concept of medicines optimisation and highlight the areas where there has been work around the topic. To support healthcare professionals with adherence and shared decision making, NICE have guidelines on medicines adherence and patient experience in adult NHS services. The documents have been hyperlinked in the guideline for the user to obtain further information.
477j	SH	Association of the British Pharmaceutical Industry	1	Full	General	General	**Additional points for consideration for inclusion in introductory section:** 2. ABPI recognises that although there are a number of references made to home setting in the context of home care throughout the draft consultation document, a more precise definition would be helpful for example to differentiate between patients' home and care homes. This would help further identify specific requirements to enable self-management at home versus care home. Remote monitoring, for example, is likely to play an even greater role in home setting than at care homes.	Thank you for your comment. The relevant text has now been added to reflect this comment.

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478a	SH	Association of the British Pharmaceutical Industry	2	Full	3.4.2	26	ABPI have concerns that the economic analysis only being modelled on the Medicines Reconciliation area of the draft guideline is a missed opportunity. There is the potential to demonstrate significant economic benefit in appropriately conducted medication reviews, helping patients to achieve their goals, avoid complications in the long term and ultimately have a better outcome [Hex et al, *Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs*].	Thank you for your comment. Health economic modelling was not undertaken on medication reviews for the reasons stated in Section 8.4 – page 10.9, final paragraph. Hex et al. reported that the majority of costs related to diabetes were as a result of complications. However, we do not have evidence from the clinical review linking a reduction in diabetes related complications to medication reviews, neither do we have clinical evidence linking an improvement in quality of life with medication review in patients with diabetes.
478b	SH	Association of the British Pharmaceutical Industry	2	Full	3.4.2	26	We also believe that the guideline could go further in considering how these recommendations might be implemented, for example via commissioned services, and how they are linked to system levers and incentives such as QOF and how the recommendations must be reflected in existing and new quality standards.	Thank you for your comment. This may be considered in the implementation needs analysis.
479a	SH	Association of the British Pharmaceutical Industry	3	Full	4.1	29	ABPI accepts that it is appropriate to prioritise the recommendations for implementation, however, we would like to see the medication review recommendations set out in section 4.2.27 and 4.2.28 and 4.2.29 included as a priority.	Thank you for your comment. The 'key priorities for implementation' section has been removed from the full guideline.
479b	SH	Association of the British Pharmaceutical Industry	3	Full	4.1	29	This section is complementary to medicines reconciliation and is important in addressing improvements in patient outcomes and experience, as well as helping adhere to NICE guidelines and treatment targets where relevant.	Thank you for your comment. This may be considered in the implementation needs analysis.
479c	SH	Association of	3	Full	4.1	29	It is also worth noting that, while it is vital that	Thank you for your comment. This

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		the British Pharmaceutical Industry					everything is done to ensure patient safety, the emphasis should be on actions which have evidence to show that they bring benefit. In particular the evidence base resulting from the PINCER study is widely accepted as providing a strong case for the use of the PINCER software available to CCGs. This has been borne out by the incorporation of a measurement for PINCER downloads in the NHS England MO dashboard.	may be considered in the implementation needs analysis.
480	SH	Association of the British Pharmaceutical Industry	4	Full	4.1	29	(Sections 4.1 (R8) and 5.7 / pages 29 and 59-60) There appears to be no mention of informing manufacturers of adverse events associated with their medicines; Manufacturers need to be kept informed of such matters so they can take appropriate action. Therefore it may worth adding and to make it clear in the text to inform the pharmaceutical company/manufacturer of the incident that occurred?	Thank you for your comment. Following further discussion by the GDG we have amended section 5.6 to reflect your comment.
481	SH	Association of the British Pharmaceutical Industry	5	Full	29	29	(Sections 29 (R17) and 6.7 (R17) / pages 29 and 77) If a patient is on certain drugs that are keeping him/her alive, and there is a notification on the notes for *Do not attempt resuscitation* (DNAR), this information should be clear in transfer communications associated with the patient's medicines.	Thank you for your comment. This example was not discussed specifically by the GDG, but would be captured in 'other information'.
482	SH	Association of the British Pharmaceutical Industry	6	Full	4.2.17	31	ABPI suggests that the patient's social situation should be a parameter to include in recommendation 17 in relation to the safe use of medicines. For example whether the patient lives alone, with family, has home help, district nurse visits, especially where any support or assistants from a family member, carer or other HCP may involve administration of medications.	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or

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								social care practitioner to determine.
483	SH	Association of the British Pharmaceutical Industry	7	Full	4.2	31	(Sections 4.2 (R10) and 5.7 (R17) / pages 31 and 61) Within the document there is no mention of specific patient groups (ABPI acknowledges this was discussed as part the original scope). However NICE may wish to recognise the vulnerability of some groups such as neonatal, paediatric, adolescents and patients with renal/liver impairment in relation to their medicines where doses are dependent on weight, measurements (especially oral liquids)and organ function.	Thank you for your comment. Following further discussion by the GDG the relevant text had been amended to reflect your comment.
484	SH	Association of the British Pharmaceutical Industry	8	Full	4.2.17	32	ABPI would like to draw to the attention of the authors the Commissioning Intentions 2015/16 for Prescribed Specialised Services, Section on Chemotherapy Drugs paragraph 88 refers to the need for all Trusts "to work with Area Teams to maximise opportunities for dose banding and vial sharing where such activity does not exist". ABPI considers it relevant and appropriate for the document to include information, including brand name, on any device or biological medicine that the patient has been given or is using in order to avoiding the patient being inadvertently transferred to a medicine or device with which they are unfamiliar. This is of particular concern where there are several possible medicines and/or devices for administering them for a particular condition. This will also ensure that MHRA guidance is adhered to [http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con207196.pdf]	Thank you for your comment. This list was not intended to be exhaustive with particulars. Where other relevant information including brand name for the medicine or device is required, then this can be included in 'other information' as not every medicine or device will need a brand to be specified. This also applies to signposting to any supporting materials or safety information available.

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							It should also include any supporting materials or safety information available such as the Patient Passport to Safer Use of Insulin [http://www.nrls.npsa.nhs.uk/resources/?EntryId45=130397].	
485	SH	Association of the British Pharmaceutical Industry	9	Full	4.2.24	33	In lines 23-25 ABPI suggests adding the following words "*understanding of the disease and co-morbidity*". These are skills which should be required by anyone carrying out medicines reconciliation.	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
486	SH	Association of the British Pharmaceutical Industry	10	Full	4.2.28	33	It is ABPI view that the skills and competencies of the identified HCP at a local level be consistent throughout the country to undertake medicines reviews on a systematic basis for the groups of patients identified in 4.2.27. NICE could work with the appropriate national body to identify which healthcare professional might be best placed to do this based on the evidence available and suitability for the patients (for example a community pharmacist). Further NICE should consider if this should be a commissionable service.	Thank you for your comment. This may be considered in the implementation needs analysis. NICE provides a range of informational services for commissioners, practitioners and managers across the spectrum of health and social care, however it is not within NICE's remit to consider whether or not to commission a service; NICE is not a commissioning organisation.
487	SH	Association of the British Pharmaceutical Industry	11	Full	4.2.29	34	We feel that this recommendation should acknowledge the short- and long-term effects a medicine review can have on a patient's outcome, for example helping to avoid long term complications arising from a poorly controlled long term condition.	Thank you for your comment. The GDG developed recommendations based on key principles of the intervention from the evidence found. The short- and long-term effects of a medication review did not form part of the evidence review.
488	SH	Association of the British Pharmaceutical Industry	12	Full	4.2.30	34	This recommendation could go further and recommend that patients are signposted to and encouraged to engage with appropriate education related to their condition on a systematic basis to	Thank you for your comment. The relevant text has now been amended to reflect this comment.

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							improve uptake rates [REF NDA 2014].	
489	SH	Association of the British Pharmaceutical Industry	13	Full	4.2	34	4.2 (30) ABPI would like to draw attention to the lack of clarity on which setting(s) self-management takes place in the first paragraph on self-management plans. There is no mention of home setting at present, which we believe should be included. See general comments on first page.	Thank you for your comment. The relevant text has now been amended to reflect this comment.
490	SH	Association of the British Pharmaceutical Industry	14	Full	4.2	34	4.2 (30) ABPI suggests inserting the following bullet point or add to the bullet point 'how to use the plan' "*Any special training needs for different administration routes"*	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health professional to determine.
491	SH	Association of the British Pharmaceutical Industry	15	Full	4.2	34-5	4.2 (31) ABPI suggests inserting the following bullet point: • *Technology available for remote monitoring of patient treatment to support appropriate use of medicines and provide warning of potential side effects.*	Thank you for your comment. The list in recommendation 31 was agreed by the GDG as the minimum information to include within the self-management plan. Self-management plans should be individualised and tailored to the person's needs, this includes providing any other additional information that meets the person's needs to support self-management. Where such technology for monitoring exists, this would be part of the tailored approach when drawing up the self-management plan with the person. The GDG was aware that not all medicines may have remote

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								monitoring technologies in place.
492	SH	Association of the British Pharmaceutical Industry	16	Full	4.2	35	ABPI would like to suggest strengthening the recommendation for the use of patient decision aids as part of the consultation. Shared decisions relating to medicines will influence whether a patient is more likely to adhere to their chosen care plan [REF: http://www.kingsfund.org.uk/publications/supporting-people-manage-their-health]. The extensive published work of Professor Richard Thomson can provide the evidence for the impact of shared decision making on patient motivation.	Thank you for your comment. The recommendation to 'offer' patients the opportunity to use a patient decision aid is a 'strong' recommendation to reflect the evidence and cannot be strengthened further.
493	SH	Association of the British Pharmaceutical Industry	17	Full	4.2	36	4.2 (41) ABPI would like to suggest the following rewording for this recommendation "*Consider training and education needs, **particularly on innovative technologies**, to support health professionals and patients in developing the appropriate skills and expertise to use patient decision aids effectively in consultations about medicines"*	Thank you for your comment. The purpose of this review question was to look at the clinical and economic evidence for patient decision aids. The GDG developed high level recommendations based on key principles of the intervention found from evidence, rather than looking at particulars of the intervention being reviewed. Training and education to support use of patient decision aids was discussed by the GDG, however the details of what this would involve was not discussed as it is out of scope.
494	SH	Association of the British Pharmaceutical Industry	18	Full	4.2	36	4.2 (44-47) ABPI would like to suggest including an additional point that would align to antimicrobial stewardship practice: • Consider technology that connects existing Systems, Electronic Medical	Thank you for your comment. For the purpose of this review question clinical decision support was defined as 'an active, computerised intervention that occurs at the time and location of prescribing, to support prescribers

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							Records, Radiology and laboratory results such as Infection Surveillance Software to enable prompt interventions in infection episodes. To further enhance and monitor appropriate drug selection and administration at point of care, surveillance software should be taken into account as a method of ensuring appropriate antimicrobial stewardship and broader surveillance of medication; which will also help manage adverse drug events.	with decision-making'. This would exclude technologies that connect systems or those used for surveillance purposes.
495	SH	Association of the British Pharmaceutical Industry	19	Full	5.7	60	(Rec 3) ABPI very much supports this recommendation. Reporting medicines-related patient safety incidents is critically important and something that the pharmaceutical industry as a whole takes very seriously.	Thank you for your comment.
496	SH	Association of the British Pharmaceutical Industry	20	Full	5.7	60	(Rec 8) ABPI believe it would be helpful to capture family members and carers in this recommendation. Older people and vulnerable patients are often cared for by family members or carers who are well positioned to observe and identify medicines-related patient safety incidents.	Thank you for your comment. This is captured in another recommendation in the section. No evidence was identified that surveyed family members or carers.
497	SH	Association of the British Pharmaceutical Industry	21	Full	5.7	60	ABPI would like to suggest that the document references those medicines which are responsible for a majority of safety incidents as an additional bullet. There are some medicines that are known to be associated with preventable adverse events more than others. The PINCER study was based on known high risk medicines/combinations and	Thank you for your comment. The purpose of this review question was to look at the clinical and economic evidence for systems for identifying, reporting and learning from medicines-related patient safety incidents. Specific medicines which may increase the risk of harm did not form part of the

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							National Prescribing Centre published a document entitled Ten Top Tips for GPs, Strategies for Safer Prescribing, in which it listed medicines commonly associated with harm in general practice. http://www.npc.nhs.uk/evidence/resources/10_top_tips_for_gps.pdf	evidence review and was outside the scope of this guideline. The GDG did acknowledge that some 'high risk' medicines have a greater propensity to cause patient harm than others, including hospital admission (see section 5.6) However, this has now also been included in the introduction of this evidence review (see section 5.1).
498	SH	Association of the British Pharmaceutical Industry	22	Full	7.7	98	(Rec 21) ABPI believes it is sensible to recognise that medicines might need to be reconciled at different stages of a hospital stay. Where the stay is long and involves several moves this is even more important. However, probably the most important time is upon discharge to ensure the best possible handover to the GP. This adds further support to recommendation 22 that medicines are reconciled as soon as possible in primary care after discharge.	Thank you for your comment.
499	SH	Association of the British Pharmaceutical Industry	23	Full	7.7	99	(Rec 25) A key principle of medicines reconciliation is that it should be patient focussed. We believe that the government's position that there should be "no decision about me without me" is fundamentally right and as such we would strongly support this recommendation.	Thank you for your comment.
500	SH	Association of the British Pharmaceutical Industry	24	Full	10.7	163	(Rec 32) ABPI fully supports the patients' involvement in decision making about their medicines and it is important they are encouraged to take an active	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.

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							role in these decisions. However, it should be recognised that some patients are unable, or initially unwilling, to make such decisions for a variety of reasons such as a lack of confidence or belief systems. This should be recognised at the outset and we would like to see this recommendation amended to read; *"Offer the opportunity and encourage all people to be involved in making decisions about their medicine. Find out what level of involvement in decision-making the person would like and avoid making assumptions about this"*	
501	SH	Association of the British Pharmaceutical Industry	25	Full	10.7	163	(Rec 34) ABPI strongly supports an evidence based approach to medication choice. We also recognise that the decision needs to also take into account clinical expertise and the patients' values and preferences. This recommendation should also be included within the medicines reviews section, or at least be made more explicit as a major point throughout the MO guidance.	Thank you for your comment. We have cross-referenced the medication review section with the recommendations in section 10.
502	SH	Association of the British Pharmaceutical Industry	26	Full	10.7	163	(Rec 35) ABPI supports this recommendation. Additionally cultural and language barriers should be accommodated and patient decision aids should be written in 'plain English' style and translated versions available.	Thank you for your comment. This detail is covered by the IPDAS criteria.
503	SH	Association of the British Pharmaceutical Industry	27	Full	11.7	178	(Rec 44) One of the central tenants of medicines optimisation is that the patient is central to the decision making process. Through an open dialogue between the HCP and patient, the	Thank you for your comment. Clinical decision support as a barrier to the uptake of technologies did not form part of the evidence review and so cannot be included within the

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							appropriate treatment for them will be prescribed and administered. Whilst this recommendation acknowledges that decision support should never replace clinical judgement, we are concerned that this will begin to erode clinical freedom. It may lead to circumstances where certain treatments are recommended based on criteria which are not aligned to broader NHS principles & policies such as those described within the Innovation, Health and Wealth report [1] & the PPRS agreement [2], which support the uptake of new innovative technologies. We suggest that this point has an additional sentence which reads "***They should also not act as a barrier to the uptake and access of new technologies***." [1] Innovation Health and Wealth, accelerating adoption and diffusion in the NHS. [2] The Pharmaceutical Price Regulation Scheme 2014	recommendation.
504	SH	Association of the British Pharmaceutical Industry	28	Full	11.7	178	(Rec 47) The training described within this recommendation appears to cover technical ability in the main, but only a single comment on 'understanding its limitations.' In line with our comment above, we believe this should have additional wording along the lines of '….to ensure that the patient's preferences and circumstances are taken into account and the appropriate medicines offered.'	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.
505	SH	Association of the British Pharmaceutical Industry	29	Full	12.7	195	(Rec 49) ABPI supports the recommendation that a pharmacist be involved in medicines discussions during the care pathway. It is, perhaps, more important though to describe the nature of that	Thank you for your comment. Wording and formatting was considered by the NICE publishing team.

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							involvement. It is not just that they bring their clinical knowledge to the discussion, but that they are also able to bring a patient focus and understanding. These skills and attitudes should be emphasised if an effective Medicines Optimisation approach is to be implemented. This should be recognised in the statement such that it reads: *"When medicines are being discussed at any point in the care pathway, involve a pharmacist with relevant clinical knowledge and skills. The skills level should be such that a truly patient focussed and shared decision can be made allied to the evidence base."*	
506	SH	Royal National Institute of Blind People	1	Full	General	General	**About the RNIB:** Royal National Institute of Blind People (RNIB) is the UK's leading charity providing information, advice and support to almost two million people with sight loss. We are a membership organization with over 12,000 members throughout the UK and 80 percent of our Trustees and Assembly members are blind or partially sighted. We encourage members to get involved in our work and regularly consult them on matters relating to Government policy and ideas for change. As a campaigning organization we act or speak for the rights of people with sight loss in each of the four nations of the UK. We also disseminate expertise to the public sector and business through consultancy on products, technology, services and improving the accessibility of the built environment.	Thank you for your comment.

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							RNIB is pleased to have the opportunity to respond to this consultation	
507	SH	Royal National Institute of Blind People	2	Full	General	General	**Equalities Act 2010:** We believe that all NICE work should reflect the duties of public bodies under the Equalities Act 2010, not just in relation to communication and accessible information, but in relation to non-discriminatory treatment. We would expect NICE to take steps to meet their legal obligations. This not only requires public bodies to have due regard for the need to promote disability equality in everything they do - including the provision of information to the public - but also requires such bodies to make reasonable adjustments for individual disabled people where existing arrangements place them at a substantial disadvantage.	Thank you for your comment. As outlined in Developing NICE guidelines: the manual, NICE has a duty to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. During the scoping phase, an equality impact assessment form was completed. The purpose of this form is to document the consideration of equality issues at the scoping stage of the guidance development process. An equality impact assessment will be carried out for the recommendations. The equality impact assessment is designed to support compliance with NICE's obligations under the Equality Act 2010 and Human Rights Act 1998 and will be published on the NICE website when the guideline is published.
508	SH	Royal National Institute of Blind People	3	Full	General	General	**Accessible information:** We believe this guideline should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English." The Equality Act expressly includes a duty to	Thank you for your comment. The format is considered by the NICE editorial team and follows NICE style. A NICE guideline, full guideline, information for the public and pathway versions will be published. Furthermore this information has been captured in the 'person-centred' care section

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							provide accessible information as part of the reasonable adjustment duty. Online information on websites should conform to the W3C's Web Accessibility Initiative Web Content Accessibility Guidelines (WCAG) 1.0, level AA, as required by the NHS Brand Guidelines and the Central Office of Information. With regard to the accessibility of print materials, including downloadable content such as PDF files, we would request that wherever possible they comply with our "See it Right" guidelines: http://www.rnib.org.uk/professionals/accessibleinformation/Pages/see_it_right.aspx	of the guideline as this states that 'treatment and care should take into account individual needs and preferences'. This has also been captured in the equality and impact assessment form.
509	SH	Royal National Institute of Blind People	4	Full	General	General	**Capacity:** In 2014, the RNIB launched a research report 'saving money, losing sight' demonstrating that delays in diagnosis and treatment resulted in individuals unnecessarily losing their sight. These problems are frequently caused by lack of capacity in eye clinics. Capacity problems result in patients not receiving optimal treatment as follow up appointments are cancelled and delayed, which in turn can lead to further NHS and social care costs. Therefore the issue of capacity should be highlighted in these guidelines.	Thank you for your comment. Staffing for services and managing capacity of services is outside the scope of this guideline.
510	SH	Royal National Institute of Blind People	5	Full	General	General	**Safety and Compliance:** The RNIB are trying to ensure every eye clinic has access to an Eye Clinic Liaison Officer and we are calling for this because they can speak with patients about their treatment and refer them to the appropriate person if there are problems with safety or compliance.	Thank you for your comment. Staffing for services and managing capacity of services is outside the scope of this guideline.
511a	SH	Royal National Institute of Blind	6	Full	4.2	30	**Patient feedback.** We would like this guideline to call for a formal mechanism, which allows patients	Thank you for your comment. The GDG concluded that the purpose

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		People					to feedback their 'medicines-related safety incidents' to clinicians. This in turn can be shared with other health care professionals as part of their training and development.	of the guideline was to set out key principles. Details of the process are for local consideration and determination.
511b	SH	Royal National Institute of Blind People	6	Full	4.2	30	We welcome the following statement in the NICE guideline entitled 'Identifying, reporting and learning from medicines-related incidents'. We would like the following points to be included in the guideline: • Avastin is being used as an unlicensed medicine to treat eye disorders and is not formulated for intravitreal use. Adverse reactions in the eye (which include permanent blindness, retinal detachment, infectious endophthalmitis, intraocular inflammation and uveitis) have been reported following intravitreal use of Avastin formed from vials approved for intravenous administration in patients with cancer. The RNIB are deeply concerned about the unapproved intravitreal use of Avastin and call for formal procedures to be implemented to ensure adverse reactions are recorded, which is the case for licensed medicines.	Thank you for your comment. Specific named medicines did not form part of the evidence review and is outside of scope. The recommendation developed in the guideline applies to all medicines.
512a	SH	Royal National Institute of Blind People	7	Full	4.2	31	We welcome a recommendation for 'Medicines-related communication systems when patients move from one care setting to another'. In addition to the guidelines recommended in this section, it would have been more helpful to include information on: • Accessibility. In that patient's information preferences should be recorded and the list made available to them in their preferred format (which	Thank you for your comment. This wording has been amended to reflect your comment following further discussion by the GDG.

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							maybe Braille, larger fonts, audio, electronic or verbal communication and adjustments made for those who do not speak/read English).	
512b	SH	Royal National Institute of Blind People	7	Full	4.2	31	We welcome a recommendation for 'Medicines-related communication systems when patients move from one care setting to another'. In addition to the guidelines recommended in this section, it would have been more helpful to include information on: A call for a formal mechanism which links high street and secondary care optometrists to the N3 network. This would enable optometrists to share patient records and manage medicine accordingly.	Thank you for your comment. The recommendation does not specify certain health or social care practitioners as this may vary depending on the care settings of transfer.
512c	SH	Royal National Institute of Blind People	7	Full	4.2	31	We welcome a recommendation for 'Medicines-related communication systems when patients move from one care setting to another'. In addition to the guidelines recommended in this section, it would have been more helpful to include information on: . • Discharge information. (1) Details of the person should include whether they have sensory impairments and/or learning difficulties. (2) Medication review to include next prescription appointment and timely follow-ups. (3) Additional support for patients, inclusion of relevant patient support group lists. (4) A list of medications the patient is currently taking should also include a treatment log to ensure ongoing medication has been administered during their stay. (5) A patient contact list if the patient has a problem when they are discharged.	Thank you for your comment. The list in this recommendation is not intended to be exhaustive but includes the minimum dataset as agreed by the GDG. Additional information may be needed depending on the person's needs, but this would be for the health or social care practitioner to determine.
513	SH	Royal National	8	Full	4.2	32	We welcome the inclusion of a recommendation	Thank you for your comment.

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		Institute of Blind People					on 'Medicines Reconciliation'. We would also like to have seen more narrative around appointment letters being sent in a timely manner and in a patient's preferred format (which maybe Braille, larger fonts, audio, electronic or verbal communication and adjustments made for those who do not speak/read English).	Method of communication used for booked appointments is out of scope for this guideline.
514	SH	Royal National Institute of Blind People	9	Full	4.2	33	We welcome the inclusion of a recommendation on 'Medication Review'. In addition, we want to ensure these guidelines include an opportunity for the patient to review how well they are complying with their medication and how to rectify any issues, through the potential use of compliance aids and district nurses.	Thank you for your comment. The list in this recommendation is not limited but includes the minimum information to consider as agreed by the GDG. Additional information may be discussed depending on the person's needs, but this would be for the health professional and the person to discuss.
515	SH	Royal National Institute of Blind People	10	Full	4.2	34	We welcome the inclusion of a recommendation on 'Self-management plans'.	Thank you for your comment.
516	SH	Royal National Institute of Blind People	11	Full	4.2	35	We welcome the inclusion of a recommendation on 'Patient decision aids used in consultations involving medicines '. We want to ensure that clinicians have discussed treatment options with their patients. Immediately after their appointment the patient can be asked if they discussed treatment options with their clinician, and this could be conducted by the reception desk.	Thank you for your comment. Details of the process are for local consideration and determination.
517	SH	AntiCoagulation Europe	1	Full	9.6	131	Section 9.6 Consideration of both benefit and resource issue. Reference made to self management for anticoagulation not being cost effective due to 'over testing' by patients	Thank you for your comment. The GDG was aware of atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor

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							We draw attention to the recent NICE Guidelines on Coagulometers for self monitoring (Sept 2014) para 6.9 *The Committee considered the cost effectiveness of self-testing and self-managing individually. The findings showed that self-management alone is highly cost effective (dominant) but that self-testing alone is not cost effective, compared with standard monitoring. The Committee noted that these findings were based on the contrasting pooled-effect estimates obtained from the meta-analysis of randomised controlled trials, based on thromboembolic events while self-testing and self-managing. The Committee discussed the impact of 1 large trial by Matchar et al. (2010) (see section 6.6) on the cost effectiveness of self-testing and noted that although this trial did not show a reduction in clinical adverse events, it did show an increase in the time in therapeutic range. The Committee discussed the impact on the ICERs for self-testing if the economic model was driven by time in therapeutic range rather than adverse events. The Committee concluded that self-testing may be more cost effective if the model had been based on time in therapeutic range. The Committee also considered the costs of self-managing and self-testing and noted that self-testing was more expensive because of higher administration costs. The Committee heard from the External Assessment Group that if the pooled-effect estimates from self-monitoring were applied to self-testing, self-testing would become cost effective even with the higher administration costs this incurred. The Committee concluded that it was likely that the increase in time in therapeutic*	(NICE guidance DG14). In the linking recommendations to evidence table section 9.6 of the medicines optimisation guideline, there is detailed discussion included in that the GDG were concerned that self-managing would not be a cost-effective use of NHS resources. The section on self-management plans includes self-testing where relevant and does not just focus on anticoagulation but on other disease areas such as asthma, diabetes, hypertension and chronic obstructive pulmonary disease. Therefore this section takes into account evidence for managing long-term conditions in general and not just specifically to anticoagulation as in the NICE guideline you have mentioned in your comment.

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							range shown for self-testing in the trial would lead to a reduction in adverse events compared with standard clinical practice in the UK. ***The Committee therefore concluded that it was likely that the clinical benefits of self-testing had been underestimated in the economic analyses and that both self-testing and self-managing were cost effective.*** **ACE comment** Has this been taken into consideration by the GDP as it may impact the interpretation by healthcare professionals who will be responsible for managing patients who want to take responsibility to self manage their anticoagulation treatment and will require the support and access to strips and devices.	

These organisations were approached but did not respond:

5 Borough Partnership NHS Foundation Trust
5 boroughs NHS Foundation Trust Partnership
Abbott Diabetes Care
Abbott Healthcare Products Ltd
Abbott Laboratories
Abbott Molecular
AbbVie
ABPI Pharmaceutical Stroke Prevention of AF Initiative
Addenbrookes Hospital
Aintree University Hospital NHS Foundation Trust
Alliance Boots plc
Alzheimer's Society

Amgen UK
AMORE health Ltd
Aneurin Bevan Health Board
Anglian Community Enterprise
Arden Commissioning Support
Association for Improvements in the Maternity Services
Association for Palliative Medicine of Great Britain
Association of Anaesthetists of Great Britain and Ireland
Astellas Pharma Ltd
Barnsley Hospital NHS Foundation Trust
Barts Health NHS Trust
Bayer plc
Belfast Health and Social Care Trust
Berkshire Local Pharmaceutical Committees
Birmingham Children's Hospital NHS Foundation Trust
Boots
Bristol Myers Squibb Pharmaceuticals Ltd
British Association of Critical Care Nurses
British Association of Dermatologists
British Dietetic Association
British Geriatrics Society
British Medical Journal
British National Formulary
British Nuclear Cardiology Society
British Pharmacological Society
British Psychological Society
British Red Cross
British Society for Rheumatology
British Society of Paediatric Gastroenterology Hepatology and Nutrition
British Specialist Nutrition Association
British Thoracic Society
British Transplantation Society
Bupa Care Services
Cannock Chase Clinical Commissioning Group
Care Quality Commission
Cegedimrx
Central & North West London NHS Foundation Trust
Central Eastern Commissioning Support Unit

Central London Community Health Care NHS Trust
Central Manchester University Hospitals NHS Foundation Trust
Children's HIV Association
Chronic Myeloid Leukaemia Support Group
City Healthcare partnership
City Healthcare Partnership Hull
College of Mental Health Pharmacy
Croydon University Hospital
Cumbria Partnership NHS Foundation Trust
Cumbria Partnership NHS Trust
CWHHE Collaborative CCGs
Cystic Fibrosis Trust
Daiichi Sankyo UK
Dermal Laboratories
Dudley and Walsall Mental Health Trust
East and North Hertfordshire NHS Trust
East Kent Hospitals University NHS Foundation Trust
Faculty of Pain Medicine of the Royal College of Anaesthetists
False Allegations Support Organisation
Ferring Pharmaceuticals
Four Seasons Health Care
Gateshead Health NHS Foundation Trust
Geneix
Gilead Sciences Ltd
GlaxoSmithKline
Gloucestershire Care Services NHS Trust
GP update / Red Whale
Greater Manchester West Mental Health NHS Foundation Trust
Group B Strep Support
Grunenthal Ltd
Guy's and St Thomas' NHS Foundation Trust
Hayward Medical Communications
Health and Care Professions Council
Health and Social Care Board NI
Health and Social Care Information Centre
Health Education Yorkshire and the Humber
Healthcare Improvement Scotland
Healthcare Quality Improvement Partnership

Healthwatch East Sussex
Hermal
Hertfordshire Partnership University NHS Foundation Trust
Herts Valleys Clinical Commissioning Group
HIV Pharmacy Association
Hollister Ltd
iCareHealth
Integrated Care 24 Ltd
Ipsen Ltd
Joint Royal Colleges Ambulance Liaison Committee
Kent and Medway Commissioning Support
Kent and Medway NHS and Social Care Partnership Trust
Kidney Research UK
King's College Hospital NHS Foundation Trust
Lancashire Care NHS Foundation Trust
Lanes Health
Leeds North Clinical Commisioning Group
Leeds Teaching Hospitals NHS Trust
Leonard Cheshire Disability
Lilly UK
Liverpool Community Health
Local Government Association
London Respiratory Team
Lundbeck UK
MAP BioPharma Limited
medical directorate DMS
Medicines and Healthcare products Regulatory Agency
Midnight Pharmacy
Ministry of Defence (MOD)
Napp Pharmaceuticals Ltd
National Association of Primary Care
National Care Forum
National Clinical Guideline Centre
National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Deaf Children's Society
National Institute for Health Research Health Technology Assessment Programme

National Institute for Health Research
National Institute for Health Research Horizon Scanning Centre
National Osteoporosis Society
National Patient Safety Agency
National Pharmacy Association
National Rheumatoid Arthritis Society
NCRI Breast CSG Working Group on Symptom Management
NHS Alliance
NHS Anglia Commissioning Support Unit
NHS Barnsley Clinical Commissioning Group
NHS Bath and North East Somerset CCG
NHS Birmingham South and Central CCG
NHS Bromley CCG
NHS Coastal West Sussex CCG
NHS Connecting for Health
NHS Coventry and Rugby CCG
NHS Cumbria Clinical Commissioning Group
NHS Durham Dales,Easington and Sedgefield CCG
NHS Fylde & Wyre CCG
NHS Great Yarmouth and Waveney CCG
NHS Hardwick CCG
NHS Health at Work
NHS Heywood, Middleton & Rochdale CCG
NHS Improvement
NHS Kernow CCG
NHS Leeds West CCG
NHS Luton CCG
NHS Medway Clinical Commissioning Group
NHS Mid Essex CCG
NHS Newham CCG
NHS North Somerset CCG
NHS Plus
NHS Portsmouth Clinical Commissioning Group
NHS Protect
NHS Sheffield CCG
NHS South Cheshire CCG
NHS South Worcestershire CCG
NHS Trust Development Authority

NHS Wakefield CCG
NHS Warwickshire North CCG
NHS West Cheshire CCG
NHS West Lancashire CCG
NHS West Suffolk CCG
NHS Wigan Borough CCG
NHSBSA Prescription Services
Nordic Pharma
Norfolk Community Health and Care NHS Trust
Norfolk Medicines Support Service
Norgine Limited
North Bristol NHS Trust
North of England Commissioning Support
North West London Commissioning Support Centre
North West London Hospitals NHS Trust
Northern Health and Social Care Trust
Northern, Eastern, Western Devon CCG
Nottinghamshire Healthcare NHS Trust
Novo Nordisk Ltd
Nursing and Midwifery Council
Nutricia Advanced Medical Nutrition
Otsuka Pharmaceuticals
Pan London Acute Medicine Network
Patients & Relatives Committee of the Intensive Care Society
Pharmaceutical Advisers Group
Pharmaceutical Mental Health Initiative
Pharmaceutical Services Negotiating Committee
PharmaPlus Ltd
Physiotherapy Pain Association
Plymouth Hospitals NHS Trust
PrescQIPP NHS Programme
Prescription Charges Coalition
Primary & Community Care Pharmacy Network
Primary Care Dermatology Society
Primary Care Partnerships
Primary Care Pharmacists Association
Public Health England
Queen Elizabeth Hospital King's Lynn NHS Trust

Queen's University Belfast
Rainbows Children's Hospice
RDaSH NHS Foundation Trust
Regional Drug and Therapeutics Centre
Rethink Mental Illness
Robert Jones & Agnes Hunt Orthopaedic & District Hospital NHS Trust
Roche Diagnostics
Royal College of Anaesthetists
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Ophthalmologists
Royal College of Pathologists
Royal College of Pathologists Lay Advisory committee
Royal College of Physicians
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Speech and Language Therapists
Royal College of Surgeons of England
Royal Cornwall Hospitals NHS Trust
Rycroft Partnership LLP
Salisbury NHS Foundation Trust
Sanctuary Care
Sanofi
Scottish Intercollegiate Guidelines Network
Sheffield Health and Social Care NHS Foundation Trust
Sheffield Teaching Hospitals NHS Foundation Trust
Sherwood Forest Hospitals NHS Foundation Trust
Shire Pharmaceuticals Ltd
Soar Beyond Ltd
Social Care Institute for Excellence
Society and College of Radiographers
South Chadderton Health Centre
South East Staffordshire and Seisdon Pennisula CCG
South Eastern Health and Social Care Trust
South Essex Partnership NHS Foundation Trust
South Essex Partnership University Foundation Trust
South Stadffordshire & shropshire Healthcare NHS Foundation Trust

South Tyneside NHS Foundation Trust
South West Essex Community Services
South West Yorkshire Partnership NHS Foundation Trust
Southern Health & Social Care Trust
Spirit Healthcare
St Andrew's Hospital
Staffordshire and Stoke on Trent Partnership NHS Trust
Steve Turner Innovations
Stockport Clinical Commissioning Group
Surrey and Borders Partnership NHS Foundation Trust
Takeda UK Ltd
Teva UK
The Christie NHS Foundation Trust
The College & Fellowship of Podiatric Medicine
The Practice Lincoln Green Medical Centre
The University of Birmingham
UCB Pharma Ltd
UK Clinical Pharmacy Association
UK Renal Pharmacy Group
University Hospital Birmingham NHS Foundation Trust
University of Bolton
University of Dundee
University of Nottingham
University of Southampton
Virgin Care
Welsh Government
Welsh Scientific Advisory Committee
West London Mental Health NHS Trust
Western Health and Social Care Trust
Wicked Minds
Wigan Borough Clinical Commissioning Group
Wirral GP Commissioning Consortium
York Hospitals NHS Foundation Trust