Shared decision making

Consultation on draft guideline - Stakeholder comments table

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Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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AbbVie UK	Draft Guideline	004	001	We suggest that the wording on why shared decision making is important could be strengthened by referencing the NHS Constitution, the legal basis for patient choice, as well as the commitments to shared decision making set out by NHS England in both their model of Personalised Care as well as the Long Term Plan.	Thank you. This is standard text and is in all NICE guidelines. The committee added a reference to the NHS constitution to the rationale and impact section.
AbbVie UK	Draft Guideline	004	004	To support embedding shared decision making at organisational level via high level leadership, an additional recommendation should be added to require senior leadership to explore the metrics and measurements that can be developed across their organisation to establish a process of regular review and monitoring. The NHS SDM Implementation Checklist calls out examples of developed and validated metrics and measurement tools including SDM-Q9, SDM – Q9 DOC and CollaboRATE.	Thank you. Recommendation 1.1.9 sets out to: "Plan internal or external monitoring and evaluation (including service user and staff feedback activities) and how to feed back the results to staff at individual, team and management level." Exploring which metrics and measurements to monitor would be part of this process. The committee also produced a research recommendation regarding "What are the best ways to measure the effectiveness of shared decision making in different contexts (in different settings and involving different people)?" which would help people implementing SDM in deciding which measures to use in the future.
AbbVie UK	Draft Guideline	004	004	Any patient director should be encouraged to act as a conduit for senior leadership to hear directly from a wider number of service users, rather than as a proxy for patient engagement. We also suggest that as shared decision making requires changes to clinical practice on the ground across specialities that this role should be required to engage with clinical and service leads within an organisation.	Thank you for your comment. As rec 1.1.4 states: "Identify one or more organisation-wide 'service user champions' to work with the senior leader, patient director and professional champions for shared decision making" they will be working directly with service user representatives if guidelines are followed, rather than as a proxy. 1.1.3 also states "Appoint one or more senior healthcare professionals to work with the senior leader and patient director as organisation-wide 'champions' responsible for shared decision making". NICE agrees patient

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					director role will be more than a proxy for service user engagement, and this recommendation is about making sure the service user voice is heard at the very top level of organisations, as well as throughout the rest of the organisation.
AbbVie UK	Draft Guideline	004	008	Recommendation 1.1.2 should be amended to 'raising the profile of the service user and their carer in shared decision making and supporting patient involvement and consultation in pathway and service design across the organisation'.	Thank you. The recommendation covers involving service users in "planning, implementing and monitoring shared decision making" which covers patient involvement in the SDM planning (and thus design) process.
AbbVie UK	Draft Guideline	004	017	In addition to involving service users at an organisation-wide level to support the implementation of shared decision making, most shared decision making will occur within specific health services and specialities and be shaped by the nuances of conditions and decision points. As such, organisations should be encouraged to support specific services to appoint and embed service user champions and mechanisms for feedback. This should explicitly include consulting service users on how to embed and conduct shared decision making within routine clinical practice as generic service user involvement in service design and delivery, while very important, does not address the specific need to improve shared decision-making on an individual basis.	Thank youfor your comment. As this was a general guideline for embedding SDM, the committee decided not to recommend specific services for organisations to appoint and embed champions to, as they thought that this would be overly prescriptive.
AbbVie UK	Draft Guideline	004	Gene ral	The rationale section of the guideline explains that recommendation of establishing a patient director is only worded as "consider" due to the	Thank you for your comment. The involvement of these organisations through the roles outlined in recommendations 1.1.1 to 1.1.4 is not ruled out, but

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				potentially prohibitive cost. Throughout the guideline, there is scope for stronger recommendations on greater engagement with, and involvement of, service users and consultation/liaison with local and relevant voluntary patient groups. Numerous expert patient groups across therapy areas and umbrella organisations, such as Healthwatch – who represent local patient populations across England through their network – can provide valuable insights and their routine involvement by health organisations should be encouraged both at the organisational level and within specific care pathways and disease areas.	due to the range and variation in health organisations and the general nature of the SDM recommendations recommending specific health organisations was not the aim of the guideline. The committee acknowledged that information from patient organisations can be useful, and added to the rationale that "Providing information is important, but the committee wanted to emphasise that it needs to be of good quality, for example NICE-accredited. The committee was aware that other quality standards exist, like the PIF TICK quality mark for patient organisations."
AbbVie UK	Draft Guideline	005	006	Amend recommendation to 'Identify existing practice in departments or teams as well as other organisations…'	Thank you. This recommendation was based on testimony that only focused on SDM in single institutions. There will be an opportunity to communicate with support networks in different organisations as part of recommendation 1.1.10: "Consider joining up the support network with others in the wider system and across the region."
AbbVie UK	Draft Guideline	005	015	Adequate information provision for patients is essential to support shared decision making – to achieve this health organisations should be encouraged to assess and meet the health literacy and information needs across their patient populations. There is evidence that improved health literacy can support improved patient outcomes: cancer patients with improved health literacy have been found to spend less time in hospital, finding it easier to navigate the	Thank you. We have added references to health literacy in the rationale and section 1.2 of the guideline.

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				health system and manage their treatment options *(Cartwright L, et al. Health Literacy Is an Independent Predictor of Cancer Patients' Hospitalizations, Health Literacy Research & Practice (2017); Fernández-González L and Bravo-Valenzuela P. Effective interventions to improve the health literacy of cancer patients (2019))*	
AbbVie UK	Draft Guideline	005	015	Adequate and appropriate information provision should be available throughout the relevant patient journey as shared decision making should ideally be an on-going and continual process. This would be supported by organisations working to plot patient journeys through specific pathways and services to understand key decision points and information needs, considering all stages and milestones of a person's life (e.g., transition from paediatric to adult care). AbbVie has supported the work of the Patient Information Forum to develop and pilot the Perfect Patient Information Journey which has demonstrated the benefits of this approach – see https://pifonline.org.uk/projects/project-ppij/ . A recommendation for services to plot and understand information needs throughout the patient pathway would reinforce shared decision making being routinely embedded into patient care and align with NICE's plan to call out	Thank you. The committee did not see any evidence to support this approach, however it did recommend sharing of information, including about patients' values and beliefs.

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				shared decision making in condition specific guidelines as they are reviewed.	
AbbVie UK	Draft Guideline	005	General	The recommended actions that sit beneath 'planning and implementing shared decision making' are quite complicated and contain limited detail on how service users should be involved at every level and within specific services – a recommendation that sets out a requirement that health organisations conduct robust patient consultations during any service or pathway changes would be a welcome addition.	Thank you. This guideline is about shared decision making, not about service user involvement in services as a whole.
AbbVie UK	Draft Guideline	005	General	An additional recommendation should be added for organisations to develop sets of metrics and measurements to monitor progress to embed shared decision making – this could include clinical measures, records of consent to decisions and Patient Recorded Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs) as well as validated and repeatable patient surveys such as the Cancer Patient Experience Survey used in oncology.	Thank you for your comment. Recommendation 1.1.9 covers feedback and monitoring SDM embedding progesss: "Plan internal or external monitoring and evaluation (including service user and staff feedback activities) and how to feed back the results to staff at individual, team and management level."
AbbVie UK	Draft Guideline	006	018	Strengthen wording of this recommendation to be explicit that service-users should "almost always be included" rather than "potentially" included to ensure patients are supported to understand and practice shared decision making. Engagement and consultation work AbbVie has conducted has suggested that	Thank you. The committee discussed this and were content with the wording of the current recommendation. The committee were aware of successful train the trainer programmes, and while some of these included service users as trainers, not all of them did, therefore they did not agree that service users should 'almost always' be included.

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				embedding the principle of 'patients know their bodies' at the heart of decision making can support greater involvement and improve patient experience, so their direct involvement is important.	
AbbVie UK	Draft Guideline	006	026	Actively promoting shared decision making to people who use services requires adequate information provision to be available as a priority to ensure they are supported and shared decision making can be meaningful. Organisations should be encouraged to work with clinicians to ensure time is allowed to provide information in a format appropriate to the individual's needs prior to consultations or decision points.	Thank you for your comment. Thank you for your comment. Time as a resource is mentioned in the qualitative review in evidence review A, and potential effects on consultation length are also discussed in the guideline. In evidence review A, the committee discussed at some length whether SDM required more time and that allowing a larger amount of time for SDM may increase consultation length and cost. Although it did not see any quantitative evidence to reflect this, it did note that the qualitative evidence highlighted 'lack of time' as a barrier to using SDM. Overall, it agreed that any additional time needed could potentially be offset by fostering a better patient-practitioner relationship in early sessions, leading to shorter ones in the future, although they also acknowledged that many healthcare professionals only see people short term. They highlighted issues around practitioners questioning what the evidence is for more time being needed, and that more research is needed into what interventions reduce time commitment.
AbbVie UK	Draft Guideline	007	010	Participation of caregivers/family can be incredibly important for shared decision making. Our engagement on shared decision making highlighted that this has been disproportionately impacted by COVID-19 necessitated service	Thank you. Please see recommendation 1.2.2 which states methods should be tailored to support shared decision making depending on setting. If this is read alongside 1.2.3 it shows caregivers/family members should be included taking into

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				changes. This recommendation should be strengthened to call on organisations to ensure family members/caregivers can access both physical or virtual consultations (where appropriate and permitted by the patient) and that this is communicated proactively to patients ahead of consultations.	account of setting, whether the discussion is happening in person or remotely by video or phone.
AbbVie UK	Draft Guideline	007	018	AbbVie welcomes and supports recommendation 1.2.4. Touchpoints between appointments should be used to encourage and reiterate a patient's right to be involved in decisions. NHS England's recent guidance on good communication with patients sets out relevant principles that could be referenced here.	Thank you for your support.
AbbVie UK	Draft Guideline	008	003	Organisations should also be encouraged to point to resources produced by relevant patient groups and organisations. As NICE continues work to embed shared decision making across disease specific clinical guidelines, these resources could be identified and ideally, referred on to or signposted to either via the guideline or NICE Evidence.	Thank you for your comment. We have added a reference to patient organisations in the recommendation.
AbbVie UK	Draft Guideline	008	005	To enable recommendation 1.2.5, organisations should also be encouraged to understand the health literacy and communication needs of their patient populations as part of service and delivery planning.	Thank you for your comment. The reasons for support given were examples and this is not an exhaustive list. These have now been removed to make it clearer it is at the professional and service user's discretion regarding need for additional support. More significant health literacy needs would be an example of this.

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AbbVie UK	Draft Guideline	008	023	Recommendation 1.2.8 could be strengthened by referencing some of the key factors clinicians should be aware of that shape an individual's needs and preferences including quality of life, health, social and personal goals and longer-term outcomes – particularly for those with chronic conditions.	Thank you. We believe all of this is covered by SDM training.
AbbVie UK	Draft Guideline	009	020	Our conversations with stakeholders have highlighted the need for consistent measurement and recording both within clinical practice and at the system and organisation level to embed shared decision making. Alongside recording the decision, organisations should explore options to routinely record when shared decision making has occurred.	Thank you. Please see recommendation 1.2.17: "When making a record of the discussion (for example, in a person's clinical notes or care plan), record any decisions made along with details of what the person said was important to them in making those decisions. Offer to share this with the person, for example in a post-clinic letter."
AbbVie UK	Draft Guideline	010	015	It is welcome that the guideline explicitly recommends the use of patient decision aids. AbbVie is aware that a number of tools have been produced by patient groups to support complex treatment decision points including MS Decisions by MS Trust and a booklet on active monitoring developed by Lymphoma Action which NICE already hosts as part of NICE Evidence. Patient decision aids can help to communicate risks and benefits of different options in a way that is accessible to relevant patient populations. To support NICE's recommendations on the use of these aids, AbbVie suggests where these exist for specific conditions they should be signposted to or	Thank you. It would not be possible to signpost to all patient decision aids. Decisions regarding highlighting specific patient decision aids will be made on a guideline by guideline basis.

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				highlighted within specific NICE guidelines as they are reviewed and developed.	
AbbVie UK	Draft Guideline	011	005	We recommend an additional action is added to encourage healthcare professionals to engage patient groups to help identify and/or develop a decision aid if they are not aware of one. Interviews AbbVie has conducted with patients over the last year have demonstrated an appetite for increased collaboration of this kind with health care services and professionals to produce and provide this type of valuable resource.	Thank you. That is outside the remit of this guideline.
AbbVie UK	Draft Guideline	011	007	Recommendation 1.3.4 could be strengthened by a centrally curated and promoted database of decision aids, building on resources available via NICE Evidence and could reduce organisational and system variability.	Thank you for your comment. There is currently no national repository for PDAs.
AbbVie UK	Draft Guideline	011	015	For treatment decisions, it is particularly essential that patients are supported to understand all the options available to them, the benefits and risks, and how these differences may align or interact with their personal preferences and circumstances. Patients with the same condition and available treatment options may have very different priorities, goals and desired health outcomes. In some cases, a particular treatment decision now may impact what options remain available in the future. Supporting meaningful shared treatment decisions therefore involves communicating	Thank you for your comment.

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				complex scientific information to patients as well as how treatment options may shape their future care. It is essential that healthcare professionals are supported and encouraged to consistently do this as well as to understand what outcomes and issues are most important to the individual patient. A recent report by Demos, *Patient Power*, supported by AbbVie UK, found that 30% would like to more involved in decisions about medications and that this rises among younger populations (40% of those under 40) and those on short term medication (58%). In addition, it found most patients (65%) routinely check advice from their doctor which Demos suggests indicates a general desire to be more informed.	
AbbVie UK	Draft Guideline	011	General	Our engagement with stakeholders regarding shared decision making, including patient groups, highlighted that the implementation of shared decision making is sometimes restricted by the fact that not all options are presented to patients or made available to them. Health care professionals need to be encouraged to discuss all available options with a patient. For some chronic condition patients, treatment options that are available in care guidelines may sometimes be additionally sequenced or limited which can mean that more effective treatments are unnecessarily delayed until later in the patient	Thank you for your comment.

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				journey, sometimes meaning patients may have unnecessarily worse outcomes or have been unable to access options that would be more suitable for their broader personal circumstances and priorities. The Demos report, Patient Power, supported by AbbVie UK, highlights examples from focus groups they conducted where individuals had felt they had not been given access to treatments they felt they should have been and where important personal goals and circumstances were not factored into treatment conversations or decisions. AbbVie echoes the recommendations made in that report that health organisations, including NHS England and DHSC should ensure patient rights in the NHS Constitution are enforced and consider the role of pharmacists and that patients are able to access joined up support from their pharmacist and/or clinical nurse specialist as they consider their options throughout their care pathway.	
AbbVie UK	Draft Guideline	014	001	We largely agree with this definition of shared decision making although suggest this could explicitly reference decisions about care *'or treatment'*. In addition, we agree with the committee's recommendation on page 17 of the rationale and impact section that 'shared	Thank you for your comment. The definition of SDM was agreed at scoping stage including consultation.

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				decision making should always be treated as an ongoing process' and suggest this should be incorporated into this definition, making clear that shared decision making should take place throughout care, rather than just at points of diagnosis or treatment initiations. It is welcome that the definition makes clear that shared decision making should encompass both immediate care or treatment decisions and care in the future. However, this is not more widely embedded in the guideline or identified as a priority for shared decision making practice. The guideline should encourage shared decision making to be used to anticipate and discuss upcoming treatment and care needs, particularly for long term chronic and progressive conditions – recognising and informed by what outcome is important to the patient. For example, for patients who may be having their symptoms monitored, pro-active regular touchpoints may be useful to ensure shared decision making happens at the right time and help anticipate changing needs.	
AbbVie UK	Draft Guideline	014	018	There is evidence from various projects and organisations who have undertaken work to embed shared decision making approaches which provide a starting point on how to measure effectiveness of approaches. Some of these were spotlighted at a showcase hosted by AbbVie in March 2020 and detailed in a	Thank you for your comment.

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				summary booklet available here. Examples include the RightStart project by NRAS which examined outcomes via Patient Reported Outcome Measures (PROMs) collected in the National Early Inflammatory Arthritis Audit; and clinical projects where services monitored changes in clinical metrics, such as reductions in surgical interventions, emergency admissions and hip fractures, before and after the implementation of a shared decision making approach. Repeatable, validated patient surveys can also provide insight – such as that undertaken by the MS Trust to measure the impact of their decision aid. In roundtables conducted by AbbVie in 2020, participants highlighted that Patient Reported Experience Measures (PREMs), and PROMs would be a step in the right direction, but the preference would be personal goal setting and measuring progress against this with patients. Before the effectiveness of shared decision making can be measured, our engagement with stakeholders has made clear that organisations need to identify metrics for measuring and monitoring if shared decision making is happening. Currently, this is seen to be more advanced in the surgical field as a result of existing consent measures. Some therapeutic	

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				areas such as oncology – which routinely uses the Cancer Patient Experience Survey and a Quality of Life metric – have shown a way forward in terms of measurement of shared decision making (although further work is still needed on implementation), but more needs to be done in other treatment pathways, particularly for key decision points. AbbVie believes central health bodies, such as NICE and NHS England should consider leading the development of system level metrics and mechanisms to monitor and incentivise shared decision making and patient choice. This could include blended payment tariffs or similar payment models that reward quality outcomes and any frameworks developed to replace the Clinical Commissioning Group Outcomes Indicator Set (CCG OIS) as ICS' are introduced into the NHS system. We would also highlight the upcoming SDM Standard, being developed by Professional Records Standards Body (PRSB) in collaboration with NHS England, Academy of Medical Royal Colleges, Centre for Peri-Operative Care, Patient Information Forum (PIF) and EIDO. It is likely to provide a good starting point to move this work forward and should be considered on publication.	

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AbbVie UK	Draft Guideline	015	005	Experience of healthcare as well as condition and health status are likely to impact the acceptability of shared decision making. A recent report by Demos, supported by AbbVie UK, found that while a large majority (62%) of the population were satisfied with their personal level of involvement in deciding their most recent medication, a significant proportion (30%) of the population wanted to be more involved. In particular, the majority (58%) of those on short-term medication wanted to be more involved in deciding their most recent medicine. The sample for this survey were largely accessing medication in primary care and it may be that those with chronic conditions in on-going secondary or tertiary care have different attitudes still. However, even for populations or groups who may be likely to believe in the authority of the healthcare professional, this should not be assumed. All patients should be offered the ability to be involved in treatment decisions, but this is still not universally happening. The Demos report found that many patients are not fully aware of the level of control they are entitled to when it comes to choosing medication, Likewise, Leukaemia Care's most recent patient survey noted that, on average,	Thank you for this information.

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				only 32% of acute and chronic blood cancer patients were offered a choice of treatment, while 84% said they would like a choice of treatment options. *(Leukaemia Care, Living with Leukaemia report (2018) Available at: https://www.leukaemiacare.org.uk/wp-content/uploads/Living-with-Leukaemia-2018-Full-Report-Web-Version.pdf (Accessed July 2020))*	
AbbVie UK	Draft Guideline	General	General	AbbVie welcomes this draft guideline on shared decision making and its aims to make it part of everyday care in all healthcare settings. The scope of the guideline includes key priorities – communication skills and embedding shared decision making within organisational culture. This is reflected in work and stakeholder engagement on this issue conducted by AbbVie throughout 2019-2020. AbbVie will be continuing to work along with others to support and encourage the implementation of shared decision making and believes this guideline can provide an effective mechanism to make this a reality for many more patients.	Thank you for your support.
AbbVie UK	Draft Guideline	General	General	The guideline is silent about the current coronavirus pandemic and how this has impacted patient involvement in treatment and care decisions. AbbVie understands that the committee’s discussion and development of the guideline may have predated the pandemic as	Thank you for your comment. The skills of SDM in remote settings are the same as in face to face settings, and this has been added to the rationale and to a recommendation. The committee also added a research recommendation for: “How do SDM skills and techniques need to be modified for remote discussions?”

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				well as NICE's desire to develop a guideline that will continue to be relevant in the longer term. However, it is very likely that as the NHS returns to a more 'normal' footing, the means by which care is delivered will be permanently changed and shared decision making will need to be delivered in a way that reflects these new ways of working and care settings. In particular, the use of technology and digital pathways has been significantly accelerated by the pandemic — as acknowledged in the recent NHSE&I January 2021 board papers. AbbVie's work programme on shared decision making found that the expansion of digital channels and virtual consultations posed new and unique challenges for some patients, which will require specific action to be addressed. More generally, barriers to patient involvement have been exacerbated in the past year as the NHS has responded to the pandemic. We found in conversations with stakeholders that communication with patients throughout the pandemic has often been far from perfect– making patient involvement in decision making harder. For example, issues were voiced in regard to initial shielding guidance.	

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				As such, we suggest specific content and guidance should be considered for inclusion on how shared decision making can and should be supported in digital pathways and the need for effective patient communication and support between digital touchpoints. If it is not possible to account for this within the initial iteration of the guideline, we recommend that an update or review be conducted to account for these issues.	
AbbVie UK	Draft Guideline	General	General	Given that patient involvement is a fundamental foundation for meaningful shared decision making, it is welcome that the guideline sets out an expectation that service users are involved and consulted. However patient involvement in service design or improvement is a distinct issue to the implementation of shared decision making across the treatment and care of an individual patient. We suggest the guideline explicitly recommends patient consultation on both these elements of the operation of health organisations. The guideline is also quite vague on how patient involvement should be achieved – limited only to a suggestion of a patient director at board level. To be effective such a role would need to have clear and defined accountability including presiding over established measurements and	Thank you. The guideline recommends both a patient director and service user champions. It further recommends setting out how people who use services will be involved in implementation and collecting service user feedback for monitoring SDM.

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				metrics to monitor implementation. Without this, the role risks being a 'proxy' for genuine patient involvement. There are several examples of trusts and services undertaking active and continuous patient involvement via several methods including patient involvement boards, consultation processes and regular patient feedback and outcome surveys. We suggest the guideline should also spotlight such examples and encourage outreach and direct consultation with patients. Where director roles are established, we suggest that the guideline should recommend a robust and accountable role description is developed.	
AbbVie UK	Draft Guideline	General	General	The guidance should set out recommendations on how shared decision making could be measured and monitored by services and organisations. There are a number of initiatives already in place across the NHS that provide a good starting point to provide guidance to organisations looking to develop and embed shared decision making across services. These include the February 2019, SDM implementation checklist produced by NHS England and recent guidance on shared decision making and consent produced by the General Medical Council . This also includes suggested clinical measures that could be used to support	Thank you. Please see research recommendation 2. "What are the best ways to measure the effectiveness of shared decision making in different contexts (in different settings and involving different people)?"

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				implementation within specific services and consultations. We would also highlight the clinical measure currently being developed by the Professional Records Standards Body (PRSB) that should be explored once it is published. Throughout AbbVie's work to explore this issue throughout 2020, stakeholders stressed to us that defining the outcomes to be measured and monitored is essential to developing organisational buy-in for shared decision making and setting a best practice expectation for shared decision making at all levels of care as well as consistency of approach. Some areas of care were highlighted as being further advanced in measuring and monitoring shared decision making – including surgical specialties where involvement in decisions is captured via consent recording mechanisms. Oncology services are an example of a speciality that annually surveys patients, providing an example for other areas of care; the Cancer Patient Experience Survey (CPES) asks specific questions relating to shared decision making and therefore helps monitor its implementation. However, this has demonstrated that there is still a way to go in making shared decision making a reality for	

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				cancer patients. AbbVie is also aware that access to shared decision making practices such as shared decision making conversations led by healthcare professionals and the production of care plans seem to vary between different cancer pathways. For example, our work suggests this may be more widespread within the care of some solid tumours compared to blood cancers. The recently published annual National Cancer Patients Experience Survey also suggests people living with blood cancer still score statistically significantly lower than other common cancers regarding communication informing people of their treatment options and being involved in decisions about their care. (*National Cancer Patient Experience Survey: 2019 national level results (2020). Available at: https://www.ncpes.co.uk/wp-content/uploads/2020/06/CPES-2019-National-Report_V1.pdf (Accessed July 2020)*)	
Academy of Medical Royal Colleges (AoMRC)	Draft Guideline	001	General	These recommendations apply to over 18 year olds only. What about young people who can evidence that they are Gillick competent? We often hear about young people struggling to transition to adult services for long term conditions and their inclusion in a shared decision-making approach could pay dividends.	Thank you. People under 18 are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents). However, please note that NICE is currently developing a guideline on patient experience of healthcare for babies, children and young people, which considers shared decision making. Please see

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					https://www.nice.org.uk/guidance/indevelopment/gid-ng10119 for information on the development of this guideline
Academy of Medical Royal Colleges (AoMRC)	Draft Guideline	001	General	It is suggested that SDM may be applicable to social care. Practitioners have always taken a goals-focused approach, which includes shared decision-making, and to suggest they only might be included seems odd	Thank you. This section is not suggesting SDM as a concept may or may not be applicable for social care, but that the NICE *guideline* on SDM may be applicable for social care. This is based on the scope of the guideline and the evidence searched and evaluated and is not a reflection on social care practice. For more information please see section 3.1 of the scope (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)
Academy of Medical Royal Colleges (AoMRC)	Draft Guideline	004	004	We welcome the recommendation of making a member of the senior leadership team accountable and responsible for the leadership and roll out of shared decision making. However, we would recommend a clearer description of some of their responsibilities. For example, will they lead on arranging for translators or longer clinic times for those patients who will require this for an effective SDM process to occur? Will they help in making the need for additional time to embed SDM practice as an explicit part of clinicians' job plans? The need for patient representation at a senior level is made but not followed through with a definite recommendation due to 'costs'. This requires full patient input and the realisation that SDM forms part of a culture of patient experience and feedback as it is unlikely that SDM will be sufficiently successful if the	Thank you. In order to be relevant to all organisations, the recommendation was kept general. The committee heard expert testimony to support the use of a patient director but did not find any published evidence to support that testimony. On the basis of the weak evidence and the cost impact of appointing a director level post in a small organisation, it did not feel able to make a strong recommendation.

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				environment is not receptive. This should include the essential requirement for patients to re-connect with the service (through defined and supported channels) after they have reflected and reconsidered. It is also unclear how these recommendations regarding senior leadership will apply in the community/general practice setting with different governance systems e.g. VCFSE sector. Our Patient & Lay committee emphasised the need for a fundamental change in organisational culture in order to successfully implement SDM, and feel that the guidance does not go far enough in promoting this shift. Patients need to be supported to gain the confidence and willingness to engage in new styles of communication and consultation - they need to be empowered by their clinicians	
Academy of Medical Royal Colleges (AoMRC)	Draft Guideline	005	016 - 019	We welcome the reference to using knowledge of that patient's previous decisions, test results and treatment plans in informing the ongoing SDM process. With increasing integration in service delivery, the widespread introduction of shared records becomes even more important to allow a whole lifetime approach to shared decision-making	Thank you for your support.
Academy of Medical Royal Colleges (AoMRC)	Draft Guideline	005	022 - 024	Any monitoring and evaluation need to be centred on the outcomes for patients, and designed with their input. Government agencies will need to accept that these may not align with the capturing of outputs, but also ensure that	Thank you for your comment.

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				equal focus is given to them in the public arena - so as well as reporting on waiting lists, the government reports publicly on the difference shared decision-making has made	
Academy of Medical Royal Colleges (AoMRC)	Draft Guideline	007	002	We firmly believe that SDM needs to be seen as a culture embedded along the whole patient journey. Though there is reference to supporting patients with SDM before and after discussions, there is an implication that this relates to a single decision. We also feel the focus upon interventions offered around the time of a clinic appointment does not reflect the need for embedding values based self-reflection of the patient along their entire journey sufficiently. We would like to see guidance reflecting the need to ensure a legacy of engagement from patients in thoughts around their ongoing care and health.	Thank you. Please see the recommendations in section 1.1 - embedding shared decision making at an organisational level, also recommendations 1.2.1 and 1.1.11,
Academy of Medical Royal Colleges (AoMRC)	Draft Guideline	010	016	Our organisation has led the successful piloting of the BRAN decision making framework (Benefits, Risks, Alternatives, Doing Nothing). There is an evidence base for using patient facing prompts and has been used extensively in Trusts such as Guy's and St Thomas' NHS Foundation Trust. Our findings, following healthcare staff focus groups, support the need for a communication framework to document shared decision making conversations for	Thank you for this information.

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				healthcare professionals. The framework of BRAN is useful for both patients and healthcare professional. We would recommend explicit referral to this framework as an effective means of aiding shared decision-making. We strongly believe there should be a workforce educational component to embedding SDM in practice. In collaboration with the Winton Centre for Risk and Evidence Communication and the Australian Commission for Safety and Quality in Healthcare, we have developed an open access e-learning module and published findings in BMJ Evidence Based Medicine (2020). We have also developed a series of shared decision making workshops in collaboration with the Centre of Perioperative Care based on a national train the trainer model. Local workshops have been developed in Torbay, Southampton and London. The workshops have improved confidence of participating healthcare professionals (doctors, nurses, allied health care professionals) across all measured domains of shared decision making. We have delivered the first virtual workshop successfully on 1 Dec 2020 and will be using this model going forward until the pandemic allows for face to face interactions. Proposing clear learning objectives for all healthcare staff curricula from undergraduate to post-graduate should be included. The	

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				suggestions for the delivery of 'numerical' information is helpful - but understanding the complexities of sharing risk / benefit profiles in a relevant and honest fashion needs to be highlighted. The incorrect risk assessment is commonly delivered – providing unrealistic expectations or concerns. This needs to be taught. Training the trainers will be a useful adjunct – but only if it is accomplished properly. Patient education is also essential – alongside formal channels to review patient feedback	
Academy of Medical Royal Colleges (AoMRC)	Draft Guideline	011	016	The selection of a 'Three Talk Model' is confusing. As mentioned in the guidance, SDM and consent are continuous processes – this 3 way approach suggests a structure that risks this continuum that explores the benefits, risks, alternatives (including no active treatment) and deferring (particularly during the current COVID pandemic). The individuality of SDM is also missing from that model.	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.
Academy of Medical Royal Colleges (AoMRC)	Draft Guideline	012	020 - 022	We welcome the recommendation to be consistent with the use of data. Using a consistent denominator to describe risk is very important.	Thank you for your comment.
Academy of Medical	Draft Guideline	014	001 - 005	The definition of SDM on page 14 is incomplete – there needs to be an addition of the discussion	Thank you for your comment. The definition of SDM was agreed at scoping stage including consultation.

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Royal Colleges (AoMRC)				including medical evidence to inform the decision ie. it requires a substrate of evidence based medicine. It should also include mention of what is relevant to that specific patient both regarding risk/benefit ratios and the values that individual holds dear.	
Academy of Medical Royal Colleges (AoMRC)	Draft Guideline	016	024 - 025	Whilst we agree that digital technology could be used to support SDM, steps to mitigate the risks of digital exclusion should be explicitly considered.	Thank you for your comment. Recommendation 1.2.5 stated that resources should be offered to service users in their preferred format, including if this is non-digital. This also extends to 1.2.18 for post-appointment materials. The accessible information standard has been added to the recommendation.
Academy of Medical Royal Colleges (AoMRC)	Draft Guideline	017	002 - 004	We are concerned that there is a feeling that widening inequalities from the roll-out of SDM is unavoidable. A significant contributing factor to inequalities that occur due to patient interactions with the healthcare service and clinicians is the fact that it is considered retrospectively rather than prospectively. We are disappointed that this is reflected in these lines, especially given contextual considerations (e.g. language) were made on pg 8, line 6. We strongly recommend that this guideline reflects the huge potential SDM has in reducing inequalities by empowering those patients who stand to benefit the most from enhanced engagement in their healthcare. This guideline must encourage clinicians to prospectively consider this issue, which will guide their use of tool, what preparations need to be made ahead of the	Thank you. All NICE guidelines have an accompanying equality impact assessment, which is published for consultation alongside the guideline. The committee have stressed that interventions should be inclusive all the way through the guideline. The committee note in the rationale and impact section that during the rollout of SDM there may be temporary inequalities between deptartments that have implemented SDM and those that haven't, however this should only be the case during the implementation of the SDM plan.

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				consultation, and what other social factors and cultural sensitivities need to be taken into account. The availability of skilled advocates for a wide range of patients (including but not limited to patients with sensory disability, learning disability or mental health issues) is essential.	
Academy of Medical Royal Colleges (AoMRC)	Methods	General	General	We believe that the inclusion criteria for the evidence review of randomised-controlled trials will have omitted mixed methods and qualitative methods that will have been informative in determining the impact of shared decision making.	Thank you for your comment. Evidence review A included qualitative analysis examining the barriers and facilitators of shared decision-making, the highest quality themes were then used to help form recommendations regarding "putting shared decision making into practice" helping contextualise the quantitative evidence found in RQ1.1 in a mixed-methods analysis
Academy of Medical Royal Colleges (AoMRC)	Other	General	General	As an Academy we really welcome NICE's focus upon generating guidelines relating to shared decision making (SDM). It is a crucial culture that needs embedding throughout a patient's journey and has the potential to increase the effectiveness, safety and experience of healthcare for all patient groups. Whilst there are many elements of these draft guidelines that are laudable, herein we document a number of comments for your consideration as to where they could be improved in order to maximise the opportunity these guidelines present for patients and clinicians.	Thank you for your comment
Academy of Medical Royal	Other	General	General	We are concerned at the lack of clarity regarding patient involvement in this consultation exercise. We feel that a guideline related to shared	Thank you for your comment. A range of patient organisations are registered stakeholders and are able to comment on the

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Colleges (AoMRC)				decision making should be led by patients from the start rather than used as an adjunct in the consultation exercise.	guideline, and the guideline committee which formed the recommendations also partly consisted of service users.
Academy of Medical Royal Colleges (AoMRC)	Other	General	General	In the context of the ongoing COVID-19 pandemic, we feel that there should be reference to the fact that many of these clinical decisions are being deferred. This should be incorporated into the decision making process from the perspective of the risks associated with deferring treatment and the fact that the decision may need to be revisited further down the line.	Thank you for your comment. Recommendation 1.2.10 states that "no change" is an acceptable decision. Regarding deferring decisions outside of SDM processes, this is out of the scope of this guideline.
Academy of Medical Royal Colleges (AoMRC)	Other	General	General	The guidance could usefully reference the work of the Personalised Care Institute, which was set up as part of the response to the Long Term Plan, in equipping care-givers with the requisite skills. It is also disappointing that these guidelines make no reference to the other aspects of personalised care, which would support the culture shift and empowerment of patients and care-givers.	Thank you for your comment. This guideline is about shared decision making, and thus cannot make recommendations on personalised care specifically.
Academy of Medical Royal Colleges (AoMRC)	Other	General	General	There was a feeling within our Patient & Lay committee that the guidelines should better recognise the need to work sensitively with those patients who do not wish to exercise choice – e.g. due to cultural issues, risk appetite or a concern about destabilising the patient/clinician relationship. Equally clinicians need to know when it is appropriate to scale	Thank you for your comment. Our context section discusses that patients may choose to what extent they want to involve themselves in decision making.

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				down the offer of sharing decision making eg in critical situations	
Alzheimer's Society	Draft Guideline	004	010	It would be useful to introduce the concept of Advocacy at this point	Thank you. The committee did not find any evidence supporting the use of advocacy at board level.
Alzheimer's Society	Draft Guideline	005	013	More clarity is needed for on patient aids and digital options as people with severe communication limitations will struggle with such technology.	Thank you. This should be addressed by the NHS accessible information standard.
Alzheimer's Society	Draft Guideline	022	024	While noting that these recommendations have been in place from 2012, would there not be a cost attached to training medical professionals in implementing the 'three-talk model'?	Thank you. All training has a cost but is part of most professionals CPD requirements. We no longer explicitly reference the three-talk model in the recommendations. NICE would like to highlight only the risk communication recommendations have been in place since 2012.
Alzheimer's Society	Draft Guideline	General	General	I think it is a great guide for medical professionals as it involves listening to the patient, not just talking at them, to tell of the diagnosis or treatment plan. It would involve a serious increase in the time that each patient session would absorb but ultimately would be better for all concerned. Efforts to improve poor communication interaction between patient and medical professional are to be commended as this is the single biggest driver of 'complaints' - so better conversations structured in the 'three talk model' would be a definite improvement.	Thank you for your support.
Anticoagulation UK	Draft Guideline	004	General	'Make' is very dictatorial…. Responsibility and accountability for SDM must have buy in across the organisation, lead person and all board members. The role should not be an ad hoc add	Thank you. NICE uses active verbs to denote strong recommendations. Please see the box in the guideline before the recommendations.

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				on to an existing Board member's responsibility, its implementation requires a strategic approach within the organisation and needs to be included as KPI for all staff, top down and will necessitate measurable outcomes.	The recommendations do not mean that SDM should only occur at a senior level, but are there to make sure that SDM is embedded at a senior level, as the committee found this was important evidence form expert testimony.
Anticoagulation UK	Draft Guideline	004	General	Recruitment criteria for Patient Director, Practitioner and service champions roles need to clearly defined and adequately budgeted for in projected business planning. Embedding SDM needs a consistent and continuous approach ensuring all staff can access adequate training to enhance their skills when engaging with patients. Whilst the approach and methodology of SDM appears straightforward, key is communication styles, emotional intelligence and timeliness of the engagement with the patient.	Thank you. This is beyond NICE's remit.
Anticoagulation UK	Draft Guideline	006	General	Agree strongly, this training has to be experiential, using patient scenarios and observations to fully embrace soft skills necessary to understand importance of adapting communication styles to meet patient needs to embed messaging and confidence in the SDM process	Thank you for your support.
Anticoagulation UK	Draft Guideline	007	General	Patient organisations can provide a plethora of resources which have been produced to meet/complement unmet patient needs and usually involve input around design and content with patient focus groups. When auditing current	Thank you for this information.

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				resources within a setting, suggest research into what patient organisations can provide and how they can support the design of new resources i.e. ACUK developed a video book to help patients understand the heightened risk of blood clots with cancer diagnosis and treatment. Identified as an unmet need for many cancer patients and used extensively by HCPs working in this area.	
Anticoagulation UK	Draft Guideline	009	General	High quality resources – NICE guidelines are excellent frame of reference, however, seeking the patient experience and responding to patient led FAQ's is key to creating patient focussed resources. ACUK are aware that many secondary and primary healthcare settings do not have a specific resource/information cost built into annual budgets/projections and this can lead to ad hoc resources being produced. HCPs who are engaging in SDM process must be confident that the resources available will meet patient needs. Resource audits need to be regularly undertaken to ensure most current clinical guidance is available for the patient and clinician.	Thank you for your comment.
Anticoagulation UK	Draft Guideline	017	013	Patient Director is a dedicated and significant role for organisations to have to put in place. The impact of this appointment on any organisation should present in improved service	Thank you for your support.

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				user feedback and hopefully, less complaints over time.	
Anticoagulation UK	Draft Guideline	018	010	Pre appointments – help the patient to prepare their questions for clinician and good opportunity to share resources to help the patient familiarise themselves with consultation process and potential options they may have. With the surge in virtual appointments, patients need to be prepared as to what to expect from their interaction with the clinician and have the option of a face to face if they require.	Thank you for your comment. The skills of SDM in remote settings are the same as in face to face settings, and this has been added to the rationale and to a recommendation. Practitioners are also reminded that in certain situation certain patients may need additional support (rec 1.2.6) The committee acknowledged the changing situation with an increased reliance on remote discussions, but felt more evidence was needed to make a specific recommendation, and thus a research recommendation has been added to look at evidence for remote discussions.
Anticoagulation UK	Draft Guideline	019	General	Measuring shared decision making – soliciting feedback from the end user/ patient. This is a real challenge and needs to reflect the personal circumstances of each patient. Best data may be collated if the patient is monitored as to medicines compliance, repeat prescriptions and blood tests, attendance for meds reviews and follow up appointments. Patient feedback needs to be measured at stage of engagement and impact thereafter, more than one measurement required.	Thank you for your comment.
Anticoagulation UK	Draft Guideline	020	027	High quality and up to date – suggest seek patient engagement when reviewing for completeness	Thank you for your comment. This section captures the committee's rationale for its decisions on recommendations, and thus only contains what was discussed.
Anticoagulation UK	General	023	General	GMC guidance on decision making and consent – comprehensive frame of reference	Thank you for your comment.

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Anticoagulation UK	General	General	General	There are mechanisms within Secondary and Primary Care to capture service users feedback of their experience of healthcare interaction and, how patients can be consulted on best ways for SDM can be improved, implemented. SDM needs to be embedded as part of the culture in any organisation much the same as the HCP 'My name is' innovation…. not a cost just a culture change. Key is ensuring that any HCP or NHS employee is exposed to this concept when in training or part of the induction process as part of any new role.	Thank you for your comment.
Aqua NHS	Draft Guideline	001	005	We would suggest that the guidance is also for third sector organisations/ voluntary organisations that support people to make decisions.	Thank you. 3rd sector organisations were not identified as one of the sectors for which the guidance was developed except those where NHS services are delivered however this does not preclude 3rd sector and voluntary organisations working in line with the recommendations outlined in the guidance. We have added "voluntary, community and social enterprise organisations" to the list of groups this guideline may be relevant for on page 1.
Aqua NHS	Draft Guideline	004	005	We would recommend that the board member responsible can evidence relevant experience/ qualifications to demonstrate understanding of the principles and challenges of SDM e.g. completed an accredited course by the PCI	Thank you for your comment. There was no evidence found, expert evidence presented or committee experience present that justified a recommendation on a particular accredited course for patient directors/board members.
Aqua NHS	Draft Guideline	004	008	We would recommend the term' People with lived experience' instead of Patient Directors. The term patient is not used in all health and social care settings i.e. mental health	Thank you. The committee discussed the wording of this recommendation in detail and decided to keep the current wording for clarity. We acknowledge that the term 'patient' is not used in all settings, but wee believe this is covered by the

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					bracket "from a healthcare service user background". Organisations are free to name the post what they choose.
Aqua NHS	Draft Guideline	005	015	In addition to supportive information systems, consider a system of understanding and improving organisational culture and attitude to risk, acknowledging it as a potential barrier to SDM	Thank you for your comment. We undertook an evidence review of barriers and facilitators to SDM which identified "applying SDM where there is a high risk of harm" as a potential barrier, but it was difficult to identify this as a coherent theme from the qualitative data found, and less evidence compared to other high quality themes. A separate evidence review of reviews of communicating risk was also used to identify the best ways to communicate risk to service users.
Aqua NHS	Draft Guideline	008	009	Regarding capacity issues and using a relative or a friend to help translate, this may result In problems with the issue of bias. A way to address this could be to recommend training advocates / volunteers / translators in the principles of SDM to help them support others.	Thank you. The recommendation is clear that family members should only be used if the patient wants them to be.
Aqua NHS	Draft Guideline	008	021	Emphasise the use of open questions and reflections.	Thank you. This would be part of the SDM training that practitioners undertake.
Aqua NHS	Draft Guideline	009	009	We would recommend emphasising that giving people time to make decisions may be about offering follow up appointments/phone calls etc	Thank you. We believe this is covered in recommendation 1.2.10: "set aside enough time to answer questions, and ask the person if they would like a further opportunity to discuss options"
Aqua NHS	Draft Guideline	009	018	Include the option for patients to initiate review of decision or change their mind- not having to wait for the healthcare practitioner to review it.	Thank you. We have added recommendation 1.2.16 that states "Explain to the person that they can review their decision earlier than the agreed review date if they want to, and can change their mind about a decision they have made at any time."
Aqua NHS	Draft Guideline	010	023	How will people know if it is evidence based and up to date?	Thank you for your comment. This would depend on the nature of the PDA database and how individual organisations approach quality assurance

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Association for Improvements in the Maternity Services	Draft Guideline	005	004 - 006	Who decides what good practice in shared decision making looks like? Please consider making recommendations for gathering service user feedback about whether shared decision making was managed well, and also how best to gather service user feedback.	Thank you for your comment. Please see recommendation 1.1.9 which states "Plan internal or external monitoring and evaluation (including service user and staff feedback activities) and how to feed back the results to staff at individual, team and management level."
Association for Improvements in the Maternity Services	Draft Guideline	006	026	Whilst supporting the overall aim here to promote service-user decision-making, AIMS believes that it is important that the term shared decision making - if this is retained - is not used in any service-user facing context, as this is likely to be highly misleading and confuse the issue of who has the right to make a decision.	Thank you for your comment.
Association for Improvements in the Maternity Services	Draft Guideline	007	001	Rewrite this bullet point to reflect the fact that the service user is always, excepting certain circumstances, the decision maker.	Thank you. Please see the definition of shared decision making in the 'terms used in this guideline' section.
Association for Improvements in the Maternity Services	Draft Guideline	007	003 - 005	We are unsure what 'interventions' means in this context: please clarify. We suggest that this point in the guidance might be a sensible place to flag up the contribution that improved staff continuity (or continuity of carer) can make to improved decision-making on the part of the service-user. Indeed we would suggest that staff continuity is crucial to improving how the service supports decision-making, and should be clearly recognised as such in this guidance. If this issue cannot be included due to lack of	Thank you. An intervention was seen as any element or strategy designed to increase or improve Shared decision making beahviour and collaboaration between the service user and healthcare professional. The committee discussed this at some length, but did not see any robust evidence that continuity of healthcare professional was an effective intervention for improving shared decision making.

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				sufficient evidence, please consider this as a research recommendation.	
Association for Improvements in the Maternity Services	Draft Guideline	008	002	We are unsure how helpful the wording 'what they hope to gain' is in this section.	Thank you. We have tried to clarify this.
Association for Improvements in the Maternity Services	Draft Guideline	008	018	Care should be taken around wording to ensure that service users understand that this is their right rather than something they are being "allowed" to be involved in. We would suggest: "Ensure the person understands they have the right to make choices about their treatment or care, and that it is their choice how much they wish to be involved in any discussion."	Thank you for your comment. We have reviewed the wording and are content with the current wording, which is also intended to convey that people do not have to be involved in decision making if they do not want to.
Association for Improvements in the Maternity Services	Draft Guideline	008	025	The practitioner should be seeking the opinion of the person whose care it is to find out how each option aligns with the person's aims rather than explaining how it aligns with their aims to them.	Thank you. The recommendation assumes the practitioner has already done this (see recommendation 1.2.9) however, for clarity "discuss" has been added to recommendation 1.2.10.
Association for Improvements in the Maternity Services	Draft Guideline	008	027 - 029	We feel that it is important in this part of the document to give consideration to the risks that people may have identified, given their unique knowledge and understanding of their individual situation. We would like to see some words added here that make it clear that the practitioner should ensure that the person's views on risks should be seen as a valid	Thank you. Please see recommendation 1.2.13: "Accept and acknowledge that people may vary in their views about the balance of risks, benefits and consequences of treatments, and that they may differ from those of their healthcare professionals"

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				consideration. Otherwise, this currently reads as the imparting of information from the practitioner to the person, rather than a two way sharing of information and opinion.	
Association for Improvements in the Maternity Services	Draft Guideline	009	002	We feel that the wording here suggests that it is only the service user who may have misconceptions.	Thank you. It is likely to be the service user who has misconceptions about tests or treatments, which is what this recommendation is explicitly talking about.
Association for Improvements in the Maternity Services	Draft Guideline	009	003	AIMS feels strongly that providing for a sufficient amount of time for appointments is an important part of the supported decision making process. This may require some organisational re-planning to ensure that resources are in place to support this (for example, as called for in the National Maternity Report (Better Births, 2016, 6.11)).	Thank you. The committee discussed this and agreed that it was not always realistic to have appointments that run as long as they need to. Therefore, they recommended offering follow up appointments if the person wanted to discuss further. See recommendation 1.2.10
Association for Improvements in the Maternity Services	Draft Guideline	009	006	We feel that the use of the word 'checking' in this section does not give appropriate recognition to the fact that both sides are experts: it feels aggressive and power laden. Is there an opportunity for service users to check that the practitioner also understands the information in relation to their specific circumstances and what is important to tham in terms of outcomes? It feels like there is an imbalance of power in favour of the practitioner which does not feel in keeping with the notion of supported decision making.	Thank you. NICE is unable to make recommendations for patients or service users. We believe the spirit of this is captured by recommendation 1.2.13

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Association for Improvements in the Maternity Services	Draft Guideline	009	011 - 0013	AIMS fully supports this point although we do not feel as though this is always reflected throughout the document. We would welcome the clear inclusion of the point that a difference of opinion should be noted, whilst making it clear that it is the service user who makes the decision.	Thank you for your comment.
Association for Improvements in the Maternity Services	Draft Guideline	009	014	We are unsure why it is a joint decision and what happens if the service user and practitioner do not agree. Can this be clarified to the effect that the service user is the final decision-maker?	Thank you. This guideline is about shared decision making. Please see the definition in the 'terms used in this guideline' section and the description in the rationale and impact section.
Association for Improvements in the Maternity Services	Draft Guideline	009	016	We feel that this section could be worded better to show that it is about clarifying understanding on both sides.	Thank you for your comment. We have reworded this.
Association for Improvements in the Maternity Services	Draft Guideline	009	020	As mentioned above, differences of opinions could also be recorded if the practitioner felt it was necessary.	Thank you. We agree.
Association for Improvements in the	Draft Guideline	010	001 - 006	We note that the guidance referred to here has not been adopted across all services. To ensure patient equity, we do not understand the inclusion of the word 'consider' in this context: why would this not be a universal offer? We	Thank you. We have amended the recommendation to "When writing clinical letters after a discussion, write them to the patient rather than to their healthcare professional, in line with Academy of Medical Royal Colleges guidance on writing outpatient clinic letters to patients. Send a copy of the letter to

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Maternity Services				would also note - thinking of midwives - that GPs are not the only relevant healthcare professional in this context.	the patient (unless they say they do not want a copy) and to the relevant healthcare professional."
Association for Improvements in the Maternity Services	Draft Guideline	010	006 - 007	We feel that the language here is misleading and does not fit with our understanding of the law. Replace 'share in making' with 'make decisions'.	Thank you for your comment. This text has been edited to "Offer to arrange additional support for people who might find it difficult to share in decision making" to clarify meaning.
Association for Improvements in the Maternity Services	Draft Guideline	011	007 - 014	To conserve scarce healthcare resources, AIMS suggests that it would be preferable to recommend the production of such decision aids at the national level, with further clarity around who should have the role of producing them (and who should be involved in their production). If they were to be produced at national level, it would then also be more straightforward to properly consult on their content; this is key to ensuring their trustworthiness and widespread support amongst health care professionals and service users alike. Where organisations/ systems have adopted decision aids to use locally, we suggest that these should <u>always</u> be easily accessible via the provider website, as well as in other formats to meet individual needs.	Thank you for your comment. There is currently no national repository for PDAs.
Association for Improvements in the	Draft Guideline	011	016	AIMS supports this section on communicating risks, benefits and consequences.	Thank you for your comment.

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Maternity Services					
Association for Improvements in the Maternity Services	Draft Guideline	012	005 - 007	We are pleased to see recognition given to the fact that information around risks, benefits and consequences should be personalised but would like to see some reference made to the fact that healthcare professionals may need to go away to find information out, and present alternatives. We feel that this will ensure that people are being provided with information that is truly personalised to their situation.	Thank you for your comment. The recommendations clarify that practitioners can provide different forms of information depending on the needs of the service user and to present all of the options available to the service user, it is also discussed that SDM is a continuous process that takes place over several appointments.
Association for Improvements in the Maternity Services	Draft Guideline	014	003	AIMS is concerned about the use of the term 'joint decision' in the definition of 'shared decision making'. This does not give appropriate weight to the fact that the choice is always, excepting certain circumstances, for the service user to make.	Thank you for your comment. The definition of SDM was agreed at scoping stage including consultation.
Association for Improvements in the Maternity Services	Draft Guideline	General	General	From a reader's perspective, the ordering of this document content is confusing. Please consider changing the order. For example, the document begins by discussing how shared decision making can be embedded at an organisational level before introducing what shared decision making is/ should look like in practice.	Thank you for your comment. SDM might happen at both an organisation and individual level at the same time but the committee wanted to emphasise that a culture of SDM needs to be spread from the 'top'. NICE guidance is read by many healthcare professionals at different organisational levels and the guideline was divided into sections based on who it is most applicable to.
Association for Improvements in the Maternity Services	Draft Guideline	General	General	AIMS strongly believes that a more appropriate term for 'shared decision making' would be 'supported decision making', and would note that this new terminology is increasingly being adopted in the context of maternity services, and as such is supported by NHS-England and	Thank you. NICE was asked to prepare guidance on shared decision making. That is the term in general use and the term that was used throughout scoping and development of the guideline. A key point of shared decision making is that the authority is shared between both parties. For example, choice of treatments available may not include their preferred choice

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				Improvement. We see no reason why this shift in terminology should not occur more widely, and not to make such a wider shift would be unhelpful. Whilst we understand that 'shared' refers to the sharing of information between healthcare professionals and service users as part of the decision making process - rather than to the decision, and the person with the authority to make the decision itself - we feel that the terminology scattered around this guidance (and in the supporting documentation) - raises an important lack of clarity around whose right it is to make the final decision. This lack of clarity is evident throughout the documents. In our view, the phrase 'shared decision making' does not appropriately convey the legal rights of bodily autonomy that exist in the UK and the fact that decisions are always for the service user to make (except in rare situations where an adult lacks capacity.) We recognise that some people will not always want to make a decision about their healthcare options, and would rather leave this to the healthcare professional: even in these cases, however, we feel that the term 'supported decision making' is the better term.	and the healthcare practitioner will need to work with the service user to choose from what is available (or no treatment, if they prefer). To acknowledge the use of a different definition for shared decision making within the context of maternity services the following text has been added to the context section of the guideline – 'in line with NHS England's personalised care and support planning guidance: guidance for local maternity systems, in maternity services this may be referred to as 'informed decision making'.
Association for Improvement	Draft Guideline	General	General	We feel, as this is a document which will be read and used by a variety of stakeholders (including service users), that the tone throughout does not	Thank you. The guideline defines SDM as "a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about

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s in the Maternity Services				adequately convey the collaborative nature of 'shared decision making'. It reads more like something which is being done to a person and that they are being 'allowed' to participate. There is little recognition that HCPs have an obligation to provide service users with the information they require to make a decision and then to support them in the decision that they make. There is no consideration given to the fact that service users may initiate a conversation about their choices, and that they are active and equal participants in the information sharing process - and indeed the primary stakeholder - with the ultimate decision about their care being for them to make.	care." We believe this adequately conveys the collaborative nature of SDM. Many recommendations capture the collaborative nature of SDM, for example: Recommendation 1.2.7 states both parties "agree" and agenda Recommendation 1.2.8 states "Ensure the person understands they can take part as fully as they want in making choices about their treatment or care." Which clarifies that SDM and the amount occurring is with the service user to decide. Recommendation 1.2.13 states: "Accept and acknowledge that people may vary in their views about the balance of risks, benefits and consequences of treatments, and that they may differ from those of their healthcare professionals." Recommendation 1.2.14 refers to "joint decisions" made. We believe these and other examples clarify the nature of service user involvement in the SDM process.
Asthma UK and British Lung Foundation	Draft Guideline	006	026	As part of our consultation response, Asthma UK and the British Lung Foundation asked people with a lung condition for their views on shared decision making through an online survey. The survey was open from 15 January to 24 January 2021, and respondents were targeted via Asthma UK and British Lung	Thank you for your comment. The committee agreed that remote discussions should be considered and have also written a research recommendation that asks "How do SDM

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				Foundation supporter mailing lists and through our social media channels. 1,038 people with a lung condition took part in our survey. The vast majority of respondents told us that they would like to be involved in making decisions about their care, with 96% finding this extremely important or very important.[1] Furthermore, 97% agree or strongly agree that they are motivated in making decisions about their care.[2] Therefore, it is important that all health related organisations and the professionals working within them actively promote shared decision making to people who use their services. Whilst we are supportive of this guideline, we believe that it will be challenging for organisations to promote shared decision making to people in this current climate with COVID-19 still present. For example, it will be hard to communicate and have effective conversations with people who are not digitally literate or rely on receiving information in a physical format. This is an issue that requires further exploration in the guideline as healthcare delivery in future is likely to rely on greater use	skills and techniques need to be modified for remote discussions?" They noted that remote discussions are not just limited to digital interventions, but can also cover telephone consultations which are less of a problem when it comes to digital literacy. The committee felt skills of SDM could be applied to remote settings as well as face to face settings, and this has been added to the rationale and also to a recommendation (1.2.2).

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[1] Asthma UK and the British Lung Foundation surveyed 1,038 people with lung conditions from 15 January to 24 January 2021.

[2] Ibid

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				of digital and remote care, which could see some patients left behind or further marginalised.	
Asthma UK and British Lung Foundation	Draft Guideline	010	012	Whilst we are supportive of this guideline, the recommendation for healthcare professionals to share information with all relevant services and ensure that patients are provided with consistent messaging will be challenging to implement in practice. This process needs to be enabled by good quality data and joined up systems that we know the NHS has historically struggled with which is unfortunate as this would make a big difference to patient care. We have however seen glimpses of hope during the COVID-19 pandemic, with NHSX making shared care records and joined up systems a priority.[3]	Thank you for your comment.
Asthma UK and British Lung Foundation	Draft Guideline	General	General	As mentioned above, most people with a lung condition find it important to be involved in making decisions about their care. 97% of people with a lung condition want to be often or always involved in making a decision about their care, with 89.5% of respondents agreeing or strongly agreeing that they have the skills and knowledge to be involved in this process.[4][5]	Thank you for this information. The guideline covers the planning and implementation of shared decision making. The committee added some discussion to the rationale and impact section about when SDM might not happen because the person and their professional might not be able to agree. The committee noted that some people may not want to be involved in shared decision making. They also noted that not all decisions can be shared. People have a right to refuse any

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[3] NHS England (2019), *NHS Long Term Plan*. Available from: https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/

[4] Ibid

[5] Ibid

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				However, only 66.5% of people with a lung condition agreed or strongly agreed that they had opportunities to make decisions about their care together with their healthcare professional.[6] When breaking down this data further, we found that people with asthma believe they have more opportunities to make decisions about their care than people with other lung conditions.[7] All people with a lung condition should feel that they have an opportunity to be listened to by their healthcare professional, involved in the shared decision making process and empowered to make decisions about their care. Therefore, it is important that all health related organisations and the professionals working within them follow the guidance and utilise shared decision making tools so people who use their services are involved in making decisions about their care. In addition, we recommend that NICE consider how patients can get support from other sources such as patient organisations, peer groups, and online forums when making decisions about their care. Furthermore, 34% of respondents told us that they did not feel confident when discussing preferences with their healthcare professional.	treatment, and similarly, healthcare professionals are not obliged to provide any treatment that in their clinical opinion is medically futile (this may require a second opinion or discussion with a senior colleague). Healthcare professionals cannot provide access to treatments that are not available.

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[6] Ibid
[7] Ibid

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				According to the data, people with a higher level of education feel slightly more confident in discussing their own opinion. Inequality is strongly linked to lung disease, so we welcome the guidance on how shared decision making can be put into practice and supported through relevant interventions such as patient decision aids.[8] In order to support the implementation of shared decision making, healthcare professionals must be aware of resources that patients find useful when making decisions, so we are pleased to see that this point is covered in the guideline. When we asked people with a lung condition what they find most useful when it comes to making decisions about their care between appointments, these are the following resources they listed:[9] • Links to further information (i.e. on the internet) • Conducting independent research on the internet • Information from charities • Personal notes from conversations with a healthcare professional	

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[8] British Lung Foundation, 2016. *The battle for breath - the economic burden of lung disease*. Available from: https://www.blf.org.uk/policy/economic-burden

[9] Asthma UK and the British Lung Foundation surveyed 1,038 people with lung conditions from 15 January to 24 January 2021.

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				• A printed summary sheet of what's been discussed with a healthcare professional • A letter from a healthcare professional after an appointment • An app or device that helps monitor their condition • An email from a healthcare professional after an appointment • Statistics and graphics • Posters or information in a doctor's waiting room • A text from a healthcare professional after an appointment In addition, we also asked people with a lung condition to list one thing that they felt would help them, and other people living with lung disease to live better. A device or app that helps people to monitor their condition was a common answer among younger audiences, whereas more opportunities to discuss options with a healthcare professional was the most popular response amongst older audiences.[10] We would recommend that NICE makes a research recommendation to develop knowledge of what resources different patient cohorts find most useful when making decisions about their care to support the implementation of this guideline.	

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[10] Ibid

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				Whilst we are supportive of this guideline, we are concerned that it doesn't include any detailed guidance on what would happen if there was a disagreement between a healthcare professional and their patient about a care decision. Our survey evidenced this as happening among 46.5% of respondents when we asked people with a lung condition to think about a time where they or their healthcare professional had different ideas or preferences about their care. Of those that recalled such a time; 43% said they went with their healthcare professionals' approach, 39% with a mixed approach and 18% reported that they went with their preference.[11] When we asked people with a lung condition to describe how they felt about this outcome, we received a mixture of responses. Most respondents reported no overall satisfaction and felt unhappy with disagreements about their care, but often went with the approach of their healthcare professional.[12] Although most people with a lung condition find their healthcare professional knowledgeable and empathetic about their condition, if shared decision making is going to be put into practice, then there needs to be more	

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[11] Ibid
[12] Ibid

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				guidance on what would happen if there was a disagreement between a healthcare professional and their patient about a care decision, and how this can be mitigated.[13]	
Bangor University	Draft Guideline	004	017	'Identify 1 or more people who use services as organisation-wide 'service- user champions' for shared decision making' – this could be made clearer, with examples of who these might be.	Thank you. We have clarified this as: "Identify one or more people who use services as organisation-wide 'service- user champions' to work with the senior leader, patient director and professional champions for shared decision making. They should be recruited from people who use services.".
Bangor University	Draft Guideline	005	002	planning and implementing SDM'. No clear mention of MDT role in SDM and standards for how MDTs could potentially be improved or seen as exemplars to implement SDM.	Thank you. Although recommendations do not mention MDTs specifically, recommendations on the principles of how shared decision making outlined in the guideline are applicable to MDT members. .
Bangor University	Draft Guideline	005	028	Consider joining up the support network with others in the wider system and across the region' – could be clearer and perhaps explicitly mention social care services and examples of this in practice?	Thank you. The committee were unaware of any examples in practice and did not want to be to specific in case of excluding certain settings. In terms of clarity, "others in the wider system and region" is interpreted to mean other networks of SDM trainers (including service users) within other organisations. This guideline does not cover social care, please see section 3.1 of the scope document. (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)

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[13] Ibid

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Bangor University	Draft Guideline	006	001	Supporting practitioner skills and competences' – could mention additional support for practitioners if they feel SDM is/has not worked/working, ways to refer, access additional support for 'complex' cases e.g. language barriers, lack of rapport, break down in trust/communication.	Thank you. The previous recommendation proposes establishing a support network for staff. Regarding complex cases eg. when a decision in not shared, the rationale and impact section now states "The committee noted that some people may not want to be involved in shared decision making. They also noted that not all decisions can be shared. People have a right to refuse any treatment, and similarly, healthcare professionals are not obliged to provide any treatment that in their clinical opinion is medically futile (this may require a second opinion or discussion with a senior colleague)."
Bangor University	Draft Guideline	007	010	Perhaps be aware that family members and carers have their own views and agenda which may not be the same as the patient. These groups may need separate SDM or additional support to agree future patient plan.	Thank you. The committee was aware of this risk and made clear in the recommendations that people should only be involved with the patient's permission and that there should be due regard to safeguarding. See recommendation 1.2.3, which states "Ask the person if they want to involve family members, friends, carers or advocates (being aware of safeguarding)".
Bangor University	Draft Guideline	008	024	1.2.9 perhaps make clear somewhere that options are not a menu with equal outcomes. It is implied with the sentence…'how this align with the person's aims'. But we know that SDM can manifest as presenting options as a long list and leaving it all up the patient to come to a decision, which is the opposite of SDM. Also need to clarify that just because a person may favour a treatment initially or say they want this or that at	Thank you. This recommendation is nly for the "before discussion" section of the guidance, and the committee felt the outcomes, communicating choice to service user and SDM as an ongoing conversation were captured by the later discussion recommendations.

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				the outset, it is not an excuse not to have a full SDM conversation.	
Bangor University	Draft Guideline	010	001	1.2.17 Would a guideline to send GP letters as routine be more helpful and instead ask if they *do not* want a letter sent?	Thank you. We have clarified this.
Bangor University	Draft Guideline	010	016	1.3.1 Maybe add something to highlight that even the very experienced SDM practitioners could potentially benefit from a suitable decision aid and experience should not dictate usage?	Thank you for your comment. Recommendations are meant for all healthcare practitioners, regardless of experience level.
Baxter Healthcare Ltd	Draft Guideline	005	013	Ensure data / information collected can be incorporated into patient records for future reference as to the activation level of the patient and previous discussions. Consider how to aggregate data to take learns from the population and reduce variation in approach / results	Thank you. Please see recommendation 1.2.15 and 1.1.9
Baxter Healthcare Ltd	Draft Guideline	006	025	Creative ways should be considered for getting the message to the public. Patients will be more confident and better prepared if they are first aware of their options for shared decision making. Waiting until they are ill and in a healthcare setting may result in confusion, reluctance or fear. Posters / media in those settings may not be seen or may be seen too late for the patient to consider the questions they	Thank you for your comment. The focus of the guideline was shared decision making in a healthcare setting and the scope of the guideline did not include public information campaigns, which are beyond the remit of NICE. Recommendations have therefore not been made in this area.

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				need to ask. Guidance should be given at each step in the patient pathway as they patients learns more about their condition and their options. Consider a proactive public information campaign helping people understand their options, what questions to ask, how to ask them and who to ask. Link this to the drive for prevention, integrated care, quality of life etc	
Baxter Healthcare Ltd	Draft Guideline	008	009	Suggest providing Patient Charity details; patient charity advocates to support. Information on Patient Charity sites aimed at patients and designed with this in mind.	Thank you. This list is exemplar. It gives examples of where support 'could' come from and is not exhaustive.
Baxter Healthcare Ltd	Draft Guideline	008	015	Needs to be made clear that the opportunity for the patient to engage on shared decision making should not be limited to "during" an appointment. To the above points this may be too late. Discussions should be taking place throughout the patient journey from first appointment with a GP through to completion of care. Information should be provided, where possible, in advance of appointments as well as during. Definition of appointments should also be expanded so as not to imply simply GP or Outpatient. Appropriate discussions should also take place, for example, during ward rounds and ahead of and during discharge processes	Thank you. The section 1.2 covers before, during, after and between appointments. Wording has been amended to make clear this is not just focused on primary care.
Baxter Healthcare Ltd	Draft Guideline	008	019	When referring to treatment, it should be made clear that this does not need to exclusively mean the physical treatment being provided. It should include other elements including location of	Thank you. The recommendation says 'treatment or care' and is intended to cover all of the elements mentioned in this comment.

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				treatment, self-administered, treatment modality options etc	
Baxter Healthcare Ltd	Draft Guideline	008	027	Care should be taken to ensure that the HCP leading the conversation is clear on all possible options potentially suitable for that patient. For example, a patient in hospital for the sole purpose of receiving an IV antibiotic may be suitable to go home using an OPAT (Outpatient Parenteral Antimicrobial Therapy) service. However, this option may not be explored if the HCP is not aware that the service is available. In this instance, the patient would almost certainly not be in a position of knowledge enough to ask. Consideration needs to be given to how to ensure all relevant services are understood and included in discussions	Thank you for your comment. It is anticipated that the healthcare professional should be aware of the options available.
Baxter Healthcare Ltd	Draft Guideline	009	024	Ensure a diverse range of information formats is available to address the individuals learning style: i.e. audio, visual, written, practical hands on if possible	Thank you. We have added a reference to the accessible information standard.
Baxter Healthcare Ltd	Draft Guideline	009	026	Provide safe websites, as patient may be fearful of finding out incorrect information. NICE guidelines may not provide appropriate information for some individuals, whereas patient charity information is specifically designed by and for patients. It is vital that patients are directed to high quality information and avoid finding misinformation	Thank you. We have modified recommendation 1.2.4 to acknowledge the role of patient organisations: "When providing information and resources: only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids." This would also cover information provided in recommendation 1.2.18

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Baxter Healthcare Ltd	Draft Guideline	010	006	Consider development of a peer support service, to provide meaningful insight into the lived experience. Utilise Patient Charity advocate services, specific to the condition. If recording conversations, take care with GDPR etc	Thank you for your comment. The committee considered that peer support services could fall under "or a suitable alternative" in recommendation 1.2.21, but did not specifically recommend a peer support service.
Baxter Healthcare Ltd	Draft Guideline	011	007	Also, provide links to Patient Charities related to specific conditions i.e. Renal, Diabetes, Heart Disease...etc	Thank you. Please see recommendation 1.2.4 where we have added "When providing information and resources: only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids."
Baxter Healthcare Ltd	Draft Guideline	016	018 - 023	If cost is a limiting factor for the inclusion of a patient director this must be addressed. This post should not be considered optional. Patient leadership is essential and many patients need advocacy from peers to support them in situations where they could be scared and confused. That experience must be accounted for at senior level. Consideration could be given to other methods of ensuring patient advocacy at a senior level through engagement, for example, with the third sector if cost is an issue	Thank you. The committee agreed that a patient director must be optional in a guideline that covers all healthcare organisations. It would be unrealistic, for example, to ask a single handed general practice to appoint a patient director.
Baxter Healthcare Ltd	Draft Guideline	017	001 - 004	This risks creating a "postcode lottery" with some patients having a more positive experience based arbitrarily on their location. It is appreciated that variation in the short term may be unavoidable but their longevity in nature will be partly dictated by an understanding of the variation that exists and how it is being addressed. Therefore consideration should be	Thank you. The committee's discussion was about how interventions may need to be modified for different settings. This should not create a post code lottery. We have added an example to clarify.

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				given to ensuring visibility of the variation and metrics showing how this variation is reducing over time. Incentives / disincentives for implementing / not implementing shared decision making to the desired standard should be considered. Audits / inspections of healthcare facilities should include a measure that ranks them against the required specification and the performance of their peers	
Baxter Healthcare Ltd	Draft Guideline	017	013	Consideration should be given to looking at this in more depth especially the conclusion this will have a "modest" impact on resources. If patients have a clear understanding of their options and how they can share decision making related to their care this could fundamentally change the direction of some care pathways. For example, the patient who chooses to medicate at home for IV nutrition, renal dialysis or IV antibiotics and requires support from a community nurse. The patient who opts for conservative treatment which takes them into physiotherapy rather than surgery. The patient who chooses support from mental health services to help them manage a physical condition. Uptake of choice from patients such as these could dramatically change the pathway landscape which is certainly the ambition of the NHS Long Term Plan in relation to integrated care and care closer to home. Consideration should be given to training and the potential for re-deployment of	Thank you. In the context of shared decision making the decision is a collaboration between the practitioner and the patient or service user. Part of that collaborative decision is the conversation about what options are feasible or available. Some detail relating to this has been added to the rationale and impact section.

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				resource to ensure that patient choice does not get blocked due to resource constraints, particularly in community and mental health care, both of which are under existing and growing strain.	
Birth Practice and Politics Forum	**Draft Guideline**	**004**	**001**	***People have the right to be involved in discussions and make informed decisions about their care*****. Suggest amend to "People have the right to have discussions with health professionals so that they are able to make informed decisions about their care". Suggesting that they can be 'involved' in discussion implies an invitation which may or may not occur.**	Thank you. Whilst this is standard text and is in all NICE guidelines, we are currently exploring the impact the SDM guideline will have on wider guidance and the wording we will use**.**
Birth Practice and Politics Forum	Draft Guideline	006	011 - 014	Sharing and discussing the information ….plan). Agreed	Thank you for your support.
Birth Practice and Politics Forum	Draft Guideline	007	001	*How can we make a decision together that is right for me*? Amend to "How can we discuss the issues together so that I can make a decision that is right for me?" Please note that after a discussion of the information available, some will decide to leave the decision to the health professional. That is a decision in itself.	Thank you. Please see the definition of shared decision making in the 'terms used in this guideline' section.

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Birth Practice and Politics Forum	Draft Guideline	012	015	Use absolute risk rather than relative risk ….doubles. Excellent suggestion.	Thank you for your comment.
Birth Practice and Politics Forum	Draft Guideline	022	028	*Shared decision making is a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care.* Suggesting that it is a joint decision is unacceptable, this implies that the health professional also makes the decision, they do not, it is the person who decides what what will or will not happen to their body who decides. Suggest amend to: Informed decision making is a collaborative process that involves a healthcare professional fully informing the person to enable him/her to make a decision.	Thank you for your comment. This was the agreed definition of Shared decision-making at scoping stage after stakeholder consultation. The full definition is under the "terms used in this guideline" section.
Birth Practice and Politics Forum	Draft Guideline	023	027 - 028	*people have the right to be involved in planning and making decisions* Suggest amend to "People have the right to have discussions with health professionals so that they are enabled to make informed decisions about their care".	Thank you for your comment. People also have the right to be involved in making decisions, not just to have discussions.
Birth Practice and Politics Forum	Draft Guideline	General	005	The title, and much of the text, suggests that health professionals share the decision, they do not, and it is misleading in the extreme to suggest otherwise. The decision is made by people, it is the discussion of the information available that is shared. Suggest that the document deletes *Shared Decision Making*	Thank you. This guideline covers the process of shared decision making where healthcare professionals and service users work together to make a decision. The definition of shared decision making is in the 'terms used in this guideline' section. It is the discussion of the options available that is contributed by the healthcare professional.

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				throughout, replacing it with *Informed Decision Making*.	
Birthrights	Draft Guideline	001	General	Line 3 should be amended to read "to work together to enable the patient to make informed decisions about their treatment and care."	Thank you. The definition of SDM was agreed during scoping and the full definition is included in the 'terms used in this guideline' section of the guideline.
Birthrights	Draft Guideline	004	001	Should be amended to read "People have the right to have discussions and make informed decisions about their care"	Thank you. Whilst this is standard text and is in all NICE guidelines, we are currently exploring the impact the SDM guideline will have on wider guidance and the wording we will use.
Birthrights	Draft Guideline	004	010-011	Would like to see an explicit recommendation about consulting service users widely (especially those from under-represented groups) if they feel that the shared decision making process is empowering them to make informed decisions and if not, listening to their ideas about how this could be improved. Our survey with Mumsnet suggested that less than half of those surveyed felt that they were the primary decision maker in their care, and 42% did not.	Thank you for your comment. Recommendation 1.1.9 states: "Plan internal or external monitoring and evaluation (including service- user and staff feedback activities) and how to feed back the results to staff at individual, team and management level." The committee agreed that this would be a mechanism by which to record service user experience. This recommendation falls under "Embedding shared decision making at an organisational level" and thus will be the responsibility of the roles highlighted in 1.1.1-1.1.4.
Birthrights	Draft Guideline	005	004-006	It should be clear that "good practice" should be judged according to feedback from service users, not what the department or service themselves think.	Thank you for your comment. Please see recommendation 1.1.9 which states "Plan internal or external monitoring and evaluation (including service user and staff feedback activities) and how to feed back the results to staff at individual, team and management level."
Birthrights	Draft Guideline	005	020-021	How service users are involved in implementation should be discussed and agreed with the service users themselves.	Thank you for your comment.
Birthrights	Draft Guideline	007	001	Amend to "How can healthcare professionals support me to make a decision that's right for me?"	Thank you. Please see the definition of shared decision making in the 'terms used in this guideline' section.

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Birthrights	Draft Guideline	008	018-019	Amend to "Ensure the person understands that ultimately decisions about their treatment or care are up to them but healthcare professionals will do all they can to support them."	Thank you. The definition of shared decision making is in the 'terms used in this guideline' section.
Birthrights	Draft Guideline	009	014	Amend to "ask the patient what their decision is" – it is not a joint decision.	Thank you. This guideline is about shared decision making. Please see the definition in the 'terms used in this guideline' section and the description in the rationale and impact section.
Birthrights	Draft Guideline	014	002-003	Amend to "Shared decision making is a collaborative process that involves a person and their healthcare professional working together to enable a patient to reach an informed decision about their care"	Thank you for your comment. This definition was agreed between all committee members and was used to inform guideline development, and thus cannot be changed.
Birthrights	Draft Guideline	023	025	Delete "shared and insert "made" instead	Thank you for your comment.
Birthrights	Draft Guideline	General	General	We raised our concerns about the term "shared decision making" in our response to the scope document for this guideline in February 2019 and recommended that the term "supported decision making" better reflected the legal reality that the decision belongs to the patient. In response NICE stated that *"The terminology used in the scope, shared decision-making, links in with national policy and initiatives, including the recently published NHS Long Term Plan and NHS England's Personalised Care Group's shared decision making programme. We feel it is important to keep the terminology consistent across national strategies and plans. We have, however, amended the scope to clarify that while the process of reaching a decision is*	Thank you. Shared decision making is broader than people's autonomy over their own bodies and may also relate to (for example) the range of treatments that are available. These decisions are reliant on the expertise of the HCP and the wishes of the patient and therefore are shared decisions. As you note, it was agreed at scoping that shared decision making would be the preferred term.

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				shared, ultimately this is to support the person to reach a decision about their care." The commitment made in the last sentence has not been carried through to this guideline. A document that employs the term "shared decision making" must work extra hard to convey that although the process is shared, the decision is not. This guideline needs more clarity throughout on this point. The fact that this is not clear only confirms our view that the term "shared decision making" does nothing to convey a clear message to healthcare practitioners that all patients have autonomy over their own bodies and that their role is to support people to make informed decisions about their care. We remain of the view that "supported decision making" is a much better term.	
Birthrights	Evidence review C	005	0032	Delete "shared and insert "made" instead	Thank you for your comment. This is the standard text used to refer to the Montgomery ruling on the NHS and NICE websites.
Birthrights	Evidence review D	006	010-012	Amend to "Shared decision making is a collaborative process that involves a person and their healthcare professional working together to enable a patient to reach an informed decision about their care"	Thank you for your comment. This definition was agreed between all committee members and was used to inform guideline development, and thus cannot be changed. The scope document is available at https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents

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Birthrights	Evidence review E	006	008-010	Amend to "Shared decision making is a collaborative process that involves a person and their healthcare professional working together to enable a patient to reach an informed decision about their care"	Thank you for your comment. This definition was agreed between all committee members and was used to inform guideline development, and thus cannot be changed. The scope document is available at https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents
Birthrights	Evidence review E	006	030	Delete "shared and insert "made" instead	Thank you for your comment. This is the standard text used to refer to the Montgomery ruling on the NHS and NICE websites.
Birthrights	Evidence review A	006	015-018	Amend to "Shared decision making is a collaborative process that involves a person and their healthcare professional working together to enable a patient to reach an informed decision about their care"	Thank you for your comment. This definition was agreed between all committee members and was used to inform guideline development, and thus cannot be changed. The scope document is available at https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents
Birthrights	Evidence review A	006	037	Delete "shared and insert "made" instead	Thank you for your comment. This is the standard text used to refer to the Montgomery ruling on the NHS and NICE websites.
Birthrights	Evidence review B	007	006-008	Amend to "Shared decision making is a collaborative process that involves a person and their healthcare professional working together to enable a patient to reach an informed decision about their care"	Thank you for your comment. This definition was agreed between all committee members and was used to inform guideline development, and thus cannot be changed. The scope document is available at https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents
Birthrights	Evidence review B	007	028	Delete "shared and insert "made" instead	Thank you for your comment. This is the standard text used to refer to the Montgomery ruling on the NHS and NICE websites.
Birthrights	Evidence review C	005	010-012	Amend to "Shared decision making is a collaborative process that involves a person and their healthcare professional working together to enable a patient to reach an informed decision about their care"	Thank you for your comment. This definition was agreed between all committee members and was used to inform guideline development, and thus cannot be changed.

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Bristol Myers Squibb	Guideline	general	general	Bristol Myers Squibb (BMS), have produced materials that may support the drafting of the NICE shared decision making guidelines and evidence reviews. A Patient Charter has been developed that sets out the care and support that patients should be able to expect when they are diagnosed with kidney cancer. This has been developed with Kidney Cancer Support Network and Kidney Cancer UK and informed by a meeting with their patient representatives. It is intended to inform policymakers about the barriers to improving kidney cancer patients' experiences and outcomes. The Charter features *'I statements'* that are composite statements backed up by evidence-based policy insights, which have been developed with kidney cancer patients and their representatives to communicate what matters most to kidney cancer patients. In relation to kidney cancer patients feeling they should be seen and heard, the following statement was produced: *"As an expert in my own experience of kidney cancer, my voice should count in my treatment as much as I want it to, and my feedback should*	Thank you for your comment.

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				be considered when planning how to deliver the best possible individualised care and treatment now and in the future." Research found that 38 per cent of patients in the UK had not been engaged at all in their treatment plans, in that their doctor had decided their treatment plan for them; this makes the UK an outlier compared to 29 per cent of patients globally reporting not being engaged in their treatment plans. Involving kidney cancer patients in service (re)design can identify barriers to patients accessing care, improve patients' experiences and ensure that services are fit for purpose. It is recommended that they should also be involved throughout the process of design and commissioning at all levels, including board level. Considering the importance of the patient voice in ensuring that kidney cancer services are fit for purpose for patients, BMS developed a Kidney Cancer Shared Discussion Guide. A plain English guide that provides patients with information and advice about kidney cancer support. The guide aims to empower patients to be involved in their own care and encourages	

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				them to voice their concerns, questions and preferences. This was developed in collaboration with Kidney Cancer UK and has been reviewed by kidney cancer patients. The guide will be hosted on Kidney Cancer UK's website and will also be shared with key stakeholders by BMS, to ensure that the guide is implemented and put into practice to appropriately support kidney cancer patients. BMS would be pleased to share these materials with NICE, if that would be of interest and also welcome the opportunity to speak with NICE with regards to our research surrounding shared decision making and how this could support the drafting of NICE shared decision making guidance.	
British Academy of Audiology	Draft Guideline	004	005	It is understood that the rationale for 1.1.1 is based on committee experience and expert evidence. However, there would be potential cost/time/bureaucracy implications with taking a more top-down approach. Is there any evidence that this would be more effective than a more bottom-up approach? It is agreed that a commitment from senior management is required, but practitioners are likely to already be practising some form of shared decision	Thank you. The committee considered this at length but agreed that SDM would only happen organisation wide if it were driven from the highest level of the organisation.

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				making. Giving them access to additional training and decision aids, may be enough to embed the practice within departments. This would also negate a staggered roll-out.	
British Academy of Audiology	Draft Guideline	005	004	It would be useful to have more specific advice here of how this could be done in practice.	Thank you. With such a broad range of target organisations it is not possible to give specific advice.
British Academy of Audiology	Draft Guideline	005	010	It would be helpful to include more detail about what qualifications/training are required for trainers/champions to ensure consistency.	Thank you. The committee did not see any evidence to suggest what those qualifications might be.
British Academy of Audiology	Draft Guideline	005	011	Training may have significant cost/time implications; how can this be surmounted?	Thank you. We acknowledge that training has time and cost implications. However training is a requirement of professional registration for most professions, and the committee thought that including specific training on shared decision making as outlined in the recommendations would improve access to shared decision making and improve patient’s experience of healthcare. The resource impact of the majority of the recommendations outlined in this guideline are expected to be minimal.
British Academy of Audiology	Draft Guideline	005	013	This implies that it would be valuable if trust IT services were involved from the offset.	Thank you for your comment. IT has an important role in supporting shared decision making but wasn’t the specific focus of this review.
British Academy of Audiology	Draft Guideline	007	006	Can any ‘methods’ be referenced/exemplified?	Thank you. This refers to all methods, not specific ones. Any kind of SDM will most likely need to be tailored to the environment in which it is being delivered.
British Academy of Audiology	Draft Guideline	008	007	Unclear where the additional support would come from. Who would do it? How would it be funded? How would we find ‘nurse, social worker, translator or volunteer (for example, an	Thank you for your comment. These are examples of individuals whose organisations could arrange additional support. The resource impact of the majority of the recommendations outlined in this guideline are expected to be minimal (e.g.,

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				advocate)' that are trained and ready to do the role?	small increases in printing costs as a result of using decision aids or because only minor updates were made to existing recommendations on communicating risk and benefits and therefore should already be part of existing care)
British Academy of Audiology	Draft Guideline	009	003	To 'set aside time' is to take time from something else during an appointment. How do clinicians decide what to omit in order to do this? Or maybe NICE should suggest extra appointment time to allow this process to happen?	Thank you. The committee recommended setting an agenda at the start of the consultation to ensure that priority issues are dealt with first (recommendation 1.2.7), the recommendation you refer to also suggests offering a follow up appointment if necessary to allow people to discuss further.
British Academy of Audiology	Draft Guideline	010	023	Can you define 'up to date'? Published decision aids (e.g. via 'Option Grid') have a 'expiry date' despite still being relevant. Does that mean we cannot use them?	Thank you. These decisions are for NHS organisations when deciding what PDA access to provide.
British Academy of Audiology	Draft Guideline	011	007	It is agreed that patient decision aids should be readily accessible to practitioners, however, if they have to be specific to a clinical area, is there a benefit to creating and maintaining an organisational database? If this is a repository of more general (modifiable) decision making tools, this could be made more explicit in the guideline.	Thank you for your comment. There is currently no national repository for PDAs.
British Academy of Audiology	Draft Guideline	011-012	General	This is very clear with the examples that are given.	Thank you for your support.
British Academy of Audiology	Draft Guideline	017	001-002	The expert evidence described might be useful presented as a little 'case study' so readers have a better insight into what worked and why.	Thank you for your comment. This is the standard format that NICE presents expert testimony and incorporates it into the discussion alongside other evidence. Expert testimony is located in appendix H of evidence review E: "effective approaches and activities to normalise shared decision making in the healthcare system".

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British Academy of Audiology	Draft Guideline	020	006-014	Perhaps the implications/feasibility could be more fully considered here.	Thank you for your comment. For a more in depth committee discussion of SDM see the "committee discussion" sections of the evidence reviews.
British Dental Association	Draft Guideline	004	008-018	Point 1.1.1 – 1.1.4 will be onerous for a small independent practice to implement. This detail describes large organisations/systems or networks but small practices with only one or two dentists – this will not be practical	Thank you. The committee (including a dentistry representative) discussed this and was aware that smaller organisations might need to adapt the recommendations to their environment. The committee reworded 1.1.1 to "This should be a board member or, if the organisation does not have a board, a leader at the highest level of the organisation." to try and make it more relevant to smaller organisations.
British Dental Association	Draft Guideline	011	023-024	This draft guideline covers healthcare professionals however not all regulated professions follow GMC guidance. Dentists will be required to follow General Dental Council guidance contained in Standard for the Dental Team. They cannot follow GMC guidance unless they are dual qualified maxillofacial clinicians. This guidance needs to recognise the other professional regulators.	Thank you. We have edited the rationale to acknowledge that "although GMC guidance is written for doctors they agreed it provided an example of good practice." The committee acknowledged that dentists cannot always follow GMC guidance.
British Dental Association	Draft Guideline	021	008-015	The information on patient decision aids would need to be done at scale and contained within a central repository for small practices to be able to access. Dentistry takes place in small and large dental practices, community dental services and dental departments in hospitals and dental hospitals. One source of patient decision aids would benefit the profession	Thank you for your comment. Dentistry was represented on the guideline committee, so we believe the views of dentists to be appropriately represented. Recommending a national database of PDAs is outside of NICE's remit.

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				without the need to replicate patient decision aids on a local level.	
British Dental Association	Draft Guideline	023 024	030 – 031 001 – 004	The reference to the GMC here again has no relevance for healthcare professions not regulated by the GMC. Dentists can only follow GDC guidance and therefore this should be referenced.	Thank you. The GMC guidance was included as an example ofgood practice, and the committee acknowledge that not all healthcare professionals can follow it (eg. Dentists).
British Dental Association	Draft Guideline	General	General	The use of digital technology has increased for patient consultations during the pandemic. In dentistry, due to the nature of the profession, this has been a new area of development. Shared decision making in relation to digital consultations may need to be considered at a future date.	Thank you. The committee discussed this and agree that the skills for SDM were the same in remote appointments as in face to face, and made a recommendation about this. They also made a research recommendation to understand better how SDM may need to be modified for remote appointments.
British Dental Association	Equality Impact Assessment	002	1.3.5	As in point 3 above producing patient decision aids on this scale for a small practice or dental setting would be very difficult. There needs to be a central repository to enable the information to be provided.	Thank you. The guideline does not recommend that small practices should produce patient decision aids.
British Dietetic Association	Draft Guideline	004	002	Large organisations it would probably be more effective to have leaderships at a more local /team level.	Thank you. The committee agreed that different kinds of organisations would need different models of leadership and so kept the recommendations general enough to be adapted to specific cases.
British Dietetic Association	Draft Guideline	004	005	Should you not recommend what knowledge and skills this board member should have with regards SDM. Just assigning it to someone does not mean they will understand what SDM is, how	Thank you for your comment. There was no evidence found, expert evidence presented or committee experience present

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				to implement it into practice or how to overcome the known barriers. The board member should be required to attend courses or have knowledge of the SDM evidence base to be able to truly lead on Trust wide SDM implementation. The knowledge of SDM should not be surface level knowledge that it is a process that involves both patients and healthcare professionals collaborating in the decision making process. It is so much more than this, and the board member should have this in-depth knowledge.	that justified a recommendation on a particular training for patient directors/board members.
British Dietetic Association	Draft Guideline	004	008	Same as comment above. Patient representative should be provided with training about what SDM is, the benefits, and what it looks like in practice.	Thank you for your comment. There was no evidence found, expert evidence presented or committee experience present that justified a recommendation on a particular training for patient directors/board members.
British Dietetic Association	Draft Guideline	004	014	There should be senior practitioners from each of the Trusts directorates/care groups. These could feed into an appointed senior practitioner.	Thank you. This would be one model that trusts could use. The committee didn't wish to go into this much specificity on the recommendations as they are broad recommendations that apply across a range of settings.
British Dietetic Association	Draft Guideline	005	004	Could there not also be a central area (NHS England) where good practice and decision aids could be stored/shared?	Thank you. This is beyond the remit of NICE.
British Dietetic Association	Draft Guideline	006	005	The training requirements provided are a bit woolly. Could more defined recommendations be included. These may include how to communicate and present risk to patients; how to clarify values; strategies to facilitate the weighing up of risk/benefits; use of advanced communication skills to have these discussions; how to include SDM in a busy clinical	Thank you. Detailing the content of training is beyond the remit of NICE.

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				environment; how to assess and account for health literacy differences between different individuals; levelling the power imbalance in the clinical consultation.	
British Dietetic Association	Draft Guideline	006	008	Could other models of SDM be reference in addition to Elwyn's et al 3 talk model. For example what about Legare's inter professional SDM (IP-SDM) model which has a lot of relevance for how MDT healthcare is delivered. Decisions not always just made between HCP-patient dyad.	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.
British Dietetic Association	Draft Guideline	006	022	Could more detail about what the training could involve be given. I am aware there is a literature base that has evaluated the role of training in the implementation of SDM in practice. In addition to role play, there needs to be a theoretical element that summarises the evidence base for SDM and interventions to implement SDM. Could also suggest assessment of post training knowledge; use of assignments to develop understanding; peer supervision/observation of clinical contacts.	Thank you for your comment. The committee felt they couldn't go into more detail in this recommendation without more evidence or without specifying specific train-the-trainer programs.
British Dietetic Association	Draft Guideline	006	026	Could patient facing pre-consultation decision tools be also mentioned. PENG have produced this list of questions for patients to ask of their HCP's when considering gastrostomy placement: https://www.peng.org.uk/pdfs/hcp-resources/having-an-enteral-feeding-tube-faqs.pdf	Thank you. Preparing patients for SDM is covered in recommendation 1.2.5. The committee saw no evidence for specific pre-consultation shared decision making tools.

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				Could 'preparing patients to engage in SDM' be added as important issue. This should involve reminding patients that they should (if they want to) be involved in the decision making process; encourage that the patients to share their views and to consider how they feel about the options/risks/benefits presented; attempt to level the power imbalance; explain in lay terms what SDM is and how a consultation may look; encourage a questioning style; advise there is not always an obvious 'right answer'. What training is available for patients/ service users? Not everyone is literate/access social media- how to reach minority groups?	
British Dietetic Association	Draft Guideline	007	002	Can you give more explicit examples of decision support tools with some links to examples? E.g. decision aids, option grids, patient information, pre-consultation tools, others	Thank you. Recommending specific decision support tools is beyond the remit of this guideline, however the committee did make general recommendations about the quality of PDAs, see section 1.3.
British Dietetic Association	Draft Guideline	008	005	All HCP's, depending on the decision being made, have responsibility for supporting patients to understand information/resources (not just those suggested).	Thank you for your comment. This recommendation is regarding people who could give *additional* support, suggesting that the healthcare professional should already be providing support themselves. The list of people able to help support the service user is not exhaustive.
British Dietetic Association	Draft Guideline	009	016	Make it clear, that not making a decision or delaying making a decision….is still a decision and that this is ok.	Thank you. Please see recommendation 1.2.10: "openly discuss the risks, benefits and consequences of each option, making sure the person knows this includes choosing no treatment, or no change to what they are currently doing"

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British Dietetic Association	Draft Guideline	009	020	Documentation important. Links in with communication comment above. Could be more detailed in the recommendation about what should be documented.	Thank you. The content of medical notes is beyond the remit of this guideline.
British Dietetic Association	Draft Guideline	010	001	Why only secondary/tertiary care? Decisions get made in primary care that also need to be shared with secondary/tertiary care providers. Would be good not to separate this out and encourage cross setting MDT collaboration when making decisions. Not only GP's that may need to be aware of outcomes of these discussions. Other MDT members have vested interest in decisions being made and may also be delivering decision support. For example, a home enteral feed dietitian may be supporting a patient considering gastrostomy placement. This option may have been introduced to the patient by the GP, who had then referred to acute gastroenterology team for gastrostomy placement. The home enteral feed dietitian would have detailed discussions with patient about what home enteral feeding involves and support decision making. All the stakeholders involved need to be communicating with each other to promote a consistent and collaborative approach.	Thank you. We have clarified this.
British Dietetic Association	Draft Guideline	010	011	More detail required in this section. In reference to multidisciplinary team supported decision making, can there be a reference to the fact that not all decisions are made in one consultation	Thank you. We have edited this recommendation (now 1.1.11) as follows and clarified it applies to an organisation as a whole: "Ensure that expertise and information can be shared effectively both within and between organisations so that

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				and may involve and require input from many members of the MDT. To make this a consistent process, the teams should have a consistent approach to the decision making process, including using consistent information and risk communication to prevent confusion that may lead to decisional conflict. Another important issue is then communication between HCP's within MDT's about how they communicate with each other about the discussions they have had with patients about decisions. This is important to ensure that decision support progresses/builds, does not go over old ground (can be frustrating for patients), and moves forward towards the informed shared decision. Often HCP's do not communicate the detail of their discussions with each other which can lead to information being given by one MDT that contradicts itself, leading to reduced trust in what is being said.	healthcare professionals provide people with consistent information. See recommendation 1.1.7 and section 1.4 of the NICE guideline on patient experience in adult NHS services." In the committee's view, shared decision making should be treated as an ongoing process rather than a one-off event. This is captured in the rationale and impact section of the guideline. "
British Dietetic Association	Draft Guideline	010	015	Though there is an obvious push to use technology to host decision aids, need to appreciate that some demographics still not able to access these due to poor IT skills or lack of hardware. Should recommend that all resources, where possible, are still made available in paper format.	Thank you. The committee did not specify a format for decision aids.
British Dietetic Association	Draft Guideline	010	017	Refer to decision aid repositories? Where can decision aids be found.	Thank you. NICE is not aware of any decision aid repositories.

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British Dietetic Association	Draft Guideline	014	001	Could a more detailed definition of SDM including presenting options; values clarification; weighing up risks/benefits for the individual; making a decision; reviewing the decision; checking understanding.	Thank you for your comment. The definition of SDM was agreed at scoping stage including consultation.
British Dietetic Association	Draft Guideline	014	013	Research questions: How do MDT's deliver a consistent approach to SDM; User centred design and evaluation of complex interventions to implement system wide SDM; how to facilitate SDM in the different phases (pre/during/post consultation); How to overcome the reported barriers to SDM in practice (time; out-of-date resources; lack of HCP buy-in; lack of knowledge/skills)	Thank you for your comment. We believe RQ 1 is covered by research recommendation 3: "What interventions are most effective at transferring shared decision making skills between people and departments, and in sustaining the implementation of shared decision making in an organisation and in clinical teams?" Research recommendations are to address gaps in the research as identified by the committee, and it is felt that barriers to SDM in practice and facilitating SDM have been covered in this review, and that the current research recommendations are of a higher priority.
British Dietetic Association	Draft Guideline	016	015	I would have liked to see more commitment to implementing SDM. Rather than having 'champions' where this would be part of many roles, I think, particularly within large organisations e.g. NHS Trusts; Social services, that this could be a whole role in itself (or even requires multiple individuals to drive through quality initiatives and training. This role could come under the quality improvement teams remits.	Thank you for your comment, for information on implementing SDM see evidence review E, and recommendation section "Planning and implementing shared decision-making". The recommendations cover embedding SDM from the highest leadership levels down to other staff in this section.
British Dietetic Association	Draft Guideline	016	024	Need to ensure digital health funding is made available to support this as devices to support this are expensive.	Thank you for your comment.

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British Dietetic Association	Draft Guideline	017	001	Can you expand on what 'successfully implementing SDM' looks like?	Thank you for your comment. This sentence refers to the use of expert testimony during the development of this guideline. Due to the lack of evidence found in the published literature on effective approaches and activities to normalise shared decision making, the committee agreed to ask those who have successfully implemented SDM, i.e., experts or examples of good practice in the field to contribute to the evidence base to allow the committee to make recommendations. This is part of our NICE guideline methodology https://www.nice.org.uk/process/pmg20/chapter/introduction
British Dietetic Association	Draft Guideline	017	003	Can you explain why SDM will create inequalities?	Thank you for your comment. This was referring to a potential uneven rollout of SDM, where services that found the most barriers to SDM implementation would be the last to benefit from it.
British Dietetic Association	Draft Guideline	018	028	This is why there needs to be a research recommendation for development of complex interventions e.g. using programme grant opportunities, to design and evaluate approaches/interventions that tackle the continuum of decision making from option introduction through to following through on decisions made.	Thank you. The research recommendations are specifically for the committee to recommend research to fill gaps in the evidence that made it more difficult for them to make recommendations.
British Dietetic Association	Draft Guideline	General	General	I feel the training and education of healthcare professionals with regards SDM is so important in the successful implementation of SDM in practice. Firstly this is to convince HCP's that SDM is important. If they don't buy in to the	Thank you. It is outside of NICEs remit to recommend training standards, which are set by professional bodies. The guideline does contain a section on supporting practitioner skills and competencies (See recommendations 1.1.12 to 1.1.15)

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				concept they will not entertain using the process. Training and education should have a section in the guidance to itself (can now see this is included but could be more detailed), with more constructive guidance on what this training should include and who will deliver it. Ideally this training should be overseen by the senior board level/senior practitioners, and deliver on the ground by HCP's within each directorate/department. For this to be successful though this needs to be part of the individuals job plans and job descriptions, as there will be no way this will work if it is a role just added to already busy HCP's workloads (as seen with many other quality initiatives where HCP time is not made available officially).	
British Dietetic Association	Draft Guideline	General	General	I am sure this will appear in the final guidance, but it is really important to have a clear definition of what you mean by the concept 'shared decision making' breaking the process down into its separate parts. This will encourage a greater depth of understanding of what is requiredHCPs demonstrated the surface level understand that it requires involvement of patients and HCP (i.e. SDM does what it says on the tin), but often have lesser appreciation for the process of integrating patient values, and the communication and weighing up of evidence based risks/benefits.	Thank you. Shared Decision Making is defined in the 'terms used in this guideline' section and the definition is hyperlinked from each section of the guideline.

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British Dietetic Association	Draft Guideline	General	General	Should rewards (?financial/staff resource) be proposed for the implementation of SDM policies/practice? I understand this has been successful in the US for the successful implementation of SDM.	Thank you. The committee did not consider any evidence about the use of rewards and so was unable to make recommendations about this.
British Dietetic Association	Draft Guideline	General	General	I love the idea of having patient SDM champions and also to involve them in the training of HCP's. This would be so powerful.	Thank you. The committee heard testimony about the effectiveness of this approach.
British Dietetic Association	Draft Guideline	General	General	Could encouragement be given to develop innovative patient information or decision aid resources. An example of innovative information is the mytube website to support people with MND making decisions about gastrostomy: https://mytube.mymnd.org.uk/	Thank you. The development of PDAs is beyond the remit of this guideline.
British Dietetic Association	Draft Guideline	General	General	To ensure inclusivity, throughout the document there should be reference to making SDM materials and approaches available to diverse population taking into account religious beliefs, cultural backgrounds, language, communication difficulties, different demographics (education/health literacy etc). So far I have not seen any mention of this, and should be more than a sweeping statement at the end about inclusivity and diversity to provide more reminders to reader.	Thank you. Please see recommendation 1.2.6. The committee also made research recommendations to address this. Please see research recommendations 1 and 4.
British Dietetic Association	Draft Guideline	General	General	Should the place of HCP's making a recommendation about what decision to make be discussed. Though a shared approach to decision making should be advocated some	Thank you. Please see recommendation 1.2.8 The committee discussed this at length and agreed that it was important to advocate SDM as the norm and not give HCPs a 'get out clause'.

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				people still want their HCP to make a recommendation. This is particularly relevant in high stakes decisions and where decisions need to be made quickly.	
British Dietetic Association	Draft Guideline	General	General	As SDM needs to be a cultural shift for both healthcare staff and patients. Further recommendations could be: o SDM should also be part of Medical/clinical training for all healthcare staff o Should it also be something that covered within school education for the population.	Thank you. Medical and clinical training is outside of NICEs remit with training standards being set by professional bodies. Similarly, NICE has no influence over the national curriculum.
British In Vitro Diagnostics Association	Draft Guideline	004	004	Whilst high level leadership is critical, the appointed person would need to be someone with experience in patient care, although recognised that a joint approach (1.1.2) and (1.1.3) is advocated, a seniority risk could occur with other priorities.	Thank you. The committee felt based on expert testimony and their experience of implementing SDM from both a healthcare professional and a service user perspective, that the roles as defined in 1.1.1 – 1.1.4 were the best way to broadly achieve these aims across organisations, and felt being to specific with who to assign roles may cause problems for different types of organisation.
British In Vitro Diagnostics Association	Draft Guideline	005	002	The plan contents should ensure that shared decision making is embedded within a quality management system to monitor and record progress and this is linked to the appointment of a senior board member for governance of the different bullet elements listed. If a process like this sits outside of a quality management system, it will never be embedded into the organisation. Where appropriate, it should also be introduced in to core job responsibilities for staff development. In addition to this, and	Thank you. Recommendation 1.1.9 covers monitoring and evaluation.

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				existing process or procedure should be removed to avoid a layering effect for staff.	
British In Vitro Diagnostics Association	Draft Guideline	006	002	This guideline is fully supported and interpreted to mean to enable to existing staff to adopt the focus within their current roles.	Thank you for your support.
British In Vitro Diagnostics Association	Draft Guideline	007	002	This section seems to only address shared decision making in terms of a longer care plan, it should include some guidance and criteria that assists in shared decision making for urgent or critical health decisions.	Thank you. Urgent or critical decisions where the person is unable to participate in SDM are excluded from this guideline. See also recommendation 1.2.2 which discusses tailoring SDM methods to the setting. However, the committee acknowledged that some SDM processes are still applicable to more urgent settings, and that the recommendations could be followed from the point of "during discussions with a healthcare professional" onward into aftercare, as SDM is an ongoing process there will then be future discussions after the urgent care in which these "before discussions with a healthcare professional" recommendations could be followed. The committee were clear that if the patient was still able to participate SDM recommendations should still be followed as closely as they can be.
British In Vitro Diagnostics Association	Draft Guideline	008	024	This is very welcome. We would encourage this part of the process to fully consider the requests of individuals for specific tests (appropriate to their condition or possible condition) and to make sure that if they have any concern with regard testing, that this is discussed. Further	Thank you. The committee recommended openly discussing each option.

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				that diagnostic testing is suggested and offered more widely based on their requests and needs.	
British In Vitro Diagnostics Association	Draft Guideline	010	012	Whilst the sharing of information in terms of expertise and best practice is included, there needs to be a more specific review mechanism linking to Guideline 1.1.1 and 1.1.5 with regards to any complaint, or errors made. A management review programme of success and sub-optimal results needs to be embedded within the organisation, the staff and external services and partners to secure a learning environment and a continual improvement of care.	Thank you for your comment. Monitoring and feedback from staff and service users will be captured as mentioned in recommendation 1.1.9: "Plan internal or external monitoring and evaluation (including service user and staff feedback activities) and how to feed back the results to staff at individual, team and management level."
British In Vitro Diagnostics Association	Draft Guideline	General	General	The guidance on shared decision making is welcome and a formalised approach to an activity which is usually undertaken in a time of significant stress and uncertainty should enable all considerations to be addressed in a trust-worthy and methodical manner. A concern with a more methodical approach would still be the requirement for those involved in leading a shared decision approach to be accommodating and understanding of individual needs and to retain the flexibility of a personalised approach with individuals. It would be a failure of care to try to fit individual needs into a strict framework and this risks situations where an individual cannot feel listened to, or part of the process.	Thank you for your support.

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British Society of Gastroenterology	General	General	General	Chronic disease patients like Inflammatory Bowel disease patients should receive a comprehensive care plan that is based on SDM decisions.	Thank you for your comment. This is a general guideline for SDM and does not provide recommendations for specific disease areas.
British Society of Gastroenterology	General	General	General	Chronic disease services are under enormous strain at present and will take time to clear follow-up backlogs. Therefore, time and resources should be commissioned for SDM to be initiated.	Thank you for your comment. This is a general guideline for SDM and does not provide recommendations for specific disease areas.
British Society of Gastroenterology	General	General	General	The level of time and resources needed for SDM depends on the situation. Like when taking consent the time and effort required should reflect the complexity of the situation. For example a simple decision can we have a blood test requires less time and effort than a complex decision on deciding between medical and surgical therapy.	Thank you for your comment.
British Society of Gastroenterology	Recommendations	007	018-020	Appointments for urgent care / decision making should not be delayed to offer additional pre-appointment material when clinical needs dictate an urgent decision to be made (for example an Inflammatory Bowel disease patient experiencing a moderate to severe flare)	Thank you. We do not suggest delaying appointments for this reason and have clarified this.
British Society of Gastroenterology	Recommendations	008	018-020	Some patients don’t take up the offer of shared decision making. They voice opinions like “Doctor, do what you think is best.” When a patient offers this view that should be respected and no decision making forced upon the patient.	Thank you for your comment. Our context section discusses that patients may choose to what extent they want to involve themselves in decision making.

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British Society of Gastroenterology	Recommendations	008	027-029	Clinicians should be reassured that they can clearly state when offering choice which choice is medically preferred and should explain why. SDM shouldn’t mean having to offer choices deemed medically not appropriate. These important considerations should be reflected.	Thank you for your comment. We feel this is covered by "explain the healthcare aims of each option" and "openly discuss the risks, benefits and consequences of each option" statement within recommendation 1.2.10
British Society of Gastroenterology	Recommendations	010	006-010	Recordings should only be ever made with the clear and explicit consent of everybody taking part in the consultation.	Thank you for your comment.
British Society of Lifestyle Medicine	Draft Guideline	General	General	We welcome this NICE guidance on shared decision making, which includes relevant breadth of disciplines and expertise, notably including Richard Thomson and appropriate lay representation.	Thank you for your support.
British Society of Lifestyle Medicine	Draft Guideline	General	General	The approach is robust, as expected, with a refreshing simplicity in the three-talk model recommended rather than other more complex options. There is concise and practical summary of engagement in shared decision making, interventions to support it, decision aids, risk communication, approaches/activities to normalise it.	Thank you for your support.
British Society of Lifestyle Medicine	Draft Guideline	General	General	However, mainly as a consequence of the development as a conventional (rather than rapid COVID) guideline, there are some striking omissions, which impact the generalisability of	Thank you for your comment.

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				the final guideline in the current healthcare environment. Namely:	
British Society of Lifestyle Medicine	Draft Guideline	General	General	There is no mention of shared decision making in a virtual or remote context, which has become essential during the pandemic (https://bslm.org.uk/vgc, Birrell et al, 2020), as well evidence that it is cost effective (e.g. Abrams et al, 2020). Abrams EM, Shaker M, Oppenheimer J, Davis RS, Bukstein DA, Greenhawt M. The Challenges and Opportunities for Shared Decision Making Highlighted by COVID-19. J Allergy Clin Immunol Pract. 2020 Sep;8(8):2474-2480.e1. doi: 10.1016/j.jaip.2020.07.003. PMID: 32679348; PMCID: PMC7358768. Birrell F, Lawson R, Sumego, M, Jessica Lewis, Harden A, Taveira T, Stevens J, Manson A, Pepper L, Jeannette Ickovics J. Virtual Group Consultations Offer Continuity of Care Globally During Covid-19. Lifestyle Medicine 2020. https://doi.org/10.1002/lim2.17	Thank you for your comment. The skills of SDM in remote settings are the same as in face to face settings, and this has been added to the rationale and to a recommendation. The committee acknowledged the changing situation with an increased reliance on remote discussions, but felt more evidence was needed to make a specific recommendation, and thus a research recommendation has been added to look at evidence for remote discussions.
British Society of Lifestyle Medicine	Draft Guideline	General	General	There is no consideration of group approaches to care and shared decision making in that context, which is often implicit (Jones et al, 2019), but increasingly made explicit (Liu et al, 2021). There is some evidence that shared	Thank you. This was outside of the scope for this guideline. We will pass your comment**s and suggested references** to the NICE surveillance team which monitors guidelines to ensure that they are up to date.

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				decision making in groups may be more effective (and this is likely, due to strong effects on self-efficacy and empowerment; Wilton-Clark et al, 2020, Russell-Westhead et al, 2020, Jones et al, 2019) as well growing evidence it is cost effective (e.g. Baqir et al, 2020). Baqir W, Gray WK, Blair A, Haining S, Birrell F. Osteoporosis Group Consultations Are As Effective As Usual Care: Results From A Non-Inferiority Randomized Trial. Lifestyle Medicine 2020. https://doi.org/10.1002/lim2.3 Jones T, Darzi A, Egger G, Ickovics J, Noffsinger E, Ramdas K, Stevens J, Sumego M, Birrell F. A Systems Approach to Embedding Group Consultations in the National Health Service. Future Healthcare Journal. 2019; 6: 8-16 Liu CS, Feasel AL, Kline GA, Billington EO. Pharmacotherapy decisions among postmenopausal women attending a group medical consultation or a one-on-one specialist consultation at an osteoporosis center: an observational cohort study. Osteoporos Int. 2021 Jan 18. doi: 10.1007/s00198-021-05823-8. Epub ahead of print. PMID: 33462652.	

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				Russell-Westhead M, O'Brien N, Goff I, Coulson L, Pape J, Birrell F. Mixed methods study of a new model of care for chronic disease: co-design and sustainable implementation of group consultations into clinical practice. Rheumatology Advances in Practice 2020. https://doi.org/10.1093/rap/rkaa003 Wilton-Clark MS, Feasel AL, Kline GA, Billington EO. Autonomy begets adherence: decisions to start and persist with osteoporosis treatment after group medical consultation. Arch Osteoporos. 2020 Sep 5;15(1):138. doi: 10.1007/s11657-020-00809-1. PMID: 32888079.	Thank you. We will forward this information to our surveillance team for their consideration.
British Society of Lifestyle Medicine	Draft Guideline	General	General	Although alluded to in the <u>Clinical guide for the management of remote consultations and remote working in secondary care during the coronavirus pandemic</u>, for 'some group appointments, for example stroke support groups, group rehabilitation sessions', a stronger indication of the strategic benefits of comments 5 & 6 are needed for this guideline. As a minimum, inclusion as separate points in 'Recommendations for Research'. However, given the lack of harm and considerable benefits from leveraging stretched clinical resources, delayed care for chronic disease and capacity of group consultation models to meet healthcare's quadruple aim (good outcomes, efficiency,	

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				patient & clinician experience; Sikka, Morath & Leape, 2015, https://bslm.org.uk/vgc), there is an argument for stronger statements in favour, in the conclusions and summary sections of this guideline. Our organisation has had experience of implementing this approach (https://bslm.org.uk/vgc) and would be willing to submit its experiences to the NICE shared learning database. Sikka R, Morath JM, Leape L. The Quadruple Aim: care, health, cost and meaning in work. BMJ Qual Saf. 2015 Oct;24(10):608-10. doi: 10.1136/bmjqs-2015-004160. Epub 2015 Jun 2. PMID: 26038586.	
Brook centres	Draft guideline	005	016 – 019	This recommendation is something that young adults are interested in, being fully equipped with information about past decision making about their bodies. It could also make it easier for patients to understand how to request their records. In practice this would cause additional administrative work.	Thank you for your comment.
Brook centres	Draft guideline	006	029-030	This idea is favourable. Often more time is needed to understand how to answer the question following the appointment/visit to the clinic. Therefore, this recommendation might need to consider how that feedback could be	Thank you. We believe this is covered in recommendations 1.2.14 and 1.2.15.

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				gathered. For example, could service-users email or text their answers after some more thought.	
Brook centres	Draft guideline	007	019-020	This recommendation is something that could also be supported via videos. For example, a tour of the clinic/service, what to expect. An animation about the procedure, like what a smear test or a coil fitting involves. Videos would need to be accessible. Content would have to ensure inclusivity and accessibility around language, representation and learning styles.	Thank you. We agree this would be a way to implement this recommendation.
Brook centres	Draft guideline	008	021 – 023	In terms of sexual health, we need to move away from assumptions that people know and understand their body and therefore breakdown the procedure. For example, asking a patient to perform a self-swab; how would they like this explained to them; verbally, pictorially, or do they not want a self-swab? Can they make this choice themselves? When having a cervical smear how can the experience be more comfortable for them; is the test explained before the person arrives at the appointment; if so, how has it been explained; can they reiterate this process to the clinician, to create a sense of empowerment over the process.	Thank you for this information. The committee did not feel this recommendation prevents the healthcare practitioner from breaking down the steps of a procedure to a service user. If the healthcare professional is concerned there is an issue with understanding, we have added a recommendation for the "teach back" method outlined in recommendation 1.2.11 which can help confirm the information being provided is being understood.

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Brook centres	Draft guideline	010	017 – 021	The recommendations in relation to patient decision aids is an area we would like to share good practice examples within sexual health clinical services. In some of our services we use the SXT emergency contraception calculator during telephone appointments with clients. This provides the client with the opportunity to understand the different methods of emergency contraception available, identify the level of risk, and consider their menstrual cycle. The client is encouraged to keep a copy of the calculator results and bring to the consultation ready as a point of reference. This helps the client to prepare for the consultation, and empowers them about the different methods of emergency contraception available and why. This supports their decision-making, and offers them an aid to draw upon before, during and after the consultation. The second tool we would like to highlight is the SXT Partner Notification online tool. We find that during consultations clients can find it difficult to discuss partner notification whereby the online tool allows them more time to decide whether they want to support this process, but it is still a choice. The tool allows anonymity, and by having the tool it is another method in which clients can make decisions about health. The process also links to a booking system so the	Thank you for your comment.

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				person notified can decide whether they want to have an appointment online without having to call a service. The process cuts down administration time.	
Brook centres	Draft guideline	015	006 - 007	Comment - encouraging people to think about their values/priorities before being presented with options may encourage them to make the most suitable choice for them, rather than trying to determine what they value while simultaneously processing their situation. Many service-users can in the moment often ask the clinician what they would do in their position. More reflection time, which feeds back into preparation of the appointment, is needed. Time might not always be an option.	Thank you for your comment. Recommendation 1.2.5 discusses the "preparation stage" of an appointment which would involve resources that help prepare service users for discussing options, this will involve thinking about their values and preferences.
Brook centres	Draft guideline	018	025 – 027	This recommendation provides challenges for people experiencing controlling/exploitative/abusive relationships (including family), and therefore always needs sensitive planning to ensure the patient has the option of attending independently in the first instance	Thank you for your comment. Recommendation 1.2.3 mentions to readers to be aware of safeguarding.
Brook centres	Draft guideline	021	004 – 007	From experience of working with young adults, often forms of communication such as apps, live chat, online questionnaires etc. could all be used instead and shared with medical professionals (with printed versions available on request),	Thank you for your comment. The printer issue is just an example, the key point here is that decision aids should be available in many different formats to ensure they're accessible to all patients.

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				which can be more accessible. Many people not owning or having access to a printer.	
Caesarean Birth	Draft Guideline	004	001	Re: "People have the right to be involved in discussions and make informed decisions about their care, as described in this guideline and NICE's information on making decisions about your care." This recommendation will be challenging in practice in maternity care because information about different birth modes is currently withheld by many NHS Trusts, and there is recent evidence that women who request a caesarean birth are not supported throughout the country: See Birthrights 2018 report https://birthrights.org.uk/wp-content/uploads/2018/08/Final-Birthrights-MRCS-Report-2108-1.pdf).	Thank you. Whilst this is standard text and is in all NICE guidelines, we are currently exploring the impact the SDM guideline will have on wider guidance and the wording we will use.
Caesarean Birth	Draft Guideline	004	005-018	Re: Appointing board member, patient director, senior practitioners and one or more service user champions. Suggest also recommending appointing someone to specifically check how well decision making is working in the context of Montgomery, and to measure patient satisfaction.	Thank you. Recommendation 1.1.9 talks about monitoring and evaluation. "Plan internal or external monitoring and evaluation (including service user and staff feedback activities) and how to feed back the results to staff at individual, team and management level."

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Caesarean Birth	Draft Guideline	006	011	Re: sharing and discussing the information people need to make informed decisions, and making sure they understand the choices available to them (including the choice of doing nothing or not changing the current plan) Following on from comment #5, is there anyone appointed within NICE to follow up when recommendations in its guidelines are not being followed? And/or is there any process of follow-up planned following the implementation of this guideline? For example, research to establish whether it has any subsequent effect on litigation claims.	Thank you. Recommendations in NICE guidelines are not mandatory. The NICE implementation team engage with organisations about implementing NICE guidelines and feed back into the surveillance process for revising guidelines.
Caesarean Birth	Draft Guideline	006	025, 029-030	Re: Promoting shared decision making to people who use services • 'What are my options?' • 'What are the possible benefits and risks of those options?' Again, this recommendation will be challenging in practice in maternity care.	Thank you for your comment.
Caesarean Birth	Draft Guideline	009	016-018	Re: At the end of an appointment, state clearly what decisions have been made to make sure the person agrees with and understands what has been decided, The wording here is concerning.	Thank you. We have reworded this to make sure there is a shared understanding between the person and their healthcare professional about what has been agreed. Regarding when a decision in not shared, the rationale and impact section states “The committee noted that some people

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				The decisions "have been made" by whom? "…make sure the person agrees with… what has been decided". Again, by whom? Could this be worded more clearly, in line with Montgomery? Also, it would be helpful, in a practical sense, if the guideline provided recommendations about what do to when a decision is not shared; when patient and healthcare professional disagree (explicitly stating a patient's rights, rather than alluding to them).	may not want to be involved in shared decision making. They also noted that not all decisions can be shared. People have a right to refuse any treatment, and similarly, healthcare professionals are not obliged to provide any treatment that in their clinical opinion is medically futile (this may require a second opinion or discussion with a senior colleague)."
Caesarean Birth	Draft Guideline	009	024-028	Re: Give people resources to help them understand what was discussed and decided in their appointment. This could be a printout summarising the options and decisions or plans made, and links to high-quality online resources (for example, relevant NICE guidelines). Ideally, give people this material to take away, or provide it very soon after the appointment. In my organisation's experience, women trying to plan a caesarean birth often bring a copy of the NICE CG132 recommendations with them, and yet are still not always provided with appropriate support in their birth plan decision. While this guideline needs to cover all areas of care provided by the NHS, given the cost of	Thank you for your comment.

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				litigation claims for maternity care, reviewing the guideline with maternity care in mind would be a very useful exercise.	
Caesarean Birth	Draft Guideline	010	006-010	Re: Offer to provide additional support to people who are likely to need extra help to share in making decisions. This could include encouraging them to record the discussion during their appointment, explaining in writing the decisions that have been made, or arranging follow-up by a clinical member of staff or a suitable alternative. This is a very helpful statement for people who may need extra support. Is it possible to include a statement that also recognises those people who are more comfortable in coming to a decision without extra help?	Thank you for your comment, the presumption is the rest of the guidance is relevant to those who do not need additional support also.
Caesarean Birth	Draft Guideline	014	002-003	Shared decision making is a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care. Why is the phrase "joint decision" included here? This contradicts NICE's assurance (see comment #2) it would make clear that the decision is ultimately the patient's: "*We have amended the scope to clarify that while the process of reaching a decision is*	Thank you for your comment. The definition of SDM was agreed at scoping stage including consultation.

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				shared, ultimately this is to support the person to reach a decision about their care." p.14 It is important to remove this inconsistency, and again, highlights valid concerns with the term 'shared decision making' leading to a 'joint decision'.	
Caesarean Birth	Draft Guideline	017	023-024	In the committee's view, shared decision making should always be treated as an ongoing process rather than a one-off event. In practice, in maternity care, this can cause unnecessary stress and anxiety for women who request a caesarean birth, but are told the final decision will not be made until ≥36 weeks into their pregnancy. Appointments for mental health support, discussions with multiple healthcare professionals, and attendance at birth clinics (examples of which in CQC reports state their aim is to reduce the caesarean rate) are all methods used to prolong the decision making, and this can be against the woman's will. My organisation asks that NICE removes the word "always" from this sentence, and replaces it with "may", in order to help protect women from experiences like this.	Thank you for your comment. SDM is a process that takes place over time and over space, between different people. However, whilst SDM is an ongoing process, the service user can decide how much they want to involve themselves in decision-making at every stage, and also always has the right to make no decision, as stated in the guideline. This description of SDM as a process should not be used as coercion to prolong making a decision.

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Caesarean Birth	Draft Guideline	022	001-004	The committee agreed that a person can only make an informed decision if they are given enough information to do so, and if the risks, benefits and consequences presented to them relate directly to their circumstances and what is important to them. Agree entirely. However, this is challenging in maternity care as many NHS Trusts (and their staff) can be selective with the information provided to women regarding their mode (not place) of birth choices.	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.
Caesarean Birth	Draft Guideline	023	020-022	Following the Montgomery v Lanarkshire case (2015), a new legal standard was set to protect patients' rights to make informed decisions when giving or withholding consent to treatment. See wording suggestion in comment #3.	Thank you for your comment.
Caesarean Birth	Draft Guideline	023-024	030-031 001-004	The General Medical Council's guidance on decision making and consent (published in 2020) says that healthcare professionals should discuss 'risks of harm and potential benefits that the patient would consider significant for any reason. These will be revealed during your discussion with the patient about what matters to them'. It also states that they should discuss 'any risk of serious harm, however unlikely it is to occur'.	Thank you for your support.

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				This is a very useful statement, and welcome in the draft guideline. In the context of maternity care in particular, information about stillbirth and pelvic floor damage risks is often lacking in antenatal care communication.	
Caesarean Birth	Draft Guideline	General	General	My organisation understands, from the 2019 NICE response to comments submitted during the Scope consultation, that the reason behind the guideline's name (Shared decision making) is consistency with other publications within the NHS: "*The terminology used in the scope, shared decision-making, links in with national policy and initiatives, including the recently published NHS Long Term Plan and NHS England's Personalised Care Group's shared decision making programme. We feel it is important to keep the terminology consistent across national strategies and plans.*" p.13 https://www.nice.org.uk/guidance/gid-ng10120/documents/consultation-comments-and-responses However, neither the word "share" nor "shared" appears in the 2015 Montgomery judgment: https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf	Thank you. NICE was asked to prepare guidance on shared decision making. That is the term in general use and the term that was used throughout scoping and development of the guideline. To acknowledge the use of a different definition for shared decision making within the context of maternity services the following text has been added to the context section of the guideline – 'in line with NHS England's personalised care and support planning guidance: guidance for local maternity systems, in maternity services this may be referred to as 'informed decision making'.

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				My organisation maintains, following its Scope comments (*on pages 19-23*), that the phrase 'shared decision making', in the context of Montgomery, is not appropriate for use in maternity care. It very much risks women being pressured into making decisions (and without all the available information), that are not aligned with their own personal preferences or tolerance of risks. https://www.nice.org.uk/guidance/gid-ng10120/documents/consultation-comments-and-responses Please see: Elwyn G et al. Shared Decision Making: A Model for Clinical Practice. J Gen Intern Med. 2012 Oct; 27(10): 1361–1367. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3445676/ "*…we propose a model of how to do shared decision making that is based on choice, option and decision talk. The model has three steps: a) introducing choice, b) describing options, often by integrating the use of patient decision support, and c) helping patients explore preferences and make decisions. This model rests on supporting a process of deliberation, and on understanding that decisions should be influenced by exploring and respecting "what*	

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				matters most" to patients as individuals, and that this exploration in turn depends on them developing informed preferences." In maternity care, this model frequently fails on all three steps (highlighted in bold). Choice is introduced in the context of birth place only, options described do not consistently include planned caesarean birth (even when a woman has risk factors such as advanced maternal age, short stature, suspected macrosomia, previous birth trauma, family history of obstetric complications), and preferences can be ignored or downplayed. A number of other charities and organisations have also raised concerns in public regarding this title, and this is something other areas of the NHS could consider when next revising their policy documents. Information may be shared, but the decision (which might be to decline making a decision, and defer to the health professional's advice) should rest with the patient. Would NICE consider taking the lead on this, and change its wording to 'Informed decision	

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				making' (or similar)?	
Caesarean Birth	Draft Guideline	General	General	The 2019 NICE response to comments submitted during the Scope consultation also state: "*We have amended the scope to clarify that while the process of reaching a decision is shared, ultimately this is to support the person to reach a decision about their care.*" p.14 Can NICE please clarify specifically how this clarifies what is outlined in the Montgomery judgment? In practice, 'supporting the person to reach a decision' in maternity care often involves 'recommending' and 'encouraging' one birth plan over another, and even restricting access to alternative choices. For example, in a decision about planning a VBAC or repeat caesarean birth, this London NHS Trust states: "You will not be seen by an obstetrician in the absence of any medical complexities or other concerns." https://www.chelwest.nhs.uk/services/maternity/pregnancy-birth/your-pregnancy/vaginal-birth-after-caesarean-at-chelsea	Thank you. This guideline sets out recommendations for healthcare organisation and practitioners to improve shared decision making. Several of the recommendations refer to providing the support that people may need, (1.2.1, 1.2.3, 1.2.6)

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				Therefore, while the draft NICE guideline states, "people have the right to be involved in planning and making decisions" (e.g. lines 27-28, page 23), in practice, this is too weak an interpretation of Montgomery, and open to interpretation within the NHS. Patients have more than the right "to be involved" in "making decisions", and my organisation would welcome a more succinct clarification of this. Thank you.	
Caesarean Birth	Draft Guideline	General	General	There is no clear, practical information about what NICE recommends when a patient and their healthcare professional do not agree on the decision. When the decision is not shared. Can this be included?	Thank you. The committee discussed this and added some detail to the rationale and impact section to reflect when a shared decision might not be possible.
Caesarean Birth	Draft Guideline	General	General	Thank you for this opportunity to comment	Thank you for your comments.
Caesarean Birth	Evidence review C	005	027-036	Re: A landmark ruling was made in 2015 by the UK Supreme Court following the Montgomery v Lanarkshire case. A new legal standard set out that adults 'of sound mind' are entitled to make informed decisions when giving or withholding consent to treatment or diagnosis. Consent 'must be obtained before treatment interfering	Thank you for your comment. The Montgomery ruling is cited and summarised in the "context" section of the guideline.

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				with bodily integrity is undertaken', and it should only be gained when patients have shared a decision informed by what is known about the risks, benefits and consequences of all reasonable NHS treatment options. It is the healthcare professional's duty to 'take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.' The words highlighted in bold are key, and my organisation suggests including them in the guideline itself.	
Cardiff University	Draft Guideline	006	001	Regarding the section – 'Supporting practitioner skills and competences' We agree with the recommendations here. However, we think it should be emphasised that tailored and more specific training might need to be provided to healthcare professionals who support patients with different decision support needs (e.g. for patients who lack capacity, patients with lower levels of literacy, younger patients who have recently transitioned to adult services)	Thank you for your comment. These recommendations were related to training for SDM, and the committee felt the training mentioned would fall under recommendation 1.1.12 and also these groups would be covered by recommendation 1.2.6. If organisations are following NICE guidance this consideration of those with additional support should then be considered when following recommendation 1.1.12. Patients who lack capacity are excluded from this guideline (please see section 3.1 of the scope document - https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)
Cardiff University	Draft Guideline	006	025	Regarding the section – 'Promoting shared decision making to people who use services'	Thank you. The committee did not see evidence to support any particular ways of doing these, and given the variety of venues

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				We are concerned about the limited detail in relation to 'offer people training' – what does this mean, what would be the main aim of that training, and what would the training involve? We are also concerned about the feasibility of this intervention in routine healthcare services. We also feel that further information should be provided regarding placement of the posters and other media. Are these for waiting areas / public spaces only, or should they be placed in consultation rooms (thus increasing the sense of 'permission' to participate), or both? Could these be sent as part of appointment letters to encourage participation?	and services in which this guideline applies, did not want to be too prescriptive. Offering training is given as an example, and the committee felt that offering training to service users is fair and balanced if you are offering training to healthcare professionals, and helps to create a collaborative space with service users and healthcare professionals on an equal footing. Both need to be involved in SDM Monitoring and evaluation (as recommended) will identify strengths and weaknesses in individual organisations' strategies.
Cardiff University	Draft Guideline	008	018	We agree with this stage. However, we feel that the guideline needs to emphasise that at this stage the 'rationale' for shared decision making should be explicit by the healthcare professional. This is included in the 'Choice Talk' phase of the Three Talk Model, but I think it is important to make sure this is clear to Guideline users. The rationale increases buy-in from patients.	Thank you. We believe this is covered in the 'before a discussion' section as 'rationale for SDM' would be covered in SDM resources that are reliable and of high quality (see recommendation 1.2.4 and 1.2.5).
Cardiff University	Draft Guideline	010	015	Regarding the section 'Patient decision aids' We have published a realist review of what works in embedding patient decision aids in	Thank you. NICE guidelines are targeted at practitioners. Recommendation 1.4.3 outlines that organisations should ensure that staff presenting information about risks, benefits

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				routine healthcare settings, on behalf of the International Patient Decision Aid Standards Collaboration, which could be considered: https://journals.sagepub.com/doi/full/10.1177/0272989X20978208 Importantly, we would argue that patient decision aids should be delivered by individuals who have undergone shared decision making training, and who have the necessary skills to involve patients in a discussion. There is also no mention of the 'Patient group' in this section, which is concerning given that these are patient-targeted tools used by both practitioner and patient. Current framing of this section feels more like these are clinician-targeted / owned tools.	and consequences to people have a good understanding of that information and how to apply and explain it clearly
Cardiff University	Draft Guideline	General	General	This document focuses on shared decision making in adult services specifically. We appreciate that different approaches will be needed in neonatal and paediatric settings, where parents / carers are also involved in the decision making processes. Could the Guideline offer some information on supporting patients who are transitioning from paediatric to adult care settings, and the specific challenges that might be faced, and how they can be overcome?	Thank you. Children and young people under 18 are excluded from this guideline. Please refer to the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents) However, please note that NICE is currently developing a guideline on patient experience of healthcare for babies, children and young people, which considers shared decision making. Please see

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					https://www.nice.org.uk/guidance/indevelopment/gid-ng10119 for information on the development of this guideline
Cardiff University	Draft Guideline	General	General	We feel that that the Guideline could benefit from the voice of the rare disease community and the specific shared decision making challenges are faced by patients living with rare diseases. On behalf of the Shared Decision Making in Rare Disease in the UK Working Group, below I include a White Paper we have prepared which presents these challenges: http://www.primecentre.wales/resources/210125_SDM%20in%20Rare%20Disease%20White%20Paper_V3_Final.pdf	Thank you. This guideline aims to provide generic recommendations about shared decision making that are applicable in all healthcare interactions.
Care Quality Commission	Draft Guideline	004	005 - 018	The use of consider for item 1.1.2 makes the list confusing – are 1.1.3 and 1.1.4 also to be considered as optional? If they are requirements it would be helpful to make this clearer. We advise this because if not clearly identified as such, there is a risk that providers which do need to improve their patient involvement and empowerment infrastructure will ignore them as being optional in meeting the aims of the guidance.	Thank you. NICE uses language in recommendations in a specific way. Making decisions using NICE guidelines explains how we use words such as "offer" and "consider" to show the strength (or certainty) of our recommendations. See https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/making-decisions-using-nice-guidelines.
Care Quality Commission	Draft Guideline	004	008	1.1.2 The phrase 'from a healthcare service user background' is too ambiguous; clarity should be	Thank you for your comment. The committee did not want to be too prescriptive in this recommendation because it has to

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				provided as to whether this should be someone with direct experience of using this service or similar services (as with our Experts by Experience) or someone with experience of working with or on behalf of service-users.	be relevant to a wide range of organisations, both in terms of function and size. They agreed that 'from a health care service user background' conveyed the need for the patient director to be a service user without restricting that choice unduly.
Care Quality Commission	Draft Guideline	004	017	1.1.4 This is a helpful recommendation but does not identify what these individuals should actually be asked to do. Providing more detail about the expectations for, and of, any individuals undertaking this role would help services to identify and recruit them, and ensure they are afforded equal consideration to the senior practitioners mentioned referenced in 1.1.3.	Thank you. We have clarified this to read: "Identify one or more organisation-wide 'service user champions' to work with the senior leader, patient director and professional champions for shared decision making. They should be recruited from people who use services."
Care Quality Commission	Draft Guideline	009	009	1.2.11 Advises giving people 'enough' time to make decisions but does not identify how 'enough' might be quantified; there is good evidence that clinical staff often judge consultation time differently to patients. It would be better to say 'ensure people are able to take the time that they need to make a decision.' We would add that it would be beneficial somewhere in the document to state that, as far as is practicable, no patient should be forced to make a decision in a timeframe that they have either not set or not agreed.	Thank you. We have modified the text here in line with what you suggest.
Care Quality Commission	Draft Guideline	009	024	1.2.16 This should also include, where applicable, resources from patient or service-user organisations, for example from	Thank you. We have modified recommendation 1.2.4 to acknowledge the role of patient organisations: "When providing information and resources: only use reliable, high-quality

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				neurological patient groups in respect of dementia treatment options.	sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids." This would also cover information provided in recommendation 1.2.18
Care Quality Commission	Draft Guideline	010	001	1.2.17 Good practice would be to ask the patient in any circumstance. We recommend removing 'consider' from this recommendation.	Thank you. We have amended the recommendation to "Ask people if they would like any clinical letters generated after their discussion with a healthcare professional to be written directly to them, with a copy sent to their GP, rather than just sent to their GP."
Care Quality Commission	Draft Guideline	010	006	1.2.18 This recommendation should include advising patients of advocacy services where appropriate, e.g. for patients who have need of external support which cannot be provided by relatives or friends. This is in line with NHS advice - https://www.nhs.uk/conditions/social-care-and-support-guide/help-from-social-services-and-charities/someone-to-speak-up-for-you-advocate/	Thank you. The committee looked for evidence of the effectiveness of advocates for shared decision making but were unable to find any of suitable quality. NICE is currently producing a guideline on advocacy. https://www.nice.org.uk/guidance/indevelopment/gid-ng10156.
Care Quality Commission	Draft Guideline	011	011	1.3.5 This recommendation should include providers having decision making aids that patients may take away or access by themselves, including online; so that they may consider the choices available outside of a clinical setting.	Thank you. We have added this to recommendation 1.2.186
Care Quality Commission	Draft Guideline	General	General	In October 2020 we were commissioned by the Department for Health and Social Care, under section 48 of the Health and Social Care Act 2008, to conduct a special review of Do Not Attempt Cardiopulmonary Resuscitation	Thank you for this information.

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				(DNACPR) decisions taken during the COVID-19 pandemic. In our review, we are exploring the use of DNACPRs as part of advance care planning during the pandemic. Our review will understand to what extent these best addressed the care and support needs of people, including those most at risk of neglect and discrimination, and protected their human rights. Including how providers and systems put people at the centre of their care and are treated as partners. There is cross over between your consultation on shared decision making and aspects of our review. We are currently in the process of drafting our report and would welcome further opportunity to discuss our findings and recommendations and explore synergies. We will be in further contact.	
Care Quality Commission	General	General	General	We are concerned that there is no reference to people's human rights in this guidance. All discussions and decision making should be underpinned by people's fundamental human rights.	Thank you. We do not believe that peoples human rights are specific to shared decision making.
Centre for Perioperative Care	Draft Guideline	004	1.1.28	The suggestion for a patient voice (or as they say a 'healthcare service user') is only a 'consideration' for a Board Director position (due, as it says in the blurb to financial considerations). It would have been a very strong guide in the consultation if it was a strong	Thank you. The committee heard expert testimony about the value of a patient director, but did not have sufficient evidence to make a strong recommendation on this issue.

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				recommendation rather than a 'consider an appointment'. We also support greater transparency on the patient involvement process for this guidance, especially as shared decision making in practice rests on active patient involvement.	
Centre for Perioperative Care	Draft Guideline	005	010	There is discussion of identifying key staff to act as trainers and to run 'train the trainer' style workshops without any help as to how to train the initial staff. I think it would be helpful to give a list of suggested resources/courses/places where it's already working well who are happy to be contacted etc to start things off	Thank you. The recommendation is to train key staff to be trainers. The availability of these trainings will vary by area and organisations will need to identify their own training providers.
Centre for Perioperative Care	Draft Guideline	005	022	In the section "Plan internal or external monitoring and evaluation" It would be helpful to link into existing systems as this is more likely to be embedded, for example, add: "Regular clinical governance meetings, Mortality & Morbidity (M&M) meetings and audit meetings should include local data and presentations, especially on complications and complaints, highlighting whether SDM might have had a different outcome, such as a different choice of treatment, optimisation of care, prevention of complications or better patient satisfaction"	Thank you. Due to differing organisational structures and process the implementation of SDM will be different in each organisation. This guideline provides the requirements for ensuring that SDM happens but how it is implemented is for individual organisations to agree.

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Centre for Perioperative Care	Draft Guideline	006	002	It should also be included in induction for new staff and any handbooks	Thank you. We have clarified this.
Centre for Perioperative Care	Draft Guideline	006	002	It is irritating to move back and forth through the guideline. Please explain the "three talk model" where it first appears as: • introducing choice • describing options, often by integrating the use of patient decision support • helping people explore their preferences and make decisions.	Thank you. The first use of a term in every section is hyperlinked to its definition. In the final version online this will mean that you can jump to the definition and back again, unlike the pdf consultation version. The three-talk model is now not explicitly referenced in recommendations but only given as an example.
Centre for Perioperative Care	Draft Guideline	006	002	In the section "actively promote shared decision making to people who use their services" Please include a recommendation to change specifics in invitations to attend appointments, for example by including a page for the patient to complete before the appointment (eg about their understanding of the Risks Benefits, Alternatives and what happens if they do Nothing (BRAN); or by recommending some pre-appointment information for those referred with a particular diagnosis)	Thank you. Please see recommendation 1.2.5 which discussed providing person access to resources in their preferred format before an appointment.
Centre for Perioperative Care	Draft Guideline	006	008	The three-talk model is the only model described, this model may resonate for some practitioners but others may work better for others eg BRAN and it might be more helpful,	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further

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				inclusive and have a better uptake if more than one is recognised as valid	and agreed that any evidence based model of SDM would be suitable.
Centre for Perioperative Care	Draft Guideline	006	011	The section on training practitioners is intended to mean training all staff. There is a wide range of previous experience. It would be better to state this. In the bullet point: sharing and discussing the information people need to make informed decisions, and making sure they understand the choices available to them (including the choice of doing nothing or not changing the current plan) It would be helpful to add a bullet point about the range of staff, such as "information and resources for patients can be used to educate staff new to the area or non-clinical staff, so they understand the common pathways and options and can identify where a patient's individual circumstances deviate from a "standard" pathway"	Thank you for your comment.
Centre for Perioperative Care	Draft Guideline	006	022	Ensuring that training is practical eg role play not only throws up issues with COVID-19 (though possibly surmountable by doing things virtually) but also makes the training considerably more burdensome in terms of time/personnel. It might be more pragmatic to suggest that basic level training is done eg as e-learning and then works up to face to face.	Thank you. This does not match with the committee's deliberations about training, nor with the expert testimony they heard, both of which emphasised the importance of practical skills training.

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Centre for Perioperative Care	Draft Guideline	008	003	Please include links to CPOC resources at www.cpoc.org.uk/patients – over 60% of patients admitted to hospitals have a procedure 10 million operations occur per year in the UK. This is highly important. Readers are more likely to be able to consider how to implement this guideline if they understand the scale of improvement possible.	Thank you for this information. The committee created a general recommendation of using "reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids." as they deemed an exhaustive list of resources would be unhelpful to include in the guideline.
Centre for Perioperative Care	Draft Guideline	008	024	In section When offering tests, treatments or other healthcare services Please include non-operative options and lifestyle changes. For example, anything from other NICE guidance around non-medical treatments and empowering patients to actively improve their health, eg Physical activity: brief advice for adults in primary care PH44] https://www.nice.org.uk/guidance/ph44	Thank you. All of these fit under the categories given.
Centre for Perioperative Care	Draft Guideline	008	024	In section When offering tests, treatments or other healthcare services Please include options on how best to prepare for an intervention, to minimise complications. For example people who improve their fitness, nutrition and psychological preparedness in the weeks before an operation have 30% - 80% fewer complications.	Thank you. That is beyond the scope of this guideline.

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Centre for Perioperative Care	Draft Guideline	009	003	Re the recommendation: "set aside enough time to answer questions, and ask the person if they would like a further opportunity to discuss options." Please note the NHS has prioritised "one stop shop" clinics, high new:follow-up ratios and a culture of monitoring waiting times, with unrealistic numbers of patients in clinic. It would be helpful to acknowledge this. For example, state: that this is a move away from a 'one-stop shop' clinics; that this may require training of other staff to help with discussions, in a similar way to 'Making Every Contact Count' training being used by non-registered staff and administrative staff to help discuss smoking cessation with patients and that many patients will require time to think and discuss with their family and should be offered a follow-up consultation.	Thank you. Commenting on the organisation of services is outside the scope of this guideline.
Centre for Perioperative Care	Draft Guideline	011	015	1.4 Communicating risks, benefits and consequences. This section on risk very clear	Thank you for your comment.
Centre for Perioperative Care	Draft Guideline	021	005	Well done for including practicalities: "some decision aids cannot be printed because of their format, for example if they have a block colour background that uses a lot of ink."	Thank you for your support.

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Centre for Perioperative Care	Draft Guideline	general	general	The guideline misses the opportunity to include non-medical treatments. This should be part of discussions. As currently written, the guideline gives the impression that there are some binary decisions to be made (operation of no operation). It also suggests that patients are passive recipients of care. • At CPOC, we have undertaken evidence reviews show reduction in complications by 30 – 80% in those who get fitter and prepare for surgery https://www.cpoc.org.uk/cpoc-publishes-major-evidence-review-impact-perioperative-care • It would be helpful if this guidance could uphold the principles of other NICE guidance around non-medical treatments and empowering patients to actively improve their health, eg Physical activity: brief advice for adults in primary care PH44] https://www.nice.org.uk/guidance/ph44	Thank you. This guideline relates to all interactions between a person and a health care professional, including physical activity discussions in primary care. Many recommendations capture the collaborative nature of SDM, for example: Recommendation 1.2.7 states both parties "agree" an agenda to prioritise together what to discuss. Recommendation 1.2.8 states "Ensure the person understands they can take part as fully as they want in making choices about their treatment or care." Which clarifies that SDM and the amount occurring is with the service user to decide. Recommendation 1.2.13 states: "Accept and acknowledge that people may vary in their views about the balance of risks, benefits and consequences of treatments, and that they may differ from those of their healthcare professionals." Recommendation 1.2.14 refers to "joint decisions" made. We believe these and other examples clarify the nature of service user involvement in the SDM process. A shared decision is not limited to binary yes/no decisions as has been suggested here, but is instead an ongoing discussion on selecting treatments or other interventions over time and enabling patients and healthcare professionals to come to a

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					shared understanding of what decisions, whether binary or more multi-faceted treatment options, they want to make.
Centre for Perioperative Care	Draft Guideline	general	general	The guideline is very focussed on elective outpatient consultations. It should specifically mention multiprofessional multidisciplinary working. Many patients have their care decided by experts within a Multi-Disciplinary Team. The document should include a statement such as "In specialties where care is decided in MultiDisciplinary Team meetings, there should be a way of feeding the patient's values and lifestyle into the discussion. At present it is commonplace for one member of the team to report the decision back to the patient. It would be better if the patient could be involved in the discussion from an early stage. The patient should always be presented with the options after the best interests meeting, especially if the outcomes are not certain."	Thank you. This guideline relates to all interactions between a person and a health care professional, including physical activity discussions in primary care. The wording of the guideline has shifted towards the term "discussion" which is defined in the "terms used in this guideline" section, and is intended to clarify that SDM applies to all interactions.
Centre for Perioperative Care	Draft Guideline	general	general	The guideline is very focussed on elective outpatients. There should be a specific statement about emergency care. For example, "Patients admitted as an emergency should have their views and values considered and decisions should be made with them. This may involve other specialties, for example surgeons, anaesthetists, elderly care physicians or interventional radiologists. They should be	Thank you. Thank you. This guideline relates to all interactions between a person and a health care professional, including physical activity discussions in primary care. The wording of the guideline has shifted towards the term "discussion" which is defined in the "terms used in this guideline" section, and is intended to clarify that SDM applies to all interactions. It is equally applicable to emergency departments except in cases where people are unable to participate in decision making (as described in the scope section 3.1)

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				invited to have carers or family members involved in all decisions. All common pathways of emergency presentation should be considered for this approach”	
Centre for Perioperative Care	Draft Guideline	general	general	The guideline is very focussed on elective outpatients. There should be a specific statement about primary care, general practice or generalist practitioners referring to specialists. The referrer should help the patient with Benefits, Risks, Alternatives and what happens if they do Nothing (BRAN). This needs to be specifically stated.	Thank you. This guideline relates to all interactions between a person and a health care professional, including physical activity discussions in primary care. The wording of the guideline has shifted towards the term “discussion” which is defined in the “terms used in this guideline” section, and is intended to clarify that SDM applies to all interactions.
Centre for Perioperative Care	Draft Guideline	general	general	The guideline should be clear about different staff and different expectations. The term ‘practitioner’ is confusing. It would be better to use the term ‘staff’ or ‘clinician’. At one point [page 13, line 19] it defines health professionals as “all healthcare workers who come into contact with people using healthcare services, including healthcare professionals and other staff such as reception staff and some administrative and management staff. Many people reading the guideline will not realise this unusual definition is in use until they get to the glossary. In other contexts, professional means registered clinical staff. The guideline should make clear that knowledge, skills and	Thank you. The term practitioner has been changed to healthcare professional throughout the guideline and a statement added to the rationale and impact section to reflect that other NHS workers may also be involved in SDM.

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				understanding are needed to incorporate SDM across every interaction and that every staff member should work up to their level of knowledge. For example, reception staff are permitted to give information from patient information leaflets and discuss pathways in general terms. The NHS currently works in silos and defers to specialist staff. The guideline would benefit from including a recommendation such as 'team-working should incorporate all healthcare staff in each pathway, including managerial and administrative staff and clinical staff who are not on a professional register as well as reception staff and registered clinical professionals'.	
Centre for Perioperative Care	Draft Guideline	general	general	In the section "actively promote shared decision making to people who use their services" Please include a recommendation for referral pathways to include key information at the outset, including patient's wishes and current health status and what information resources have been given to the patient. Many CCGs currently have referral management protocols. For example, MSK services (MusculoSKeletal) often have a checklist of what needs to be included at the point of referral.	Thank you. Please see recommendation 1.1.11: "Ensure that expertise and information can be shared effectively both within and between organisations so that healthcare professionals provide people with consistent information." and recommendation 1.2.17: When making a record of the discussion (for example, in a person's clinical notes or care plan), record any decisions made along with details of what the person said was important to them in making those decisions. Offer to share this with the person, for example in a post-clinic letter.

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Centre for Perioperative Care	Draft Guideline	general	general	Great to concentrate on organisational recommendations.	Thank you. The committee was clear that organisational commitment is key to successful SDM.
Centre for Perioperative Care	Draft Guideline	General	General	There is understanding that many practitioners already believe that SDM is part of their everyday practice but when compared to the definition of SDM it is clear this is not the case; Shared decision making is far more than many perceive it is. This should be alluded to in the guidance eg reference to papers demonstrating the gap between perceived and observed behaviour or quotes from those who've been on courses otherwise there's a big risk this gets ignored as a 'we already do this'	Thank you. The committee discussed this. It agreed that the monitoring activities in the organisational level recommendations (including by service users) would highlight any tokenism.
Centre for Perioperative Care	Draft Guideline	General	General	Shared decision making has been something that GPs and primary care clinicians have been involved in and using for several years. It is fundamental to the way GP's communicate with patients. The guidance is very secondary care focussed and although the principles apply to primary care the reference throughout the guidance do not really apply.	Thank you. The guidance applies to all settings where NHS services are delivered.

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Centre for Perioperative Care	Draft Guideline	General	General	The overarching principles of the guidance also apply to children and young people. Shared decision making has long been a part of paediatric care with involvement of parents and carers and the child/young person, with the understanding that the discussions are age appropriate and where possible all agree on the final decision. In cases where there are differences of opinion the Gillick competence and Fraser guidelines are pertinent. I feel we should, in our consultation response to NICE, request that a section of their NICE guidance refers to the specific needs of children and young people and their parents / carers	Thank you. Children and young people (aged under 18) are outside the remit of this guideline. Please see section 3.1 of the scope document. **https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents**
Centre for Perioperative Care	Evidence review A	054	044	Evidence review A states "it did note that the qualitative evidence highlighted 'lack of time' as a barrier to using SDM." This does not appear in the guideline. Please put it into the guideline. This is a major barrier to SDM. It needs to be acknowledged. Please put it into the guideline, perhaps in the section Why the committee made the recommendations On Page 16	Thank you for your comment. The "lack of time" barrier was used, alongside the other barriers and facilitators, to inform the recommendations that are included in the review. Concerns about time are captured in the "how the recommendation might affect services" section, and there is a longer discussion in the committee discussion section of the evidence review.
Centre for Perioperative Care	Evidence review B	057	002	Evidence review B states "there was some evidence that these kinds of interventions [pre-appointment information] increased people's knowledge and their satisfaction with their appointment." This does not appear in the guideline. Please put it into the guideline, perhaps in the section	Thank you for your comment, this evidence led into the formulation of recommendations that do appear in the guideline, see the "before a discussion" section.

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				Why the committee made the recommendations On Page 16	
Centre for Perioperative Care	Evidence review E	012	010	The Evidence review E states: The committee felt that the structure of the recommendations needed to reflect the "Three pillars" of support for SDM: "the organisation", "the healthcare practitioner" and "the person using the service". This is helpful. It should be stated in the guideline, perhaps in the section Why the committee made the recommendations On Page 16	Thank you. This is a framework the committee used to structure their discussions. It is not possible to reflect all of the committee discussions in the guideline, which is intended to be a brief document. However, the evidence reviews with the full committee discussions are all hyperlinked from the guideline.
Centre for Perioperative Care	Evidence review E	015	048	This is stated in Evidence review E: The committee commented on how difficult it can be to change practitioner's behaviour. Most clinicians work in quite routine ways. It was the committee's experience that practitioners develop a certain style early in their career that requires conscious change A key barrier to implementing SDM is that many practitioners think they do it already. This is not clearly articulated in the guideline. It would be better if this statement were included in the guideline, perhaps in the section on why the committee came to its recommendations.	Thank you for your comment. This was not something the committee felt was a key underpinning of their recommendations, however this information (in the evidence reviews) is published alongside the guideline for people interested in this level of detail.
Centre for Perioperative Care	Evidence reviews	general	general	The evidence reviews are very extensive. The NICE guidance would benefit from including a summary of these. The evidence reviews of over 1000 pages are difficult for busy clinicians (or	Thank you for your comment. SDM is presented in the standard guidance format that all our guidance is available in, with the most important information easily visible and available. The rationale and impact section is intended to be a distillation

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				managers, etc) to navigate. It is noted that in some reviews 7,251 articles were considered, but only 22 considered relevant [Evidence review 1, page 9, line 29]. This suggests that different criteria might have resulted in different papers being included. Furthermore, with qualitative studies, interpretation is more important than in quantitative studies. To help the reader, the section on 'The committee's discussion of the evidence" in each evidence review should be highlighted, eg in different colour in the index. Alternatively, these sections could be collated as an appendix to the guideline. SDM is currently not well understood, so the evidence behind the recommendations needs to be made more available to all readers.	of the larger committee discussions found in the evidence reviews.
Centre for the Advancement of Interprofessional Education	General	General	General	Overall this is an important document that actively involves healthcare professionals and patients/service users in making joint decisions in a person-centred manner. The statements included in the text are detailed and impressive. Specific points: • I am surprised that shared decision making does not include a greater emphasis on interprofessional team decision making involving	Thank you for your comment. Shared decision making is defined by Montgomery and this guideline as 'a collaborative process that involves a person and their healthcare professional working together'. Interprofessional decision-making between team members was not in the scope of this guideline.

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				patients/service users. The emphasis is mostly, if not entirely, on the individual professional. • There is no reference to the principles of values-based practice (VBP) and interprofessional education (IPE) that underpin both shared individual and team decision making. • Collaborative practice, which is informed by effective IPE, is concerned with issues of shared decision making with patients/service users and involves a shared accountability, within a professional team, for making the best decision(s) (Fulford, Peile and Carroll, 2012). • IPE using a VBP approach allows a rehearsal of shared balanced decision making to take place in a learning environment which can then be translated into effective collaborative practice involving patients/service users (Merriman et al., 2020). IPE should be	

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				part of the training the trainers/educators process specified by NICE. • Individuals with experience and understanding of IPE and interprofessional issues need to be embedded at all stages of the NICE process. This is similar to the conclusion from Hugh's review on UK pre-reg IPE • The workshop that Jenny and I developed is very relevant to this topic and ? could be offered by CAIPE as part of the training package they mention. • Would it be helpful to share a copy of our IPE Handbook with the NICE Team? It could help provide them with a background to IPE and relevance. I have discussed this with Jenny and she is in agreement. References:	

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				Fulford, K.,Peile,E., and Carroll, H (2012) *Essential Values-Based Practice*. Cambridge University Press, Cambridge. Merriman, C., Chalmers, L., Ewens, A., Fulford, K., Gray, R., Handa, A, & Westcott, E (2020) Values-based interprofessional education: how	
Chronically Awesome	Draft Guideline	008 - 009	General	We welcome this layout, but question how practical it is in the time frames allowed for appointments. This is particularly true for patients with complex illnesses where treatment options and potential ramifications of decisions may be more complex too. It is also particularly true for those with cognitive impairments who may require additional time in order to understand treatment options, diagnoses, risks, benefits, outcomes etc. These guidelines fail to recognise the time that shared decision making requires, and the lack of it in appointments.	Thank you for your comment. In evidence review A, the committee discussed at some length whether SDM required more time and that allowing a larger amount of time for SDM may increase consultation length and cost. Although it did not see any quantitative evidence to reflect this, it did note that the qualitative evidence highlighted 'lack of time' as a barrier to using SDM. Overall, it agreed that any additional time needed could potentially be offset by fostering a better patient-practitioner relationship in early sessions, leading to shorter ones in the future, although they also acknowledged that many healthcare professionals only see people short term. They highlighted issues around practitioners questioning what the evidence is for more time being needed, and that more research is needed into what interventions reduce time commitment. There are also recommendations and evidence for normalisation of SDM at an organisational level in section 1.1 of the guideline and evidence review E. Recommendation 1.2.10 also allows the person to ask if they would like a further opportunity to discuss options.

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Chronically Awesome	Draft Guideline	009 - 010	General	While this guideline recognises that patients may change their minds and/or be fluid in their feelings about their treatments and health, we feel more could be done to bolster shared decision making by supporting patients between appointments. Many patients leave appointments feeling overwhelmed by the amount of information they have received, and it is over the next days and weeks, as they research and consider, that questions, clarifications and concerns often arise. Many consultants in the private sector are happy to answer simple questions, clarifications etc by email between appointments to help their patients feel secure in their decisions, without the need for a full appointment. We feel that this could be a useful tool for reducing the number of appointments needed, while allowing patients to continue the shared decision making process in a supported way in between appointments.	Thank you. We have added recommendation 1.2.19 which states "Ensure that information provided after discussions includes details of who to contact with any further questions."
Chronically Awesome	Draft Guideline	010	General	Sharing information between services continues to be a clunky, ineffective process. GPs do not have the time or expertise to coordinate care between multiple specialisms, and patients are left on long waiting lists for often simple questions (e.g. "should we be concerned about X?"). In an ideal world we would have multidisciplinary teams that could meet to truly coordinate care, with the patient present. Recognising this is unlikely to happen, a portal	Thank you for your comment.

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				that is open to all consultants and the patient, where questions, letters, referrals etc, can be sent back and forth would be invaluable in including the patient and ensuring everyone is on the same page, significantly improving decision making by making it more informed.	
Chronically Awesome	Draft Guideline	General	General	We feel that this guideline does not recognise the fact that advocating for oneself requires skills and confidence that comes with time and practice. It is a skills set not used in other areas of life. Many patients feel that they cannot ask questions or challenge a doctor because the doctor is in the position of power. Even more feel they cannot complain or ask for a different doctor because they would be challenged to prove their complaint, and would not be believed against the medical practitioner in question (i.e. the institution would protect it's own). In essence this guideline misses the fact that a true move towards shared decision making requires a wider shift in power dynamics and how doctors and patients perceive themselves and each other.	Thank you. Advocacy, self-advocacy and service user involvement are not in the remit of this guideline. The committee did discuss these issues, and some of the research recommendations aim to explore the power imbalance in consultations.
Chronically Awesome	General	General	General	In good practice we have experienced, shared decision making goes beyond the three talk model. In our experience, at the next appointment the first item on the agenda was to review decisions made at the last appointment, and to check that all parties are still happy with them, with the option to talk everything through	Thank you for your comment. SDM being a changing process over time was discussed in depth with the committee, as can be seen on page 18 of the guideline under "why the committee made recommendations", and in the themes captured in evidence review A.

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				again, change decisions and not continue with planned treatments and procedures. This guideline is static in that it looks at shared decision making in one appointment, but true shared decision making is a process over time, that changes and adapts as the patient and their clinical team comes to understand the patient's health landscape.	
Chronically Awesome	General	General	General	For shared decision making to be meaningful, all options must be presented for consideration. But for that to happen, doctors must be trained and knowledgeable about conditions, treatments, and the costs and benefits of said treatment options. There needs to be time allocated to be able to go away and research an illness, treatments etc., in order to be able to come back to the patient equipped with the relevant information so that the SDM process can begin properly. We raise this with particular emphasis on GPs who are more likely to not have seen or had experience with certain illnesses or treatments, but who are still expected to be an integral part of the SDM process. They need to be supported with time to research and prepare when needed if SDM is to be implemented effectively.	Thank you for your comment.
Chronically Awesome	Recommendations for Research	015	004	The recommendations for research include "What influences the acceptability of shared decision making in populations that predominantly believe in the authority of the	Thank you for your comment. The research recommendations are to address gaps in the evidence retrieved. The committee feels the current evidence base and recommendations give

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				healthcare professional?". There needs to be an additional recommendation for research: "What influences the acceptability of shared decision making in healthcare professionals that predominantly believe in the authority of the healthcare professionals?". Many doctors have worked from a position of authority for years, if not decades, how do we change their deeply ingrained mindset? What happens if a healthcare professional doesn't want to change?	enough of a guide on how healthcare professionals should perform SDM.
CILIP	Draft Guideline	004	005	Leadership for shared decision making The Health Libraries Group welcomes clear leadership for shared decision making. We propose that the responsible lead should also be accountable for ensuring that decisions are based on evidence (notably that patient information materials are evidence based) and for ensuring that health literacy skills are spread to facilitate shared decision making.	Thank you. There was no evidence found, expert evidence presented or committee experience present that justified a recommendation on board member oversight of evidence in SDM. However, we do have recommendations that cover use of information in SDM: 1.2.4 states: "only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids." Since this is included in NICE recommendations it would fall under the remit of managing embedding of good SDM practices. The same as above is true regarding health literacy, 1.1.12 states: "Organisations should ensure that knowledge, skills and confidence to support shared decision making are included in the induction, training and continuing professional development

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					of all healthcare staff. This should include access to clinical supervision." .
CILIP	Draft Guideline	005	013	Ensuring information materials are evidence based The information systems and processes should include checks to ensure that patient information materials and other decision aids are based on the best evidence. We recommend that health staff in the NHS and other organisations should liaise with their library and knowledge service to check the evidence used. For details of local services see: https://hlisd.org/	Thank you. Please see the recommendations in section 1.3 about decision aids. There is also recommendation 1.2.4 which states: "only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids"
CILIP	Draft Guideline	005	018	Rights under Accessible Information Standard Under the Accessible Information Standard, patients with particular format needs (such as British Sign Language) have a right to having these needs recorded and information provided in formats that meet these access needs. We recommend that the Accessible Information Standard should be referenced explicitly https://www.england.nhs.uk/ourwork/accessibleinfo/	Thank you for your comment. The guideline now references the accessible information standard.
CILIP	Draft Guideline	006	009	Health Literacy skills	Thank you for your comment. The committee agreed that "teach back" and "chunk and check" were important methods

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				In order to make shared decisions, individuals need to understand the information that is being shared with them. We recommend that health literacy awareness and techniques (notably "Teach Back" and "Chunk and Check") should be included in the training for shared decision making.	in delivering information and checking it had been understood. They agreed to add these methods as a way to implement existing recommendation 1.2.11
CILIP	Draft Guideline	007	007	Online consultations as a setting We recommend that online and telephone consultations should be referenced as explicit settings, as these have implications for information sharing and the tools available for shared decision making.	Thank you for your comment. The skills of SDM in remote settings are the same as in face to face settings, and this has been added to the rationale and to a recommendation. The committee acknowledged the changing situation with an increased reliance on remote discussions, but felt more evidence was needed to make a specific recommendation, and thus a research recommendation has been added to look at evidence for remote discussions.
CILIP	Draft Guideline	009	024	Information to take away from consultations We welcome the inclusion of information to be taken away at the end of a discussion in the guidance. We recommend that this should be evidence-based information and that the guideline allows for electronic formats where the consultations have taken place online or by telephone. NHS and other health library and knowledge services can assist in checking the evidence base or sourcing evidence-based patient information. For details of health library and information services, see https://hlisd.org/ .	Thank you. This guideline is about shared decision making. The committee did not look at any evidence for the content of discharge or summary documents or of information prescriptions.

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CILIP	Question 3	General	General	What would help users overcome any challenges? We recommend that health service providers should refer to the expertise of health librarians and knowledge specialists when identifying evidence-based information. In many instances, these staff have also been trained to provide health literacy awareness training and to share health literacy. Details of services can be found here: https://hlisd.org/	Thank you for your comment.
College of Mental Health Pharmacy	Draft guideline	006	007-008	We very much support the proposal for board level leadership and representation of minority groups to drive SDM. Having piloted SDM in mental health services we have seen the beneficial impact of SDM on compliance and people feeling that they have been listened to. Particular areas to raise are • Time needed: the model we piloted in community services was similar to that proposed by NICE but did need wholescale change in how services were set up with more time initially to set objectives, change in timing and length of appointments to allow people time to review information, resources	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.

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				were made available, letters were changed for patients and outcomes were measured. This required a change in practice across the service and if not supported at the highest level is impossible to sustain in pockets • Acceptance by all professional groups of the importance of SDM. Time will be needed to ensure importance is understood • Use of 2 validated tools supplied by AQUA in our pilot showing patients felt more engaged in their care and more informed too • Access to specialist pharmacists, resources and knowledge for SDM around medication. We are not convinced that the "three talk model" is the best approach for shared decision making to happen in all patient-groups; it might not be so effective in mental health. For true shared decision making, there is a need for a two-way sharing of information between service-user and practitioner. The "three talk model" describes the sharing of information from the practitioner to the service user and exploring their preferences about *those* choices. However, we think it is important to provide an opportunity to the service to say what is important to them at the	

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				outset. This is especially important in mental health- service users views and experiences about medication have a huge influence on behaviour and it is important to elucidate those early in the discussion. The "three talk model" seems to suggest offering treatment options and then obtaining views from the service user about those options. We feel that it is important to ask the service user about their views and experiences first and then tailoring treatment options based on their responses.	
College of Mental Health Pharmacy	Draft guideline	006	009-010	People with learning difficulties might need pictorial illustrations. In order to be inclusive, written information should also be available in languages other than English too.	Thank you. The recommendations in section 1.2 recommend providing information in different formats and checking that people understand. They also recommend support where it is needed.
College of Mental Health Pharmacy	Draft guideline	006	015	We welcome this comment but more information is needed about *how* this should be done- verbal during the conversation? Written by the service user? Digitally?	Thank you. We would expect a variety of methods to be covered in training.
College of Mental Health Pharmacy	Draft guideline	007	020	Please also include online resources/websites. These need to be evidence based and in patient-friendly format. Service users frequently access online resources for information about medication. Many are not evidence based or are patient blogs which can have a powerful influence.	Thank you for your comment. The examples given in recommendation 1.2.5 are examples and not intended to be an exhaustive list. Apps are in the list of examples.
College of Mental	Draft guideline	008	006	Please also include people with learning disabilities.	Thank you. The reasons for support given were examples and this is not an exhaustive list. These have now been removed to

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Health Pharmacy					make it clearer it is at the professional and service user's discretion regarding need for additional support.
College of Mental Health Pharmacy	Draft guideline	012	009-028	It is very difficult/almost impossible to find numerical data about efficacy with medications used in mental health. So please add an exemption in the case of psychotropic medication.	Thank you for your comment. This is a general guideline for SDM and does not provide recommendations for specific disease areas.
College of Mental Health Pharmacy	Draft guideline	014	005	Please add "a relapse signature" that is frequently used in mental health. The relapse signature is the agreed treatment plan between practitioner and service-user about the preferred medication choices during a relapse. During relapses, service-users can lose insight and hence might not be able to engage in shared decision making.	Thank you for your comment. The definition of SDM was agreed at scoping stage including consultation.
Compassion in Dying	Draft Guideline	005	017	Having access to a person's records is vital for a well-informed consultation. Therefore, we suggest strengthening this recommendation on information systems - e.g. – Ensure that patient information systems enable easy access to patient records including information on their values and past decisions. – For further information please see the Professional Record Standards Body	Thank you. This is covered in recommendation 1.1.7. The committee could not make a stronger recommendation as evidence relating to IT systems outside of expert testimony was not found.
Compassion in Dying	Draft Guideline	005	020	It may be helpful to have a few examples of how people who use services will be involved in shared decision making in this bullet point. Examples could include adding a question on how involved people felt during consultations in patient feedback forms and publicising the	Thank you. Due to differing organisational structures and process the implementation of SDM will be different in each organisation. This guideline provides the requirements for ensuring that SDM happens but how it is implemented is for individual organisations to agree.

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				principles and ethos of shared decision making within the organisations	
Compassion in Dying	Draft Guideline	006	005	If training is to meet the real needs of service users, the course materials must necessarily be based on real people's experiences. We therefore recommend including a bullet point on the importance of co-producing training materials with service users and/or patient-facing organisations. An example of a useful resource which includes information on what people want from healthcare professionals can be found in our report, *I wish I had known…reflections from supporting 25,000 people plan for the end of life (2018)* https://compassionindying.org.uk/library/i-wish-i-had-known/	Thank you. This could be one way that service users are involved in the implementation of SDM as detailed in recommendation 1.1.6. Service users are recommended to be involved at higher organisational levels and should be able to make decisions on how training for SDM is implemented alongside other senior organisational staff. (see recommendation 1.1.4)
Compassion in Dying	Draft Guideline	006	011	We strongly recommend making reference to the Montgomery v Lanarkshire case here in order to draw attention to the law around information provision.	Thank you. This case is discussed in the context section. The recommendations are about actions, not about information.
Compassion in Dying	Draft Guideline	006	016	Please include attorneys (Lasting Power of Attorney for health and welfare) in the list of people that may be involved in supporting the patient	Thank you. People who lack capacity are excluded from this guideline (see section 3.1 of the scope document). The guideline only covers carers and family members if the person chooses to involve them.
Compassion in Dying	Draft Guideline	006	027	We are sceptical about how practical it is to 'train' service users on shared decision making. Instead we recommend publicising the organisation's commitment to listening to and working with individuals to make treatment and	Thank you for your comment. Offering training is given as an example, and the committee felt that offering training to service users is fair and balanced if you are offering training to healthcare professionals, and helps to create a collaborative

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				care decisions (e.g. posters in GP surgeries). Any information for service users should also identify who they can speak to for more support on expressing their views, asking questions and making decisions about their care. Highlighting that patient feedback includes a question on how included and involved someone felt during their consultations is another way in which the value the organisation places on patient voices and shared decision making can be demonstrated.	space with service users and healthcare professionals on an equal footing. Both need to be involved in SDM.
Compassion in Dying	Draft Guideline	008	004	Resources could also include award-winning publications from charities and condition-specific organisations – for example, the Compassion in Dying *What now?* publication won the Special Award for Decision-Making in the 2018 BMJ patient information awards. Developed following research with more than 600 people living with a terminal illness or caring for someone at the end of life, *What now?* is designed to help people find the information they need and ask questions, so that they can make informed decisions about their treatment and care - https://compassionindying.org.uk/compassion-in-dying-celebrated-at-bma-patient-information-awards/	Thank you for your comment. We have added a reference to patient organisations in the recommendation.
Compassion in Dying	Draft Guideline	008	024	In light of the poor DNACPR practices that have been reported in the last year and the ongoing CQC investigation into it, we strongly	Thank you. Specific decision making contexts are outside the scope of this guideline, which does not cover emergency

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				recommend including a special note on when decisions such as CPR are not "shared". An explanation that for CPR, the clinician and patient/family must come to a "shared understanding" would be an invaluable addition to this guidance. See Dr Zoe Fritz's explanation of this - https://medium.com/death-dying-and-digital/dnacpr-and-shared-understanding-46a5a8a82d4f. NHS England has also committed to publishing information for professionals and for patients on how decisions on CPR should be made. It could be useful to reference this information if it is published in advance of this guideline being finalised.	decisions where the patient is unable to participate in shared decision making.
Compassion in Dying	Draft Guideline	009	011	This point about accepting differing views of patients is very important. We recommend including an additional point about conscientious objection and the referral obligations that go with it in the event that a clinician is unable to continue caring for a patient due to conflicting religious or personal beliefs. We suggest making reference to the GMC guidance on Personal Beliefs and Medical Practice to strengthen this recommendation.	Thank you. That is beyond the scope of this guideline.
Compassion in Dying	Draft Guideline	009	027	Please make reference to resources made by charities and condition-specific organisations as they often have user-friendly, user-tested materials which may be more accessible and helpful to patients for meeting their immediate	Thank you. We have modified recommendation 1.2.4 to acknowledge the role of patient organisations: "When providing information and resources: only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant

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				needs as well as for providing ongoing support. This is particularly helpful in light of the growing role of Social Prescribers.	NICE guidelines and quality-assured patient decision aids." This would also cover information provided in recommendation 1.2.18
Compassion in Dying	Draft Guideline	011	023	To highlight the law on information provision, we suggest making reference to the Montgomery case alongside the GMC guidance.	Thank you for your comment. The Montgomery ruling is cited and summarised in the "context" section of the guideline.
Compassion in Dying	General	General	General	To demonstrate the culture change that this guidance is seeking to contribute to – i.e. moving from paternalistic medicine to more person-centred care – we suggest including a few introductory sentences on how shared decision-making is vital for achieving genuinely individualised care as envisaged by the NHS long term plan.	Thank you for your comment. The importance of SDM and the reason for the guideline are discussed in the "context" section.
Crohn's & Colitis UK	General	General	General	We welcome this update of the guideline on Shared Decision Making (SDM). The IBD Standards 2019- which define what good Inflammatory Bowel Disease (IBD) care looks like - state: • *Patients should be supported to make informed, shared decisions about their treatment and care to ensure these take their preferences and goals fully into account (IBD Standards, statement 3.3)* • *Patients should be fully informed about the benefits and risks of, and the alternatives to, immunomodulator and*	Thank you for your comment

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				biological therapies, including surgery (IBD Standards, statement 1.13)	
Crohn's & Colitis UK	General	General	General	We would also like to take this opportunity to strongly support the Patient Information Forum's (PIF) submission which makes reference to: • Health Literacy • Information Standards • Digital equality of access	Thank you for your comment.
Crohn's & Colitis UK	General	General	General	The current guidance would be strengthened by recommending that services, led and supported by high level leadership, regularly measure patient experience in respect of shared decision making. For example, the IBD Patient Survey which was launched in 2019 asks specific questions on SDM and the standard of information provision. This data can be used to benchmark performance, identify differences in experience between different patient groups, and identify areas for quality improvement or further research.	Thank you for your comment, the guideline includes a research recommendation on the best ways to measure shared decision-making in different contexts.
Crohn's & Colitis UK	General	General	General	We would welcome further clarity about where PALs/Healthwatch sit within the implementation of this guidance. We would like to see the guidance recommend that high level leadership	Thank you. The recommendations do refer to planning how monitoring and evaluation will take place. Organisations may choose to use their PALS service (for example) however the

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				work with PALS/Healthwatch to both monitor and embed SDM, based on the findings of regular patient survey data.	guideline is not prescriptive as it has to apply to all settings where NHS services are delivered.
Crohn's & Colitis UK	General	General	General	We are disappointed the guidance makes limited reference to personalised care and person-centred care as set out by NHS England and the Welsh Government. We are concerned that the guidance does not make the link between patient activation, personalised care and support planning and effective supported self-management in strengthening Shared Decision Making. We would like to see specific references to all three and how they support each other. We would like to highlight some questions patients may have which are not fully covered by the guidance: ○ I'm not happy with the decision what can I do next? ○ What if I don't want to change the drug/service/X? ○ What if things go wrong - how do you revisit this decision?	Thank you for your comment. This guideline is about shared decision making, and thus cannot make recommendations on personalised care and support planning specifically. It considered evidence about the effects of patient activation on shared decision making - please see evidence review B in the project documents (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents). This is a guideline for shared-decision making generally and will not have a recommendation for every question a service user may ask, but instead recommends how these conversations should be conducted. There is no requirement to make a decision as the guideline states that "no change" to what they are currently doing also counts as a decision (Recommendation 1.2.10).
Crohn's & Colitis UK	General	General	General	In alignment with the IBD Standards 2019, information for patients should be regularly evaluated and reviewed at a service level in	Thank you for your comment.

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				partnership and preferably co-produced by patients.	
Crohn's & Colitis UK	General	General	General	The guideline should recommend that decisions are recorded in a personalised care and support plan.	Thank you for your comment, this guideline is for shared decision-making, and thus cannot make recommendations regarding personalised care or support plans.
Crohn's & Colitis UK	General	General	General	COVID has highlighted the challenges of delivering high quality personalised care in a highly pressured environment. It also raises the importance of updated NICE guidelines being relevant to the emerging world of digital healthcare delivery. We would like to see the guideline strengthened with recommendations setting out the importance of continuing to share information/communication in different forms before, during and after digital consultations, such as in writing, for those who prefer it.	Thank you for your comment. The skills of SDM in remote settings are the same as in face to face settings, and this has been added to the rationale and to a recommendation. The NHS Accessible Information Standard (SCCI 1605) mandates that all healthcare and adult social care providers must provide information in a format their patients can read. The recommendations consistently refer to ensuring people understand and receive information in their preferred format. Please see for example recommendations 1.2.4, 1.2.5, 1.2.18.
Crohn's & Colitis UK	General	General	General	We would welcome the guidance giving greater clarity around the role of written communications in facilitating shared decision making. A written letter, in isolation of other forms of communication/interaction, informing a patient of an imminent action that is going to be taken in relation to their care/treatment, such as a medicine switch, does not conform to the	Thank you for your comment. As stated in the guideline, written communication is not the only way SDM would be facilitated, and service users should be presented with information in their preferred format.

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				principles of SDM and should be discouraged. We believe this serves to further disadvantage groups of patients, such as patients that are not 'activated'.	
Crohn's & Colitis UK	General	General	General	The guideline should encourage the NHS to measure the success of (for example) introducing new drugs or switching to an alternative type of drug not on just how much money is saved, but how well SDM is realised – as a key outcome of good care.	Thank you for your comment, the guideline includes a research recommendation on the best ways to measure shared decision-making in different contexts.
Crohn's & Colitis UK	General	General	General	Future guidance should recommend that patient education and self-management courses/open days/education opportunities include SDM and option of training in decision making tools. This should be made routinely and regularly available to patients with long-term conditions like IBD.	Thank you. That is beyond NICEs remit.
Crohn's & Colitis UK	General	General	General	We would like to see greater use of peer discussion in supporting patients to make meaningful decisions- for example in surgery. The IBD Standards 2019 recommend that: • Patients with IBD being considered for surgery should be provided with information in a format and language they can easily understand to support shared decision making and informed consent and offered psychological support.	Thank you. The committee did not see evidence that this could improve shared decision making.

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				• Patients who are considering pouch surgery or an ileostomy should have the opportunity to talk with patients who have had this operation. It's also important to offer psychological support at this time as self-esteem and body image can be affected.	
Epilepsy Action	Draft Guideline	004	005	Suggest board member or member of senior leadership team identified as accountable and responsible for shared decision making to be similarly responsible for health literacy and patient activation. Alternatively make reference to the need for senior leader responsible for shared decision making to work closely with senior leaders responsible for health literacy and patient activation.	Thank youfor your comment. Whilst we have not recommended this specifically, as far as health literacy and patient activation apply specifically to SDM, this is covered by the remit of the patient director, see recommendation 1.1.12 that states: "Organisations should ensure that knowledge, skills and confidence to support shared decision making are included in the induction, training and continuing professional development of all healthcare staff. This should include access to clinical supervision". Health literacy resources are listed in the rationale section as an example of training.
Epilepsy Action	Draft Guideline	005	004	Welcome acknowledgement of the need to share good practice in relation to shared decision making between departments and teams. Potential to expand to explicitly note the potential of sharing good practice between branches of medicines and medical specialities. For example good shared decision making practice in oncology services can and should be shared with neurology, and other, services. https://www.england.nhs.uk/ourwork/patient-participation/health-decisions/	Thank you for your comment. This sharing of shared decision making across departments and branches of medicine would be possible if both services exist within the same organisation (as defined as a single hospital/clinic or cluster of clinics), and could also be achieved through recommendation 1.1.10, which states: "Establish a support network within the organisation for shared decision making trainers (including service users who are trainers) and healthcare professionals. Consider joining up the support network with others in the wider system and across the region." This ensures examples of good practice are reaching individuals who will then pass this practice on to the rest of the teams through training.

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Epilepsy Action	Draft Guideline	005	007-008	Prioritising the departments and teams where shared decision making can be most easily put into practice could embed poor practices around shared decision making in harder to engage departments and patient groups. This could exacerbate existing health inequalities. Prioritisation of shared decision making between departments and teams could be better informed by clinical and patient need and reflected as such in the guidance.	Thank you. The committee discussed this at length and agreed that SDM should be embedded in departments where it can be done most easily first. This begins the cultural change that can pervade other departments and helps to normalise shared decision making.
Epilepsy Action	Draft Guideline	005	014-015	Suggest noting that patient decision aids should be appropriate for health literacy level and/or Patient Activation Measure of the patient.	Thank you. We believe this is covered by the recommendations in section 1.2
Epilepsy Action	Draft Guideline	007	006-009	Scope for the guideline to be more explicit in relation to shared decision making in clinical settings other than primary care. Suggest further references in the guideline other clinical settings including community care. Scope for explicitly referencing shared decision making in the context of virtual consultations. Suggest refereeing virtual consultations and the challenges posed to shared decision making in the guidelines.	Thank you for your comment. The committee acknowledged that some language seemed overly focused on primary care, and this has been amended (eg. the removal of "appointments" for "discussion with a healthcare professional". This guideline is applicable to all setting. The skills of SDM in remote settings are the same as in face to face settings, and this has been added to the rationale and to a recommendation.

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Epilepsy Action	Draft Guideline	008	027-029	For people with epilepsy, shared decision making is particularly important in relation to medicine optimisation. Suggest explicit reference to medicine reviews and clarifying, or linking to relevant resources that explicitly note, the need for dosing regimens, potential side effects and drug-to-drug interactions to be discussed and fully understood by patients. Scope to explicitly reference pharmacists here as well in relation to medicine reviews. Suggest linking to best practice in relation to shared decision making, e.g. for people with epilepsy this is set out in the NHS RightCare epilepsy toolkit. https://www.england.nhs.uk/rightcare/wp-content/uploads/sites/40/2020/03/rightcare-epilepsy-toolkit-v2.pdf	Thank you. As a general guideline about shared decision making it is not possible to link to all the relevant condition specific resources.
Epilepsy Action	Draft Guideline	009	024-025	Suggest noting that patient resources should be appropriate for health literacy level and/or Patient Activation Measure of the patient.	Thank you. We have added this.
Epilepsy Action	Draft Guideline	010	001-005	Suggest including reference to recording shared decision making in patient care plans, particularly for those with long-term health conditions such as epilepsy. This would also	Thank you. Please see recommendation 1.2.18 where we have clarified this: "Offer people resources in their preferred format to help them understand what was discussed and agreed. This could be a

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				support and improve sharing between services, (P.10, lines 11-14).	printout summarising their diagnosis, the options and decisions or plans made, and links to high-quality online resources."
Epilepsy Action	Draft Guideline	011	007	Suggest referencing existing NICE resource, linked below, that could act as an interim library of patient decision aids (PDAs) to reduce burden on individual NHS organisations ahead of a national library of PDAs being operational. The NICE resource includes PDAs from NICE and other organisations. https://www.evidence.nhs.uk/search?om=[{%22ety%22:[%22Patient%20Decision%20Aids%22]}]&s=Date&sp=on	Thank you. NICE does not maintain a library of PDAs. A search of NHS evidence will just find ones that are part of NICEs organisation accreditation scheme.
Epilepsy Action	Draft Guideline	011	015	Suggest explicitly referencing the need to discuss fatality risks where clinically necessary, for instance for people with epilepsy. Aware that these conversations can be difficult for both clinicians and patients but in the context of broader shared decision making in relation to decisions about lifestyle and other risks it is vital that people are equipped with the knowledge necessary to make informed decisions. This also links with earlier comments around patient activation and health literacy. As per the NHS RightCare epilepsy toolkit:	Thank you for your comment, We undertook an evidence review of barriers and facilitators to SDM which identified "applying SDM where there is a high risk of harm" as a potential barrier, but it was difficult to identify this as a coherent theme from the qualitative data found, and less evidence compared to other high quality themes. A separate evidence review of reviews of communicating risk was also used to identify the best ways to communicate risk to service users. The risk communication section of this guideline is designed to be general recommendations for risk communication and does not make specific recommendations for specific diseases. The committee felt that dealing with more severe risk when necessary would fall under recommendation 1.4.1 "Discuss

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				"There are still significant gaps in clinical/patient knowledge on epilepsy fatality risks, so decisions about lifestyle aspects mentioned in the MECC such as drinking/smoking/drugs are made from a position of risk ignorance, which can put people with epilepsy even more at risk" The toolkit also emphasises the importance of embedding Making Every Contact Count (MECC) in relation to shared decision making in epilepsy services. Suggest explicitly referencing MECC approach in the guideline to link the guideline in with existing best practice resources, such as the RightCare epilepsy toolkit. "Embed Making Every Contact Count (MECC) in all settings Training with epilepsy specialists in Making Every Contact Count will give them the confidence to have brief conversations and shared decision making strategies with patients about how to improve their overall health and wellbeing. It is extremely important for people with epilepsy and clinicians to understand why MECC is important for them in relation to their individual epilepsy. There are still significant gaps in clinical/patient knowledge on epilepsy	risks, benefits and consequences in the context of each person's life and what matters to them. Be aware that risk communication can often be supported by using good-quality patient decision aids or graphical presentations such as pictographs (see recommendations 1.3.1 to 1.3.3)."

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				fatality risks, so decisions about lifestyle aspects mentioned in the MECC such as drinking/smoking/drugs are made from a position of risk ignorance, which can put people with epilepsy even more at risk." (p.28) https://www.england.nhs.uk/rightcare/wp-content/uploads/sites/40/2020/03/rightcare-epilepsy-toolkit-v2.pdf	
Epilepsy Action	Draft Guideline	011	020	Suggest explicitly noting previous issues around shared decision-making involving female patients as highlighted in the recent report of the Independent Medicines and Medical Devices Safety Review 'First Do No Harm'. Suggest highlighting the need for shared decision making conversations to also include risks that may be specific to particular groups of people, such as women and girls of childbearing age. https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf	Thank you for your comment. This is a general guideline for SDM and does not provide recommendations for specific disease areas or populations, risks should be specific to the service user as outlined in recommendation 1.4.1 and 1.4.2.
Epilepsy Action	Draft Guideline	General	General	The draft guideline does not refer to patient activation or Patient Activation Measures (PAM). Patient activation and PAM should be referenced in the guidelines and integrated into	Thank you. The evidence for patient activation in shared decision making was considered as part of evidence review B (see https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)

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				planning and management of shared decision making in order to better join up these initiatives and approaches as part of the broader NHS England/ Long Term Plan focus on personalised care. https://www.england.nhs.uk/wp-content/uploads/2018/04/patient-activation-measure-quick-guide.pdf	
Epilepsy Action	Draft Guideline	General	General	The draft guideline does not refer to health literacy. As with patient activation in comment 1, identifying and reflecting differing health literacy needs is important for shared decision making to be effective and of benefit to patients. This should be reflected and referenced in the guidelines.	Thank you. The evidence for health literacy in shared decision making was considered as part of evidence review B (see https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)
Epilepsy Action	Draft Guideline	General	General	Suggest referencing information quality standards for patient resources, for example Patient Information Forum PIF TICK quality mark. https://pifonline.org.uk/pif-tick/	Thank you for your comment. The committee has made a note of the PIF-TICK quality mark in the rationale of the guideline.
Epilepsy Action	Draft Guideline	General	General	Epilepsy Action is currently working on a project to produce Patient Decision Aids for people with epilepsy alongside the Cochrane Collaboration. Suggest the guideline and/ or the guideline team references how PDAs should be shared with	Thank you. To the best of our knowledge such a mechanism does not currently exist.

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				healthcare services and professionals for inclusion in any future PDA libraries.	
Epilepsy Action	Draft Guideline	General	General	Epilepsy Action would like to associate ourselves with and express support for the Patient Information Forum (PIF) response to this consultation.	Thank you.
Faculty of Intensive Care Medicine	Draft Guideline	010	General	The use of decision-making aids is another issue that could be explored more.	Thank you. Please see section 1.3on patient decision aids. The committee agreed more research on PDAs and SDM would be useful, but there were more urgent evidence gaps to address in the research recommendations.
Faculty of Intensive Care Medicine	Draft Guideline	General	General	Clinicians are now in receipt of multiple examples of guidance on patient consent and it is important that there is consistency. This guidance needs to be clear and be able to be implemented in practice so consideration of the support needed for implementation of this guidance is important. Some patients want and need accurate information about their options and risk/benefits, and it is important that this is conveyed in a way they can understand to enable them to make an informed choice. This guidance has adopted the concept of a shared decision-making process as the way to achieve this. Other phraseology and models convey a more nuanced meaning e.g. supported decision-making. It is important to note that the decision is one for the autonomous	Thank you for your comment, NICE approached SDM from the perspective that it is enshrined as a principle in the NHS constitution, with principle 4 stating that, 'Patients, with their families and carers, where appropriate, will be involved in and consulted on all decisions about their care and treatment'. They also acknowledged that individuals prefer not to take an active role in decision making, but they should always be given the opportunity to. By facilitating this from the point of view of what the service user would prefer, rather than trying to assume what they are able or required to do, this ensured the guidance was looking at SDM as a collaborative approach from the outset.

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				competent patient and the role of the doctor is to facilitate that decision, not to make the decision for the patient. Within this guidance, we suggest that it is made clear whether NICE's starting point is that: 1. Individuals with unimpaired decision-making capacity will wish to share their decision making with others, but need to be provided with the information and support to facilitate that; or 2. A person with unimpaired decision-making capacity is both able and required to make a decision if provided with the information and support to do so? These two starting points give rise to different ways of framing the approach to engaging with patients. .	
Faculty of Intensive Care Medicine	Draft Guideline	General	General	The recent decision in Bell & Anor v The Tavistock And Portman NHS Foundation Trust [2020] EWHC 3274 (Admin) suggests that there is a distinction between the information that has to be understood, retained, used and weighed by the patient in order to be able to give consent to a procedure, and the information that has to	Thank you. Both people who lack capacity and children are excluded from this guideline. Please see section 3.1 of the scope (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents) For information on decision making in children and young people see information at https://www.gmc-uk.org/ethical-

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				be provided by a doctor to comply with their duties at common law. If, as the Divisional Court said "it is not appropriate to equate the matters that a clinician needs to explain, as set out in *Montgomery*, to the matters that a child needs to understand to achieve *Gillick* competence [to be able to consent to a procedure]" (paragraph 131) which standard does NICE consider should be applied to determining whether the patient can consent to a procedure? It is important to note that whilst this judgment related to children, the Divisional Court drew on case-law relating to mental capacity in the context of adults, raising the same question.	guidance/ethical-guidance-for-doctors/0-18-years/making-decisions NICE also has this guideline currently in development - Babies, children and young people's experience of healthcare, which includes the following question 'How do children and young people like to be involved in planning their healthcare and making shared decisions about their health? This new guideline should address the concerns you've raised.
Faculty of Intensive Care Medicine	Draft Guideline	General	General	It has been recognised that recording of meetings either by the doctor or the patient may perform a useful role in assisting competent patients to make decisions There is an opportunity for NICE to consider ownership of recording of meetings which has been omitted from other recent guidance eg by the GMC. The GMC Guidance provides that where the doctor records the meeting the recording is part of the medical records of the patient. Where a patient records a consultation the GMC Guidance suggests that that record belongs to the patient. It is suggested that some regulation is required in relation to patient owned recordings as there	Thank you. Please see recommendation 1.2.21: "1.2.21 Offer additional support to people who are likely to need extra help to engage in shared decision making. This could include encouraging them to record the discussion, explaining in writing the decisions that have been made, or arranging follow-up by a clinical member of staff or a suitable alternative.".

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				may be serious concerns how that could later be used or disseminated.	
Faculty of Intensive Care Medicine	Draft Guideline	General	General	Whilst appropriate decision-making aids are recognised as having an important place to play in communication with competent patients, we are concerned as to the realism of this model in the intensive care setting. The guideline does not address questions of what and how this approach is to be used where patient participation is necessarily limited by the severity of their illness or injury or the urgency of the decision-making process required. As identified in relation to comment 2 above, the decision in *Bell* has highlighted the extent to which there are two potentially separate processes which are going on: (1) determining whether a patient has capacity either to make the decision (or to participate in the process of identifying what might be the right decision); and (2) the doctor ensuring that they have taken the steps that they need to ensure that they are complying with obligations upon them to ensure that any decision is properly informed. Both of these will be more difficult in the intensive care setting than in e.g. a clinic or primary care	Thank you. It is beyond the remit of this guideline to deal with the legal issue of defining capacity.
Fair Treatment	Draft Guideline	004	008	Would advise strengthening the word 'consider' to simply 'appoint'. Whilst we appreciate the	Thank you. The committee did not believe the evidence was strong enough to support a strong recommendation.

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for the Women of Wales				Committee's concerns that smaller organisations would not be able to afford to appoint a patient director, we would suggest that such appointments could be costed at a level proportionate to the organisation's income. Without patient involvement in the creation, roll-out, and evaluation of Shared Decision-Making processes, the likelihood of success, at least in terms of improving patient outcomes, will be limited.	
Fair Treatment for the Women of Wales	Draft Guideline	004	012	Would suggest that this section emphasises co-production, and how patient leadership and involvement at every level will support the implementation of Shared Decision-Making throughout an organisation's practice, including design and delivery of training, and evaluation.	Thank you for your comment. The current recommendations in other areas of the guideline cover training 1.1.12 -1.1.15, and evaluation 1.1.9 and this embedding of shared decision making will be overseen by a team consisting of both practitioners and service users as outline in recommendations 1.1.1 – 1.1.4.
Fair Treatment for the Women of Wales	Draft Guideline	005	002	Consider inserting a reference to identifying and working towards overcoming existing barriers to Shared Decision-Making as a vital preliminary step, including challenging unconscious bias, and an appreciation of different communication styles, for example.	Thank you. We believe this to be adequately covered by recommendations 1.1.1 to 1.1.5
Fair Treatment for the Women of Wales	Draft Guideline	005	002	Would suggest that any organisational plan, in the first instance, should seek to identify essential preliminary steps to making Shared Decision-Making a multi-level reality, including training on identifying and challenging attitudinal barriers such as unconscious bias. Also, for Shared Decision-Making plans and processed to work, there needs to be a full appreciation of	Thank you. We believe this to be adequately covered by recommendations 1.1.1 to 1.1.5

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				contexts and obstacles which might prevent implementation, including some acknowledgement of how (devolved) NHS systems might create barriers to shared decision-making between patient and healthcare professional when it comes to referrals out of local area and accessing certain clinical settings, interventions, or medicines.	
Fair Treatment for the Women of Wales	Draft Guideline	006	009	Where language and terminology is concerned, the key to effective dialogue is not to make assumptions about individuals' linguistic capabilities and choices, but rather to listen and take the lead from the person. It is very important to avoid being paternalistic or patronising.	Thank you for your comment.
Fair Treatment for the Women of Wales	Draft Guideline	006	011	Would urge the Committee to incorporate a reference to both the expertise that comes with people's lived experience and that discovery / learning can be a reciprocal process. Would advise including a reference to empowering people to carry out their own research as well as the need for healthcare professionals to be open to the receipt and discussion of information or resources people / patients have themselves collated and feel are important to the Shared Decision-Making process.	Thank you. Recommendation 1.2.5 addresses this as the service user could bring their own knowledge and information to the discussion in the form of what matters to them, what they hope will happen as a result of the discussion, and what questions they would like to ask. Recommendations 1.2.7 – 1.2.17 frame the discussion as a two-way exchange with both individuals providing information, knowledge and experience.
Fair Treatment for the	Draft Guideline	006	015	Would include a reference to 'listening'	Thank you. Listening skills are not specific to shared decision making, however the bullet wording has been amended and implies that the healthcare professional will be listening to the person talk about what's important to them.

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Women of Wales					
Fair Treatment for the Women of Wales	Draft Guideline	007	018	This section should also refer to the development of mechanisms that enable people to share their own resources before and after appointments and advise that practitioners be prepared to accept and engage with resources that people bring to appointments.	Thank you. The committee did not see any evidence to support this.
Fair Treatment for the Women of Wales	Draft Guideline	008	014	Would ask that this section also include a recommendation that avenues be made available and known to people to discuss and challenge situations where they feel that shared decision-making hasn't been achieved to their satisfaction.	Thank you. All NHS organisations have grievance policies and complaints procedures to deal with this. We have added a section about seeking a second opinion to the rationale under the section "during discussions with a healthcare professional".
Fair Treatment for the Women of Wales	Draft Guideline	008	024	In this section, it would be prudent to refer to the need for practitioners to be transparent about situations where particular interventions or services are not accessible to the individual, including where NHS systems do not allow for straightforward referrals. In instances like this, there is much to be said for seeing healthcare professionals being proactive in advocating for patient needs at a higher level, investigating and challenging obstacles to care which both parties agree would be best practice.	Thank you. The committee recommended openly discussing each option.
Fair Treatment for the Women of Wales	Draft Guideline	009	004	Would ask that 'further opportunities for discussion' refer also to the offer of an alternative practitioner / second opinion if this is what the individual wants.	Thank you for your comment. The potential requirement for a second opinion regarding further discussion is addressed in the rationale: "People have a right to refuse any treatment, and similarly, healthcare professionals are not obliged to provide any treatment that in their clinical opinion is medically futile

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					(this may require a second opinion or discussion with a senior colleague). Healthcare professionals cannot provide access to treatments that are not available.”
Fair Treatment for the Women of Wales	Draft Guideline	009	022	Would ask that notes also include a reference to instances where the individual has expressed a dissenting opinion or preferred option which is unavailable to them.	Thank you. Recommendation 1.2.17 states “record any decisions made along with details of what the person said was important to them in making those decisions”. The examples mentioned fall under “details of what was important to them”. ..
Fair Treatment for the Women of Wales	Draft Guideline	009	024	This section needs to make clear that provision of resources and information can be initiated by the patient as well as the healthcare professional.	Thank you for your comment. This has been reworded to “offer” from “give” to make it clearer the decision is also with the service user should they request the information. If service users request the information regarding decisions made it would also be provided, but should already be offered regardless of need for service user to initiate this request, as outlined in recommendation 1.2.18
Fair Treatment for the Women of Wales	Draft Guideline	012	001	Would suggest that staff are also sufficiently knowledgeable about the availability of services locally, referral pathways, and are able to discuss openly with patients any logistical difficulties or barriers to accessing services.	Thank you for your comment. This guideline is specifically about SDM and thus does not make recommendations for practitioner knowledge regarding general services and pathways.
Fair Treatment for the Women of Wales	Draft Guideline	014	010	This bullet point also needs to make explicit how ‘choice’ may also incorporate a lack of choice, especially if the discussion is focused upon accessing tertiary / specialised services which may not be available locally.	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.
Fair Treatment for the	Draft Guideline	014	018	Would advise that there is emphasis here on how any measurement of Shared Decision-Making must be co-productive to ensure that citizens / patients’ voices are key to evaluating	Thank you for your comment.

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Women of Wales				processes and making recommendations about improved practice.	
Fair Treatment for the Women of Wales	Draft Guideline	016	020 - 023	We would disagree with the rationale here. Organisations of different sizes, structures, and types can appoint patient directors or equivalent at a level and cost that is proportionate to their size and income. For very small organisations with limited income, engaging volunteers with lived experience is also a possibility. The suggestion that patient involvement is merely optional undermines the principle of Shared Decision-Making and makes effective, co-productive approaches to the development of resources, training, and evaluation less likely. This will inevitably have knock-on effects on the quality of Shared Decision-Making processes in the consulting room and, by extension, patient experience.	Thank you for your comment. This piece of rationale is not referring to patient involvement overall, but to the appointment of a patient leader with a large financial investment. As stated in your comment there are other approaches that can be taken to achieve this, which is why this is only recommended as an option to consider.
Fair Treatment for the Women of Wales	Draft Guideline	018	021	Would recommend considering signposting to NICE guidance on Independent Advocacy. Would also suggest taking note of the Social Services and Wellbeing (Wales) Act 2014 which incorporates access to independent advocacy.	Thank you. NICE has not yet published its guideline on advocacy services.
Fair Treatment for the Women of Wales	Draft Guideline	020	002	Would advise that any recommendation for research into measuring / evaluating Shared Decision-Making should emphasise the need for that research to be co-produced, from inception through design, content, conclusions, and implementation.	Thank you for your comment. Research recommendations are to suggest areas for future research, we do not recommend a certain organisation or body to take on this research. For more detail on this research recommendation see evidence review A.

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Fair Treatment for the Women of Wales	Draft Guideline	020	024	Include a reference to listening, not being judgemental, an awareness of bias and efforts to challenge it.	Thank you for your comment. Considering how the views of service user/practitioner may differ is covered in recommendation 1.2.13. In evidence review A the committee acknowledged that both practitioners and service users should be aware of their own biases. And that being listened to and trusted is an important part of the service user experience of SDM.
Fair Treatment for the Women of Wales	Draft Guideline	021	017	Would include 'Options' in this heading to reflect the fact that many appointments, certainly in primary care settings, may also involve discussion and decision-making in the context of choice of / referral to secondary and tertiary care.	Thank you for your comment. This section is specifically focused on communication of risk. The committee agreed that discussing risk using the word "risk" alone could be seen as unnecessarily negative because of the way people interpret the word risk, and therefore it agreed that it would be more useful to refer to "risks, benefits and consequences" to convey the range of meanings covered by healthcare professionals use of the word 'risk'.
Fair Treatment for the Women of Wales	Draft Guideline	023	001	Consider including a reference to choosing personnel, clinical settings, social prescribing interventions.	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.
Fair Treatment for the Women of Wales	Draft Guideline	023	003	Would amend to 'both person and healthcare professional'.	Thank you for your comment.
Fair Treatment for the Women of Wales	Draft Guideline	023	006	As a patient-led organisation, we feel that there is a lack of recognition here that, sometimes, the options that person and healthcare professional discuss are limited as a result of barriers imposed by the NHS system in operation,	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.

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				something that is particularly applicable to those areas where there is no patient charter enshrining patient choice. This has considerable impact on the efficacy and appropriateness of Shared Decision-Making as a concept and can, unfortunately, have negative consequences for people's relationship with health services and providers.	
Fair Treatment for the Women of Wales	Draft Guideline	023	029	Consider amending to include an expectation that the healthcare professional will advocate for patient need, and challenge processes and practices that act as barriers to best care, as discussed and agreed by both parties.	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.
Fair Treatment for the Women of Wales	Equality Impact Assessment	001	General	Include 'Independent Advocate'	Thank you. Advocates are mentioned in the recommendations and NICE is currently producing a guideline on advocacy.
Fair Treatment for the Women of Wales	Equality Impact Assessment	002	General	Include 'Independent Advocate'	Thank you. Advocates are mentioned in the recommendations and NICE is currently producing a guideline on advocacy.
Fair Treatment for the Women of Wales	Equality Impact Assessment	002	General	Whilst, ostensibly, NICE guidelines are designed for use by those using / working in NHS England, has the Committee considered implications for those using devolved NHS systems and how those systems might present barriers to full and effective Shared Decision-Making, especially where second opinions and	Thank you. This is outside the remit of NICE.

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				referrals into tertiary care / services are concerned?	
Fair Treatment for the Women of Wales	Equality Impact Assessment	003	General	We do not consider the recommendations to be as explicit as they could be with regards to discussing choices around clinical personnel and / or settings.	Thank you for your comment. Regarding choice of healthcare professional, the committee have added to the discussion that a second opinion can be sought if a shared decision cannot be reached. Choice of setting for treatment in the NHS in many cases is a legal right for the service user, and thus was not covered in the shared decision making guideline.
Fair Treatment for the Women of Wales	Equality Impact Assessment	003	General	Would advise a change to social model language here which would see references to 'disabled people' and 'people with impairments'.	Thank you. The language used is consistent with the language used to describe the protected characteristics.
General Medical Council	Draft Guideline	005	015	Information about risks, benefits and consequences can also be provided before the consultation (eg when the GP refers to an orthopaedic surgeon, they could indicate the possible/likely procedures and recommend the patient views information on the nhs.uk website and any available NICE guidelines); during the consultation (as the guideline suggests) or in between appointments. Initiatives such as explainmyprocedure.com can provide patients with generic information about the risks, benefits and consequences of a growing number of procedures before their consultation, and	Thank you. We have now included recommendation 1.2.4 which states: "only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids."

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				encourage them to think about what matters to them in advance, so that the doctor and patient can make the most of the time they have during the consultation to personalise the information to what matters to the patient, and to their specific clinical circumstances.	
General Medical Council	Draft Guideline	007	018	Initiatives such as explainmyprocedure.com can provide patients with generic information about the risks, benefits and consequences of a growing number of procedures before their consultation, and encourage them to think about what matters to them in advance, so that the doctor and patient can make the most of the time they have during the consultation to personalise the information to what matters to the patient, and to their specific clinical circumstances.	Thank you for this information.
General Medical Council	Draft Guideline	009	006	It would be helpful to give examples of how a clinician can check that the patient understands the information they've been given. The 'talkback' method was recommended by several respondents to our consultation on our *Decision making and consent* guidance, and other methods may well be effective.	Thank you for your comment. NICE has added clarification that "teach back" and "chunk and check" methods can be used in recommendation 1.2.11, to ensure understanding of information provided.
General Medical Council	Draft Guideline	009	020-022	In deciding what should be recorded about a discussion, it is perhaps inevitable that clinicians will want to act defensively in recording every risk that was discussed regardless of what the person says is important to them in making the decision. We agree that the latter is more	Thank you. We have added this to the rationale and impact section of the guideline.

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				important, but it might be reassuring if it's stated explicitly in the guideline that recording what is important to the patient is, for example, better evidence that a meaningful dialogue about risk and benefit has taken place than a list of generic risks would be.	
General Medical Council	Draft Guideline	010	002-003	It's not clear whether the suggested letter to the patient, copied to their GP, would be replacing the usual letter to the GP copied to the patient. This was a recommendation in Baroness Cumberlege's Inquiry report and, as such, should perhaps be more strongly worded than 'consider asking the person if they would like' – eg to 'offer the person…'	Thank you. We have amended the recommendation to "Ask people if they would like any clinical letters generated after their discussion with a healthcare professional to be written directly to them, with a copy sent to their GP, rather than just sent to their GP."
General Medical Council	Draft Guideline	011	015-016	And elsewhere in the document where it refers to 'risks'. We use the term 'risk of harm' or 'potential harm' throughout the GMC guidance on *Decision making and consent* because our Task and Finish Group concluded that 'risk' is a likelihood that a harm would occur, when it is the potential harm itself (as well as the likelihood of it occurring) that should be communicated to the patient. So we talk about discussing 'the potential benefits and risks of harm of each option'. Having said that, we do acknowledge in the side note to paragraph 20 that 'risks' is commonly used to mean 'the risk of a harm occurring'.	Thank you for your comment. The committee agreed that the term 'risk' by itself was jargon and was not understood by patients and service users in the way it was intended by professionals. They used the phrase risks, benefits and consequences as a way to clarify that risks were not necessarily negative.

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				In terms of the 'consequences' referred to in the guideline, our equivalent is to say that the information doctors must give patients will usually include 'the nature of each option, what would be involved, and the desired outcome' (paragraph 10d) and also 'the potential benefits, risks of harm, uncertainties about and likelihood of success for each option, including the option to take no action' (paragraph 10e). The description of the purpose of the dialogue in paragraph 9 includes 'to try and reach a shared understanding of the expectations and limitations of the available options.'	
General Medical Council	Draft Guideline	011	023-024	We appreciate the reference to our (GMC) guidance on *Decision making and consent* ('DMC'). However, it seems strange that it is referenced in relation to signposting more information on dealing with uncertainty (which is dealt with in paragraphs 25-26 of DMC). There are numerous other potential cross-reference points which would likely be equally helpful – we'd be happy to suggest them if that would be appropriate. We believe it would be helpful to doctors to know that by following this guideline they are acting in line with our guidance, and vice versa, rather than these being two separate and potentially conflicting requirements they need to fulfil.	Thank you. We have added to the rationale and impact section to make clear that professionals need to act in accordance with guidelines from their professional bodies. The guidance was referred to specifically here as a model of good practice that could be useful to any health professional.

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General Medical Council	Evidence Review A	007	007	*Exceptions don't mean that there's no need to seek consent or have a dialogue* In the PICO table on p7 of the Evidence Review A, there are two exclusions set out relating to situations which are not appropriate for applying SDM: • Unexpected life-threatening emergency needing immediate life-saving care • Situations in which people lack mental capacity to make their own decisions about healthcare at that time. Our (GMC) guidance on *Decision making and consent* still applies to each of these situations, however, and – while this isn't in conflict with the guideline as it stands – it would be helpful to see the guideline acknowledge that, while a formal SDM approach may not be appropriate, it is still necessary to have a dialogue with patients in these circumstances, and to seek the patient's consent or (where patients lack capacity) follow the steps set out in the relevant legislation to make sure that you have the required legal authority to proceed with any treatment. For the first exclusion we agree that there wouldn't be time to – eg - apply the 3 talk model; but we would still expect doctors to attempt to engage a conscious patient in a dialogue and try	Thank you for your comment. If areas are out of scope as agreed through the scoping process, they will not have been considered as part of this guideline. The scope was put out for stakeholder consultation and then finalised to complete this guideline. If not a formal SDM approach but instead a conversation that is outside the scope of this guideline. People who lack mental capacity under the age of 18 are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)

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				to make sure that the patient knows what treatment is being proposed and that they have the right to object.	
General Medical Council	General	General	General	While the 3 questions you ask respondents to address seem more for employers/healthcare provider organisations to address, we would like to comment on the potential impact of these guidelines. By promoting shared decision making (SDM) and – in particular – by recommending that SDM is embedded at an organisational level, this guideline will enable doctors to practise in line with our (GMC) guidance on *Decision making and consent.* During our research and consultation phases one of the barriers we were most consistently told about to implementing our guidance – which SDM is very much in line with – was buy-in at a senior leadership level. We fully support the guideline and are very excited about its implementation, as we move forward with our own plans to help doctors follow our guidance on D*ecision making and consent*.	Thank you for your comment.
Health Education England	Draft Guideline	004	005	Accountability to include oversight of evidence base We welcome the guidance that a Board member (or a member of the senior leadership team) should be accountable and responsible for the leadership and roll out of shared decision	Thank you. There was no evidence found, expert evidence presented or committee experience present that justified a recommendation on board member oversight of evidence in SDM..]

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				making. We recommend that this role should include responsibility for oversight of the use of evidence in shared decision making, linking to local NHS-funded library and knowledge services.	However, we do have recommendations that cover use of information in SDM: 1.2.4 states: "only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids." Since this is included in NICE recommendations it would fall under the remit of managing embedding of good SDM practices.
Health Education England	Draft Guideline	005	013	Information systems We recommend that trusts review the ways in which shared decision making is or could be supported via the electronic patient record and via clinical-support systems (such as *BMJ Best Practice*, in which Health Education England invests as a national clinical decision support tool for the NHS workforce in England). Information processes Information processes to support shared decision making need to include access to: current evidence; and patient information resources that are based on current evidence. We recommend that the accountable lead establishes effective processes to develop and update evidence-based patient information resources, working closely with their NHS library and knowledge services team.	Thank you. Recommendation 1.1.7 states: "Review how information systems might support shared decision making, for example by - providing ready access to patient decision aids or information about risks, benefits and consequences during discussions with a healthcare professional - showing the person's past decisions and preferences, values and other information from previous discussions, for example through a patient-held record", and we feel this includes clinical-support systems. Regarding the use of high quality current evidence recommendation 1.2.4 states: When providing information and resources: only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids." As these recommendations are in the guideline under section 1.2 it is expect people assigned to roles in section 1.1 will follow these recommendations.

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Health Education England	Draft Guideline	005	015	Patient decision aids 'Patient decision aids' is a very specific term. At trust level, a broader range of patient information resources is used widely for shared decision making, including websites and leaflets produced by voluntary organisations. The guidance should cite this wider breadth of content alongside patient decision aids.	Thank you for your comment. "Patient decision aid" was specifically defined in the Cochrane review used to inform recommendations, and identified by the committee as a specific component to appraise. For a review of other interventions, including information resources, that can support shared decision making, please refer to evidence Review A and B and recommendation 1.2.4.
Health Education England	Draft Guideline	005	018	Recording individual preferences We note that there is a legal obligation for trusts and adult social care to record individuals' preferences to receive information in accessible formats (such as British Sign Language). We recommend there is specific reference to the Accessible Information Standard https://www.england.nhs.uk/ourwork/accessibleinfo/ .	Thank you for your comment. The guideline now references the accessible information standard.
Health Education England	Draft Guideline	006	005	With regards supporting practitioners' skills and competences, and putting shared decision-making into practice, I refer you to the following resource that I would suggest your training plan includes: Health Education England (HEE) and NHS Education for Scotland (NES) have collaborated to develop a new, free e-learning module for people working in health and care to understand the role health literacy plays in the health and social care systems.	Thank you. This guideline is not about health literacy, however the committee have added a mention of the resources to the rationale and impact section of the guideline.

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				Health literacy is about people having enough knowledge, understanding, skills and confidence to use health information, to be active partners in their care, and to navigate health and social care systems. Therefore, to access, assess and apply health information, people need to be health literate. People working in health and social care need to be aware of health literacy and of the techniques that can help to increase understanding. The e-learning resource takes about 30 minutes to complete. At the end of the module learners will know why health literacy is important and how to use some simple techniques, including Teach Back, chunk and check, using pictures and simple language to improve communication and check understanding with others. After each section learners complete an action plan, detailing how they plan to use the techniques in practice. This plan can be used as evidence of learning in appraisals or professional portfolios. The resource supports a more blended approach to learning and spreading awareness of health literacy, building on the NES resource in The Health Literacy Place and HEE's health literacy toolkit.	

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				Click here to do the e-learning: https://www.e-lfh.org.uk/programmes/health-literacy/	
Health Education England	Draft Guideline	006	009	Health literacy training The guideline recommends training on 'communicating with people in a way they can understand'. We recommend that the guideline should refer explicitly to health literacy training, which we noted was identified as a specific need in Evidence Reviews A and C and was an explicit intervention examined in Evidence Review B.	Thank you. The committee added a reference the HEE health literacy training to the rationale and impact section.
Health Education England	Draft Guideline	007	007	Settings Virtual consultations and telephone consultations have been omitted from the list of settings. These have an impact on the tools available and how they are used. We strongly recommend that these are addressed as explicit settings.	Thank you for your comment. The skills of SDM in remote settings are the same as in face to face settings, and this has been added to the rationale and also to a recommendation.
Health Education England	Draft Guideline	007	019	Quality of information offered: evidence-based patient information The guidance refers only to the need for resources to be supplied in advance in an individual's preferred format. We strongly recommend that the guideline also refers to the need for all such resources to be evidence based, in order that shared decision making is meaningful and to mitigate the risk of exacerbating inequalities. Again, health care staff are invited to work with their local NHS-funded library and knowledge service to identify	Thank you for your comment, the committee agreed that providing information was important, but that the information needed to be of good quality. Examples of quality standards have been given in the rationale section.

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				or, if necessary, develop material of the appropriate standard.	
Health Education England	Draft Guideline	009	024	Summary of appointment discussions for patients We welcome provision of a summary document at the end of each consultation or appointment. We recommend that documentation this should include the name of any condition with which a person has been diagnosed and the name of any treatment options discussed, so that individuals look up the correct medical condition and treatments when seeking information for themselves. We propose that NICE should refer to the literature on information prescriptions to inform the guidance.	Thank you. This guideline is about shared decision making. The committee did not look at any evidence for the content of discharge or summary documents or of information prescriptions.
Health Education England	Draft Guideline	009	028	Evidence-based information at each stage of the information pathway At each stage of the pathway, including at the close of the appointment, the information should be based on current evidence, with evidence checked in liaison with NHS-funded library and knowledge services. Again, health care staff are invited to work with their local NHS-funded library and knowledge service to identify or, if necessary, develop material of the appropriate standard.	Thank you for your comment. We have modified recommendation 1.2.4 which now states "When providing information and resources: only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids." This would also cover information provided in recommendation 1.2.18
Health Education England	Draft Guideline	012	010	Understanding numbers There are clear issues about understanding risk; the health literacy materials developed by Health Education England raise the awareness of	Thank you for your comment. The committee agreed that "teach back" and "chunk and check" were important methods in delivering information and checking it had been understood.

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				health and care staff that this relates to a broader issue about numeracy. In England, 61% of adults aged 16-65 struggle to understand health information that contains both words and numbers (Rowlands et al 2015 https://bjgp.org/content/65/635/e379). Numeric information should therefore be discussed using health literacy techniques, such as "teach back" and "chunk and check" to facilitate understanding.	They agreed to add these methods as a way to implement existing recommendation 1.2.11
Health Education England	Draft Guideline	General	General	Question 3: What would help users overcome any challenges? Equipping health and care staff with the necessary skills: Health Education England has developed E-Learning programmes and a toolkit that will equip staff with the necessary skills: • Shared decision making E-Learning https://www.e-lfh.org.uk/programmes/shared-decision-making/ • Health Literacy E-Learning https://www.e-lfh.org.uk/programmes/health-literacy/ - developed in partnership with NHS Education for Scotland. • A health literacy toolkit https://www.hee.nhs.uk/our-	Thank you for this information. We have added a reference to the e-learning materials in the rationale and impact section of the guideline.

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				work/population-health/training-educational-resources – developed in partnership with NHS England, Public Health England and the Community Health and Learning Foundation. These resources equip organisations with training resources that are particularly valuable in instances where train-the-trainer options are not available. Local training support As the strategic lead for NHS-funded library and knowledge services, Health Education England has invested in upskilling local NHS library staff to enable them to deliver a suite of health literacy training tools. NHS librarians and knowledge specialists are therefore a resource to draw upon for training within NHS organisations. Using evidence-based patient information Local NHS library and knowledge services staff provide efficient, tailored access to relevant evidence, for further details see https://library.nhs.uk/. Knowledge specialists can play a key role in enabling trusts to be assured that the information being provided to support	

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				shared decision making is current and informed by evidence. Patient information materials should also be based on current evidence.	
Health Education England	Evidence Review A	059	General	The description of the intervention for the search strategy states "ensuring a patient understands this information". We suggest that the term "health literacy" should therefore have been an explicit part of the search strategy.	Thank you for your comment. Health literacy was included in searches for evidence review B for interventions to support shared decision making.
Health Education England	Evidence Review A	074	004	The quantitative search strategies do not include "informed decision", "informed choice" or "informed consent". This is inconsistent with the qualitative search strategies and inclusion of these terms could have led to more results that emphasise the importance of evidence-based information to make an informed choice.	Thank you for your comment. Informed decision and informed choice can be seen in the quantitative search strategy in line 1 and 2. This quantitative review was an update of an earlier Cochrane review, and thus the search strategy was preserved from that earlier review.
Health Education England	Evidence Review B	075	015	The search strategy includes both "health literacy" and the technique "teach back", but we suggest that it should also have included the technique "chunk and check" – this health literacy technique emphasises sharing content in stages and would fit well with the wider approach in this guideline, underlining the importance of health literacy techniques for shared decision making.	Thank you for your comment.
Health Education England	Evidence Review D	006	030	Some of the terms identified in the PICO table (notably NNT) have not then been applied to the search strategy.	Thank you. Studies that reported NNT or the other criteria would have been picked up by this search.

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Health Education England	Evidence Review D	033	014	As an evidence review for risk communication, we suggest that "health literacy" should have been included explicitly in the search strategy.	Thank you for your comment. Health literacy was included in searches for evidence review B for interventions to support shared decision making.
Health Literacy UK	Draft Guideline	001	011	Who is it for: Adults (aged 18 and over) using … we suggest adding and any VCSEs supporting them	Thank you. This is detailed in the scope (section 3.1) "Adults (aged 18 years and over) using healthcare services, and their families, carers and advocates if they choose to involve them" We have also added "voluntary, community and social enterprise organisations" to the list of groups this guideline may be relevant for on page 1.
Health Literacy UK	Draft Guideline	001	012	It may also be relevant for: add VCSE (Voluntary, community and social enterprise) organisations	Thank you for your comment, these organisations were added to the "who is it for" section of the guideline. We have also added "voluntary, community and social enterprise organisations" to the list of groups this guideline may be relevant for on page 1.
Health Literacy UK	Draft Guideline	004	General	We welcome and endorse the need for organisational and system approaches. You suggest it is a Board Member where there is a Board or a senior leadership team member. We suggest, and also a senior leadership team member to support operational delivery.	Thank you. The wording of this recommendation has changed from "board member" to "senior leader" and specified that "This should be a board member or, if the organisation does not have a board, a leader at the highest level of the organisation."
Health Literacy UK	Draft Guideline	005	028	Is there an existing network, how is good practice to be shared	Thank you. NICE is unaware of any of these networks that might exist. Good practice would be shared by joining up networks as suggested in the recommendation.
Health Literacy UK	Draft Guideline	006	008	There is no indication of why the three talk model is recommended in the main text. It would be useful to summarise why it is for readers. Particularly as we note that it is not	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further

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				uncontested/universal, Hanna Bomhof-Roordink et al. BMJ Open 2019;9:e031763	and agreed that any evidence based model of SDM would be suitable.
Health Literacy UK	Draft Guideline	006	009	Teachback, is a well- tested and effective tool used in improving practitioner's health literacy practice so that they can be sure patients have understood the discussions and are able to appraise and to act /make decisions on such discussions. We suggest adoption of this use of this technique would support delivery of these aspects of SDM. There are multiple references including Shersher, V., Haines, T. P., Sturgiss, L., Weller, C., & Williams, C. (2020). Definitions and use of the teach-back method in healthcare consultations with patients: A systematic review and thematic synthesis. Patient Education and Counselling, 104(1), 118-129.	Thank you for your comment. NICE has added clarification that "teach back" and "chunk and check" methods can be used in recommendation 1.2.11, to ensure understanding of information provided.
Health Literacy UK	Draft Guideline	006	018	Health Literacy Train the trainer training commissioned by HEE and NHSE and delivered by the former CHLF now owned by Reaching people provides a useful model which could support SDM	Thank you. This guideline is not about health literacy, however the committee have added a mention of the resources to the rationale and impact section of the guideline.
Health Literacy UK	Draft Guideline	006	022	Health literacy Awareness training commissioned by HEE and NHSE and delivered by the former CHLF now owned by Reaching people provides a useful model which could support SDM	Thank you. This guideline is not about health literacy, however the committee have added a mention of the resources to the rationale and impact section of the guideline.
Health Literacy UK	Draft Guideline	006	023	We welcome the recommendation that people should be actively encouraged to ask questions	Thank you. Offering training is given as an example, and the committee felt that offering training to service users is fair and

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				to support SDM. The suggestion of providing 'training' for people seems heavy- handed and discordant with what is proposed as a partnership. Education and support to enable people to participate effectively is suggested as a more appropriate approach. As part of this, we welcome the questions proposed, which seem to be an adaptation of "Ask me three" a well-used and tested technique. There are many examples of use of this including by some of your expert witness but explicit recognition/promotion of it would enable practitioners to consult references for it such as Miller, M. J., Abrams, M. A., Barbara, M., Cantrell, M. A., Dossett, C. D., McCleeary, E. M., ... & Sager, E. R. (2008). Promoting health communication between the community-dwelling well-elderly and pharmacists: The Ask Me 3 program. Journal of the American Pharmacists Association, 48(6), 784-792. Lapiz-Bluhm, M. D., Weems, R., Rendon, R., & Perez, G. L. (2015). Promoting health literacy through "Ask me 3.". JNPARR, 5, 31-37.	balanced if you are offering training to healthcare professionals, and helps to create a collaborative space with service users and healthcare professionals on an equal footing. Both need to be involved in SDM.
Health Literacy UK	Draft Guideline	007	018	We welcome this but suggest also making the patient aware of local or national organisations/resources who might provide support or information, including local or national VCSEs	Thank you. We agree this is an example of what could be done.

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Health Literacy UK	Draft Guideline	008	005	Suggest wording could be perceived as pejorative/value laden, we recommend replacing with a statement that there are a number of reasons people might find it more difficult to share in decision making, for example...	Thank you. NICE recommendations are active rather than informational. We have reworded this to make clearer the committees intent.
Health Literacy UK	Draft Guideline	008	037	We suggest RCTs/systematic reviews of RCTS to narrow a search for evidence in this field and clearly unlikely to yield results given the nature of this issue. As NICE has previously done with Public health guidance it needs to access a wider range of research evidence recognising the limitations of RCTs as a source of evidence in this context	Thank you. NICE identified substantial numbers of RCTs in this area and therefore prioritised this gold-standard methodology for effectiveness questions.
Health Literacy UK	Draft Guideline	009	020	Ensure that notes are written in a way that complies with good practice in producing written information	Thank you. The content of medical notes is beyond the remit of this guideline.
Health Literacy UK	Draft Guideline	010	015	Resources as well as decision aids should be evidence based and up to date. Include reference to NHS website	Thank you for your comment. Please see recommendation 1.2.4 where we have added "When providing information and resources: only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids."
Health Literacy UK	Draft Guideline	012	008	We suggest practitioner's attention is drawn to the high levels of adults who have difficulty with understanding and using numerical information and tailor discussions accordingly.	Thank you for your comment. The recommendations suggest using a mixture of both numerical and pictorial formats, and to be aware that risk may be interpreted differently depending on the service user.
Health Literacy UK	Draft Guideline	016	005	We welcome the use of qualitative evidence but a summary of what it found /contributed here would be helpful	Thank you for your comment, a summary of the qualitative evidence can be found in evidence review A

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Health Literacy UK	Draft Guideline	016	018	We welcome the committee's proposals for ways of ensuring patients influence the SDM process at the highest level but suggest that other ways of engaging patients should also be explored and adopted e.g., patient participation groups, patient consultation, and experience surveys, and focus groups	Thank you for your comment. Monitoring and feedback, including service-user feedback, is covered in recommendation 1.1.9: "Plan internal or external monitoring and evaluation (including service user and staff feedback activities) and how to feed back the results to staff at individual, team and management level." This rationale and impact section is specifically focusing on embedding SDM at the highest level. The methods you mentioned could be potential ways of collecting service user feedback under 1.1.9
Health Literacy UK	Draft Guideline	016	024	Whilst recognising that digital technology can be used to support SDM its is essential to recognise that in SDM as elsewhere it can also result in further inequalities and exclusion if this possibility is not recognised and explicitly addressed	Thank you for your comment. Recommendation 1.2.5 stated that resources should be offered to service users in their preferred format, including if this is non-digital. This also extends to 1.2.18 for post-appointment materials.
Health Literacy UK	Draft Guideline	017	003	. The Muscat 2019 study which is referenced, used the English national Skilled for Health Resources. However, there is no reference/ signposting to the Skilled for Health resources currently hosted on the Reaching People website. https://www.reachingpeople.co.uk/training-consultancy/training-resources/ Reaching People in agreement with NHS England, Public Health England and the Department for Education have been asked to host the national Skilled for Health resources temporarily whilst a long-term solution is discussed and agreed. These evidence-based	Thank you for this information.

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				resources were co-produced and extensively tested by the Department of Health, the Department for Education, and the learning charity ContinYou, the predecessor body, of the Community Health and Learning Foundation as part of a national partnership. An external evaluation of the resources showed they improved people's skills, knowledge, and confidence about their health as well as their language, literacy, and numeracy. They were subsequently updated and tested again by CHLF via funding from NHS England and the Department for Education. They are available and may be accessed and used freely. Training on their use and on Health literacy developed by the former CHLF can be accessed via Reaching People and their website as noted above.	
Health Literacy UK	Draft Guideline	017	024	We Suggest excellent and health literate communications as the latter can be defined and has standards which can be measured and applied consistently	Thank you for your comment. Shared decision making has other facets beyond health-literate communications thus the wider term has been employed here.
Health Literacy UK	Draft Guideline	018	024	This fails to acknowledge the role and contribution of VCSE organisations as sources of professional information advocacy and support to which patients can be signposted or may choose to access. It suggests professional support is the gift of the health care system. The implication of this decision as elsewhere	Thank you. Patient organisations have been added into the relevant recommendations.

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				emphasises SDM as something given to patients by the system.	
Health Literacy UK	Draft Guideline	024	006	The studies mentioned here describe teach back as a patient activity done by the patient to the practitioner. We would suggest that this is recognised as an outcome of good health literacy practice by the provider to facilitate this. It should be recognised as the responsibility of the provider to ensure that their communication enables the patient to do this.	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.
Health Literacy UK	Draft Guideline	General	General	Whilst we welcome the recognition that Health Literacy is a fundamental component of Shared Decision Making, we are concerned that the work reviews evidence and makes recommendations consistently on the basis that health literacy is applicable only to patients/clients. However, the WHO adopted a definition of health literacy in 2015 which makes it clear that health literacy is a two-way process. It is" the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about health". This definition highlights that Health literacy is a two- way process; practitioners need to adopt health literate good practice, tailoring the message to their client. We are concerned that without explicit two way action to improve health literacy of practitioners and people SDM cannot	Thank you. Improving health literacy is beyond the remit of this guideline, however we believe that recommendations 1.4.1 to 1.4.4 cover the points you raise in the context of SDM.

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				be successful. Evidence suggests that there is a significant gap between the levels at which information is produced and the literacy and numeracy of the population. This approach to health literacy may contribute to or why the guidance also appears to be transactional rather than relational and comes across as top down rather than partnership focused. An approach suggesting a one way process of giving the patient information which we suggest is incompatible with a process defined as ‘shared’ which requires working in partnership. Moreover, it needs to be recognized that there are a number of risk factors which increase the risk of low health literacy and that these are common to the experience of health inequalities more widely and also impact on SDM for example experiencing social disadvantage BAME, Long term conditions or disabilities. These challenges need to be recognized in embedding SDM	
Health Literacy UK	Draft Guideline	General	General	We welcome the recommendation that patient decision aids should be evidence based and up to date. We suggest that the role of other resources used to support the process should also be promoted and subject to this quality check.	Thank you for your comment: Recommendation 1.2.4 now states: “only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids” To cover other resources.

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Health Literacy UK	Evidence Review A	General	General	Whilst we welcome this evidence review as collating useful information it disappointingly only looks at work done to improve the health literacy of patients (generally those with low health literacy). Failure to understand and use the WHO definition of health literacy which supports the principles of SDM provides a barrier to implementation. Even the only reference to 'teach back' recognised as an effective method for practitioners to check the effectiveness of their communication with patients by asking them to explain it, uses a study which sees it as a test of patients.	Thank you for your comment. This wider definition of health literacy is covered in other areas of the evidence reviews, for example the qualitative aspect of evidence review A, looking at the barriers and facilitators of SDM including patient empowerment. Access to information at both an organisational level and individual level is also discussed in evidence review E.
Health Literacy UK	Evidence review B	General	General	Whilst we welcome the recognition that Health Literacy is a fundamental component of Shared Decision Making, we are concerned that the work frames health literacy as an intervention aimed solely at improving patient's literacy. It frames it as an intervention addressing a patient deficit. However, the WHO adopted a definition of health literacy in 2015 which makes it clear that health literacy is a two-way process. It is" the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about health". This definition highlights that Health literacy is a two way process;	Thank you for your comment. The nature of SDM as a two way process is discussed in detail throughout the guideline, including the importance of clinician attitudes and skills and their responsibilities in the SDM process. Whether an intervention was aimed at a patient or practitioner was taken into account as part of the review process (see evidence review A and particularly the qualitative analysis).

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				practitioners have a responsibility to adopt health literate good practice tailoring the message and format to their client . This is fundamental to embedding SDM	
Health Literacy UK	Evidence review C	General	general	We suggest that Patient decision aids need to be checked for their readability and to be health literate.	Thank you for your comment. Recommendation 1.3.4 states that staff have access to quality-assured patient decision aids (assessed against the International Patient Decision Aid Standards)
Health Literacy UK	Evidence Review D	General	General	We note that understanding and making decisions which require an understanding of risk requires a high level of health literacy, but this review contains no reference to health literacy even though action to support improvement in both patients and practitioner's health literacy in this is a necessary basis for understanding and participation.	Thank you for your comment. The recommendations cover both the patient's and practitioners "understanding" of the resources provided is considered. This is also covered in other sections of the recommendations outside of the risk communication section.
Health Literacy UK	Evidence Review E	General	General	We welcome the range of evidence considered in the review and the recognition of the contribution of qualitative research and of expert witnesses, In this context we are disappointed that the key role of tools and techniques demonstrated to improve health literacy in both practitioners and people is not recognised. We suggest that both are fundamental building blocks of effective SDM	Thank you for your comment. The recommendations cover both the patient's and practitioners "understanding" of the information/resources provided is considered.
Health Literacy UK	General	General	General	Question3 Understanding of Health Literacy as defined by the WHO; a two-way process, which is the responsibility of both individuals and practitioners and thus a fundamental building	Thank you for your comment.

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				block for SDM not just an intervention aimed at a perceived deficit in patients. Access to and use of health literacy resources for professionals and people. For example, Health Education England website-hee.nhs.uk training and resources Health literacy Toolkit. Skilled for Health resources on Reaching People website https://www.reachingpeople.co.uk/training-consultancy/training-resources/ Health Literacy UK website https://www.healthliteracy.org.uk/	
Healthwatch Cambridgeshire and Peterborough	Draft Guideline	004	002	Adequate resources and support for patient representatives should be made available to ensure equity in knowledge and influence. More robust arrangements for existing patient experience groups would be a starting point.	Thank you. The quality of patient representation in NHS organisations is not the remit of this guideline.
Healthwatch Cambridgeshire and Peterborough	Draft Guideline	008	018	Decisions should not be placed upon people who do not wish to take on the responsibility. Shared decision making should be a positive experience and not an expectation for everyone.	Thank you. We hope that recommendation 1.2.8 conveys this: "Ensure the person understands they can take part as fully as they want in making choices about their treatment or care".
Healthwatch Cambridgeshire and Peterborough	Draft Guideline	009	024	People who have additional communication needs should be offered information in a format that meets their needs, as stated in the NHS Accessible Information Standard.	Thank you. We have added a reference to the accessible information standard.

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Healthwatch Cambridgeshire and Peterborough	Draft Guideline	010	012	How cross-speciality information is presented to people should be considered before appointments, so that people are clear how different treatments might interact. Timelines should be included.	Thank you for your comment. The recommendation (now 1.1.11) has been modified to clarify this information and moved to the "Embedding shared decision making at an organisational level" section, to clarify this should be done before during and after discussions, and also modified to clarify information can be shared both within and between organisations: "Ensure that expertise and information can be shared effectively both within and between organisations so that healthcare professionals provide people with consistent information. See recommendation 1.1.7 and section 1.4 of the NICE guideline on patient experience in adult NHS services."
Healthwatch Cambridgeshire and Peterborough	Draft Guideline	010	015	It would beneficial if a standard decision making aid could be adopted, or least some good practice frameworks recommended.	Thank you. Please see recommendation 1.3.4 which refers to the IPDAS standard.
Healthwatch Cambridgeshire and Peterborough	Draft Guideline	014	015	Further research would be very welcome to help understand best ways to engage people from groups who tend to be socially excluded. This could also investigate different perspectives of health inequalities.	Thank you for your comment, NICE agrees more research is needed in this area, thus the research recommendations for both measuring SDM in different contexts and for how to increase acceptability of SDM in populations who predominantly believe in the authority of healthcare professional.
Healthwatch Cambridgeshire and Peterborough	Draft Guideline	014	018	Qualitative research on measuring outcomes-based impacts could also give new insights on health inequalities.	Thank you for your comment, NICE agrees more research is needed in this area, thus the research recommendations for both measuring SDM in different contexts and for how to increase acceptability of SDM in populations who predominantly believe in the authority of healthcare professional.
Healthwatch Cambridgesh	Draft Guideline	General	General	Setting out a guideline for how healthcare professionals include people in decisions about	Thank you for your support.

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ire and Peterborough				their health is very welcome and has the potential for huge population health benefits. Meeting this guideline will require many healthcare professionals to undergo a significant shift in thinking and culture, it will need a significant investment of will and resources on the part of Trusts, to truly see this change. Local Healthwatch and other 'voice' organisations have a role to play with supporting this culture change and help develop actions and planning.	
HealthWatch UK	Draft guideline	007	001	Rather than 'How can we make a decision together that is right for me?' a better way of wording this question would be: 'How will you support me so that I make the decision about my care that is right for me?'	Thank you. Please see the definition of shared decision making in the 'terms used in this guideline' section.
HealthWatch UK	Draft guideline	007	010 - 016	The statement about safeguarding is too weak. We would recommend replacing this section with: *Ask the person if they want to involve family members, friends or advocates, remembering that family members and friends may not be aware of proper boundaries, or might deliberately choose not to observe them, and may infringe on the service user's/patient's autonomy. It is the responsibility of the professional to check, so far as possible, that the patient understands - and can exercise - their right to decide for themselves. If it seems proper to do so, include family members and friends in discussions as a way to help the person ...*	Thank you. NICE recommendations aim to be concise, and the committee was aware that all health professionals have to be trained in safeguarding.

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HealthWatch UK	Draft guideline	008	009	There is an assumption here that a family member or friend will be skilful enough to perform adequately as a translator and it also ignores the (often blurred) boundary between translating and influencing or persuading. In addition it ignores the risk of coercive control and inability for the healthcare professional to safely ask about potentially unsafe and confidential matters (such as domestic violence). We would recommend that NICE considers the following NHS England Guidance (the policy guidance document refers to relevant legislation and duties, including those under the Equality Act): https://www.england.nhs.uk/primary-care/primary-care-commissioning/interpreting/.	Thank you. We have not recommended that family are used as translators, and the recommendation is clear that safeguarding must be taken into account.
HealthWatch UK	Draft guideline	009	009 - 010	It is important not to give the impression that the capacitous patient's family members or friends are making (or even should be making) the decision rather than the patient themselves. We would suggest rewording these lines to: *Give people (and their family members or carers, as appropriate) enough time to discuss and consider the issues around tests and treatments. Consider deferring the final decision to a later date where possible.*	Thank you. The wording of this recommendation has changed.
HealthWatch UK	Draft guideline	011	009	The statement about the database of decision aids is too weak: instead of saying "[e]nsure the database is maintained so that decision aids are regularly reviewed and updated" the guideline should say something like "*make sure that a*	Thank you for your comment. The strength of recommendation for NICE is based on the quality of available evidence, and the committee believed the current strength of this recommendation reflects this.

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				nominated person or group of people is responsible for maintaining the database so that … etc.“	
HealthWatch UK	Draft guideline	014	006 - 012	The ‘three-talk’ model does not deal fully with the patient’s needs. Firstly, at line 12 the model should say: “*helping people explore their preferences and make decisions. In particular, the patient should be encouraged to articulate what treatment outcome it is that matters most to them; this may be cure, stabilisation of disease, improved mobility, pain relief etc but whatever it is should be fully understood by the HCPs who are providing care for that patient.*” Secondly, the model does not include the important option of the HCP saying to the patient: “if you are unsure about the best choice, would you like me to advise you on what I feel is the best decision?”. Many patients feel confused if doctors (especially) simply present them with a menu of options without saying what they (the doctors) thinks is best.	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.
HealthWatch UK	Draft guideline	016	003 - 004	The guideline admits that much of the evidence in this area is weak and that the guidelines group has had to rely on “expert evidence ... and their own expertise”. The poor quality of the evidence base is crucial in making decisions about implementation: without better evidence it is going to be hard to persuade trusts to commit staff time and financial resources to training staff members in SDM beyond a fairly basic level –	Thank you for your comment. We have made the research recommendations in the relevant section of the guideline.

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				see comments 8, 9 and 10. Research recommendations should match the gap	
HealthWatch UK	Draft guideline	General	General	The draft document does not define or state explicitly what NICE thinks shared decision-making (SDM) is or what it is meant to achieve. There is little point in promoting SDM, and little chance of it being adopted enthusiastically, unless its purpose is clearly stated and justified. We also wish to emphasise that, in the great majority of cases, the process will be one of supporting the person to make a decision rather than some form of horse-trading between the patient and the health-care professional, i.e. what we are talking about is <u>supported</u> decision-making rather than <u>shared</u> decision-making. We suggest the following wording: *supported (or shared) decision-making is important for clinicians, patients and for the NHS itself. Without SDM it is difficult to fulfil the clinical imperative of informed consent. Moreover, without it clinicians are left open to challenge about the decisions they have taken. For patients it is the best way to achieve outcomes which best match their short- and long-term goals, and which are most likely to lead to them being happy with the process. Where patients would prefer to leave treatment options in the hands of their clinicians this should be respected but must be documented. Similarly, clinicians should document why they cannot offer*	Thank you. Shared Decision Making is defined in the 'terms used in this guideline' section and the definition is hyperlinked from each section of the guideline.

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				interventions that some patients wish to have (for example "for professional reasons", such as if they are illegal, too harmful, not indicated, if other safer or cheaper alternatives have not been tried first or NICE has recommended "Do not offer" or "offer only in research") See also comment 11 below.	
HealthWatch UK	Evidence Review A	018	General	This table shows that, out of 17 studies on patient-targeted interventions, all but one were of low or very low quality. The same pattern is seen in table 6 (interventions targeting healthcare professionals), table 7 (interventions targeting patients and HCPs) and tables 8 to 10. We appreciate that this is the 'best available evidence' but it justifies strong research recommendations.	Thank you for your comment. You can see the research recommendations in the relevant section of the guideline.
HealthWatch UK	Evidence review B	016	General	The quality of studies on pre-consultation interventions, as assessed by GRADE, is again low or very low in nearly all cases. The same is true of table 10 – only one high-quality study identified – and the picture is only slightly better for patient activation (table 13). Again, this justifies strong research recommendations.	Thank you for your comment. You can see the research recommendations in the relevant section of the guideline. The scope document is available at https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents
HealthWatch UK	Evidence Review B	056	014 - 017	It is very worrying to read the statement that: "[there is a] lack of evidence focusing on ethnic minorities, persons with lower health literacy, less experience of using digital technologies (e.g. some older patient groups), more co-morbidities, people from lower income backgrounds, and other groups who have been	Thank you for your comment. You can see the research recommendations in the relevant section of the guideline.

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				less likely to engage with SDM", in other words, the very people who are likely to need the most help with decision-making. We welcome the call for more research but, once again, would caution against the commitment of large amounts of resource by healthcare trusts until the picture is clearer.	
Hospice UK	Draft Guideline	004	008	We suggest that the appointment of a Patient Director (from a healthcare service user background), in offering representation at the most senior level is critical to the successful embedding of a shared decision making approach and ethos.	Thank you for your support.
Hospice UK	Draft Guideline	005	002	Close attention must be paid to organisational cultures and systems in order to put shared decision making into practice successfully. Cultural change takes time and it is vital that staff see benefits of these approaches in order to help overcome any obstacles to implementation.	Thank you for your comment.
Hospice UK	Draft Guideline	006	027	Our general comment above (#1) illustrates that a much more nuanced approach is needed to shared decision making within the context of end of life care. This is turn highlights the importance of developing the essential communication skills to support shared decision making.	Thank you. This recommendation is about promoting shared decision making to service users, not about communication skills. The guideline aims to be applicable to all settings and therefore cannot be nuanced to any single specific setting.
Hospice UK	Draft Guideline	009	019	The emphasis on reviewing decisions with end of life care is critical. Further timely conversations provide opportunity to revisit previous decisions and preferences in the light	Thank you for your comment.

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				of an illness's progression and any changes to a person's circumstances or wishes.	
Hospice UK	Draft Guideline	010	015	Evidence-based tools to support shared decision-making can be valuable in helping people to clarify their personal values and consider care options. However, shared decision making must never become a tick box exercise reliant on a decision aid. It's important that patient decision aids recognise the need to assess individuals' preferred roles in decision-making ahead of beginning that process. We have noted above (Guideline; General comment) that not everyone wishes to fully participate in shared decision making. Equally, research (Phillips et al, 2019) suggests that patient decision aids within the context of end of life care should flag individuals' needs for family involvement before shared decision making gets under way, so that healthcare professionals can take these needs into account in moving forward. There is room for the development of further patient decision aids aimed specifically at supporting shared decision making in the context of end of life care. Such tools should be mindful of varying needs arising from types and	Thank you. Please see recommendation 1.3.1. We based recommendation 1.3.1 on a Cochrane review which did not contain this recent study by Phillips et al, 2019.

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				stages of disease and illness, cultural preferences and individuals' preferences and values (Phillips et al, 2019). Phillips G, Lifford K, Edwards A, Poolman M, Joseph-Williams N. (2019) Do published patient decision aids for end-of-life care address patients' decision-making needs? A systematic review and critical appraisal. *Palliative Medicine* 33(8):985-1002. doi: 10.1177/0269216319854186.	
Hospice UK	Draft Guideline	023	001	Reference to advance care planning should also make clear the expectation that these conversations and documents should be regularly updated in response to the potential for changes in an individual's needs, preferences and circumstances. Equally, discussion of future care wishes should ideally take place when a person is not acutely unwell, but within the understanding that a person's illness or condition is serious and that the end of life may be anticipated.	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.
Hospice UK	Draft Guideline	General	General	Patient choice is a key principle of palliative and end of life care and informed shared decision making provides a clear process to enable this and deliver person-centred care. However, within the context of end of life care, making informed and shared decisions takes	Thank you for this information. The recommendations are intended to apply to all populations, including those at end of life.

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				place within an arena of uncertainty, complexity and variety (derived, for example, from diagnoses of multiple health conditions; making choices about continuing with life-sustaining treatments and quality of life, acceptance of an illness's progression etc.) and heightened emotion as people contemplate the approach of the end of life. Ultimately, shared decision making within palliative and end of life care is based upon the recognition that the person may not get better and may die from their illness. Thus shared decision-making for someone approaching the end of life is quite different to situations where prevention or cure are anticipated. These decisions span immediate outcomes, as well as future care considered within the context of advance care planning. They are conversations which consider goals of care, along with weighing up quality of life and uncertainties in treatment outcomes. The process of decision making at these life points requires time and levels of personal energy on behalf of the person receiving care and those close to them. It must also take into account that some individuals may not have a clear understanding of the progression of their	

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				illness so may not recognise that it is terminal (Kendall et al, 2015). The national framework, 'Ambitions for palliative and end of life care' (2015) highlights the importance of personalised care planning, pointing out that in creating such plans, the opportunity for informed discussion and planning should be universal. The need for sensitive communication is also echoed in 'Priorities for Care' (2014) which requires that the dying person, and those identified as important to them, are involved in decisions about treatment and care. This approach to the care of people who are dying also requires that decisions about care are made in accordance with the person's needs and wishes, and that these decisions are reviewed and revised regularly by healthcare professionals. It is worth recalling that the National Survey of Bereaved People (VOICES) England (ONS, 2015) reported that 20% of respondents said that decisions were made about the patient's care, which the patient would not have wanted. Whilst there is evidence that many people wish to be involved at least to some degree in decision-making (Bélanger et al, 2011), there is also evidence that some may wish to delegate this role or engage at a more passive level, so	

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				conversations with individuals about their preferred level of engagement before the decision-making processes actually begin are important. Preferences may also vary according to the type of decision being made. In a scoping report for 'Building on the best' (a quality improvement partnership for acute hospitals which aimed to improve patients' quality and experience of care), several transition points that may provide a focus for shared decision making were highlighted (National Council for Palliative Care & Macmillan Cancer Support, 2016): • 'an acute admission and discharge of patients who may be in the last year of their life • on acute deterioration often associated with a review by specialist teams • recognition of poor prognosis / uncertain recovery / gradual deterioration / "failure to thrive" • on diagnosis of a terminal or life-limiting condition • patients who are "discharged" from hospital care.' Case studies illustrating shared decision making from the Building on the best' project are available on Hospice UK's website: https://www.hospiceuk.org/what-we-	

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				offer/clinical-and-care-support/clinical-leadership/building-on-the-best With careful implementation there is much opportunity for improvement in this area. Bélanger, E., Rodríguez, C. & Groleau, D. (2011) Shared decision-making in palliative care: A systematic mixed studies review using narrative synthesis. *Palliative Medicine* 25(3): 242–261. doi: 10.1177/0269216310389348. Kendall M, Carduff E, Lloyd A, Kimbell B, et al. (2015) Different experiences and goals in different advanced diseases: comparing serial interviews with patients with cancer, organ failure, or frailty and their family and professional carers. *J Pain Symptom Manage*. 50(2):216-24. doi: 10.1016/j.jpainsymman.2015.02.017 Leadership Alliance for the Care of Dying People. (2014) *One chance to get it right: improving people's experience of care in the last few days and hours of life.* Leadership Alliance for the Care of Dying People.	
Human Rights in Childbirth	Draft Guideline	General	General	Human Rights in Childbirth (HRiC) is an international organisation that advocates for and defends the human and reproductive rights of women and babies in pregnancy and childbirth. We are especially focussed on advocating	Thank you. Shared decision making is not a replacement for informed consent and should never be substituted for it. The skills of shared decision making may improve consenting processes by helping ensure that the patient or service user

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				against mistreatment and abuse of women in pregnancy and childbirth, an all too pervasive subset of gender-based violence affecting women at their most vulnerable, that is, when giving birth. This advocacy includes the examination, through a legal and human rights lens, of the mechanisms that potentially lead to or lend themselves to such mistreatment and abuse. In this submission, we address additional questions (1) and (2) with a focus on the concept "shared decision making" in the context of maternity health services. We express our concern with the legal, human rights and practical implications of substituting the practice of obtaining "informed consent" with the legally fluid concept of "shared decision making". By way of summary, it is our submission that "shared decision making should not be used to replace the well-established, legally required and essential practice of obtaining informed consent, particularly in relation to women in childbirth. To do so would be to dilute a gold standard in medical practice developed over decades and endorsed by the WHO, International Confederation of Midwives and the International Federation of Gynaecologists and Obstetricians. It would also interfere with the	understands what they are agreeing to, but consent is not covered in this guideline.

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				contractual and consumer rights of patients entitled to relief at law. The better proposition would be to strengthen the national laws around “informed consent” and, more importantly, to impose administrative and enforcement strategies that require evidence of meaningful and practical applications of this human right at the institutional level in relation to maternity heath care. Informed Consent A key legal concept enshrined in human rights law and codified in some national laws is the right to informed consent. It is founded on the right to bodily autonomy and the right to health [Committee on Economic, Social and Cultural Rights, General Comment No. 14, The Right to the Highest Attainable Standard of Health, UN Doc. E/C.12/2000/4 (2000), para. 8]. International instruments and caselaw make it clear that the failure to afford informed consent during pregnancy and childbirth is a violation of a woman’s fundamental human rights. Examples are set out below.	

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				In its General Recommendation No. 24 on the core obligations of States parties under article 12 of the Convention (women and health), the Committee on the Elimination of Discrimination Against Women stated: *"States parties should also report on measures taken to ensure access to quality health-care services, for example, by making them acceptable to women. Acceptable services are those that are delivered in a way that ensures that a woman gives her fully informed consent, respects her dignity, guarantees her confidentiality and is sensitive to her needs and perspectives." (para 22)* In *I. V. v. Bolivia* [Report No. 72/14, Merits, Inter-American Commission on Human Rights, Case 12.655 (August 15, 2014), para. 186], the Inter-American court stated, in relation to the sterilisation of a pregnant refugee without consent: "*the informed consent of the patient is a sine qua non condition for the medical intervention, which is based on respect for the patient's personal autonomy and*	

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				freedom to choose her life plans without interference." Article 5 of the European Convention on Human Rights and Biomedicine 1997 provides: *"An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.* *This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.* *The person concerned may freely withdraw consent at any time."* Informed consent rests upon an assumption that, despite the esoteric nature of medical knowledge, ordinary people are more than capable of assessing their medical needs and making a decision in their best interests — including a decision not to follow a doctors' advice. HRiC is concerned that this assumption is often overlooked in the training of, and practice by, maternity healthcare personnel, whether they are nurses, midwives or doctors, as evidenced by the recent landmark UK Supreme Court	

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				decision in "*Montgomery v Lanarkshire*" (hereinafter *Montgomery's case*). The answer to this problem is not to dilute or deviate from the legal obligation to obtain informed consent. It is to train *and oblige* personnel to properly apply the requirement as a matter of good everyday practice and to administratively enforce the requirement to obtain informed consent. The principles for satisfying the requirement to afford informed consent are simple enough; two integrally linked, reciprocal requirements must be met before treatment can commence: (1) the duty to inform and (2) the right to consent. It acts as a contractual agreement between the parties for each recommended medical treatment: the offer (based on full disclosure of "terms and conditions") and the acceptance or rejection of that offer. On the right to consent or refuse medical treatment, while *Montgomery's case* is often hailed as new law, there is ample, established precedent in UK medico-legal caselaw on this question: *"A mentally competent patient has an absolute right to refuse to consent to medical treatment for any reason, rational or irrational, or for no reason at*	

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				all, even where that decision may lead to his or her own death." (MB, Re [1997] EWCA Civ 3093) Despite these early judicial interventions to preserve the rights to bodily autonomy, health and the privacy of pregnant women as persons equal before the law, the recent *Montgomery's case* is evidence that "consent", as a legal concept, remains a heavily contested issue in the everyday practice of maternity health services at the institutional level, where the boundaries between a practitioner's duty to inform and the woman's right to consent are constantly being shifted in favour of the practitioner. *Montgomery's case* does, however, judicially affirm the specific obligations of careproviders when seeking consent for a treatment. By law, careproviders are now required to do much more than engage in the usual practice of securing a signature on a standard consent form. They must offer timely information that will enable a pregnant woman to either consent to or refuse treatment, which includes an assessment of the material risks and benefits and the discussion of reasonable alternatives to the proposed treatment.	

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				Rhetoric vs Reality In most high-income countries like the United Kingdom, comprehensive judicial precedent, policies and guidelines together establish resources for obtaining informed consent. Unfortunately, these materials appear to have limited impact on the practical realities faced by the people who consume maternity health services. In our work today, the fact pattern in *Montgomery's case* of dismissing women's concerns and requests for information and the failure to obtain informed consent prior to initiating treatment (or even, in some cases, over objections to that treatment) remains the norm. In some countries, including middle to high income countries, disrespect and mistreatment is so common that women speak of themselves as being "lucky" if they survived the childbirth experience unscathed. In 2015, the extent of the mistreatment in both high and low income countries prompted the World Health Organisation to publish a statement on the extent and impact of abuse and disrespect of women in facility based childbirth. The abuse and disrespect are documented as a violation of women's human	

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				and reproductive rights, and a subset of gender-based violence against women. This was followed by the 2018 WHO recommendations on intrapartum care advocating for a holistic, human rights-based approach to the provision of maternity health services. In practice, the broad majority of health facilities have become impervious to a birthing woman's human rights. Focussing only on hastening the delivery of the infant, maintaining hospital process lines and gender based stereotypes about women and motherhood, many personnel simply do not "see" the rights violations and gender-based violence being perpetrated in their presence. As a result, careproviders are dismissive, angered or genuinely confused by complaints about violations of rights, especially the failure to afford informed consent. For example, in *Montgomery's case,* the plaintiff gave evidence, in relation to a birth that took place in 1999, that she was pleading with her care providers to answer her questions and to respond to her repeated questions about needing a Caesarean Section. Her careprovider admitted that she did not attempt to understand, let alone meet, the plaintiff's needs because, in her view, the doctor knew better. Despite the obvious violation of her human rights, it took the plaintiff nearly two decades and lengthy, repeat	

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				court battles to receive judicial acknowledgement that a failure to afford informed consent had caused harm to her and her infant. In addition, the ongoing response to *Montgomery's case* has raised questions about continued careprovider confusion around the concept and application of informed consent. Human rights lawyers saw the UK Supreme Court's determination as a nod to the inviolable yet poorly enforced principles of informed consent in the provision of maternity care in the UK. By contrast, the UK's Royal College of Obstetricians & Gynaecologists considered implementing processes to warn women about the risks of having a vaginal birth – a spontaneous bodily function which, in and of itself, is clearly not a medical intervention and therefore should not require *any* consent. On the human rights front, little has changed since Mrs Montgomery gave birth. In 2019, the UN *Special Rapporteur on violence against women, its causes and consequences on a human rights-based approach to mistreatment and violence against women in reproductive health services with a focus on childbirth and obstetric violence* [UN Doc. A/74/137] expressed virtually identical concerns based on reports	

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				received globally. In that report, the Special Rapporteur cited a failure to afford informed consent based on harmful gender stereotypes about motherhood and women's subordinate role in society, and the unequal power dynamic within provider-patient relationships as root causes of mistreatment and violence in childbirth. Then there is the abuse of the doctrine of medical necessity. In *Montgomery's case,* the plaintiff's careprovider retrospectively sought to justify her actions by asserting the doctrine of medical necessity. Two decades later, the UN Special Rapporter reported an abuse of that same doctrine, citing examples of where it was used to justify a violation of women's human rights, in particular the right to informed consent. These difficult circumstances are exacerbated when already constrained health systems are caring for birthing persons from non-English speaking backgrounds, or who are refugees, immigrants, in domestic violence situations, differently abled or identify as LGBTIQ. When in balance, informed consent will constitute an agreement between care provider and woman over what treatment option to take in each instance, how it will be performed and whether it can result in any side effects, well before contact is made with the woman's body.	

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				That balance, particularly in the provision of maternity health services, is fragile. Women in labour are already vulnerable, made more so if they are young or socio-economically disadvantaged. They are unfamiliar with hospital protocols and the time restrictions being imposed on them. They feel restrained, exposed and displaced by repeated interventions and interactions with multiple and everchanging care providers. They are intimidated by the professional strangers pushing them into medical interventions. Equally, careproviders weighed down by liability concerns, professional and employment obligations, and cost cutting measures will inevitably elevate practical or medical expedience and outcomes over unmeasurable concepts such as compassion and dignity. When careproviders are supported by the authorities or administrative bodies also seeking to avoid liability, the resulting power imbalance between woman and careprovider cannot be overstated,. As the Committee for the Elimination of Discrimination against Women determined in *S.F.M v Spain* [CEDAW/C/75/D/138/2018] (reported in 2020):	

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				"The Committee considers that stereotyping affects the right of women to be protected against gender-based violence, in this case obstetric violence, and that the authorities responsible for analysing responsibility for such acts should exercise particular caution in order not to reproduce stereotypes. *In the present case, the Committee observes that there was an alternative to the situation experienced by the author, given that her pregnancy had progressed normally and without complications and that there was no emergency when she arrived at the hospital but that, nevertheless, from the moment she was admitted, she was subjected to numerous interventions about which she received no explanation and was allowed to express no opinion.* *Furthermore, the Committee observes that the administrative and judicial authorities of the State party applied stereotypical and thus discriminatory notions by assuming that it is for the doctor to decide whether or not to perform an episiotomy, stating without*	

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				explanation that it was "perfectly understandable" that the father was not allowed to be present during the instrumental delivery and taking the view that the psychological harm suffered by the author was a matter of "mere perception", but that they did show empathy towards the father when he stated that he had been deprived of sexual relations for two years." As shown above, without the oversight of legal and human rights principles protecting the right to informed consent, that power imbalance can quickly shift in favour of the careprovider, without appropriate accountability. As we discuss in the next section, shared decision cannot address this deficiency in practice. It will only provide further means for avoiding responsibility and accountability in relation to obtaining consent. "Shared Decision Making" The Committee has described shared decision making as a "collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care".	

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				In contradistinction to what we have outlined in relation to informed consent above, this definition seeks to conflate the two distinct legal concepts of "practitioner obligation" *vis-à-vis* "woman's right", treating the final decision on the care received by the patient as involving a "joint decision". In cases involving criminal assault and battery, both avenues being applicable (but uncommon) to medical practice, the question of consent is significant because evidence of consent is either a complete defence or can, at the very least, establish that the criminal standard for conviction, ie "beyond reasonable doubt", has not been met. In medical negligence, such as with *Montgomery's case,* informed consent is an essential component of the transactional agreement between provider and patient without which, the practitioner can be said to have breached their duty to inform of the material risks and to offer alternatives. In this context, shared decision making as a practice raises several legal questions: (a) If decisions on care are jointly made, does the patient also share in the obligation to provide medical information and knowledge?	

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				(b) Who makes the final decision or has the right to decide what treatment options to adopt? (c) Who is accountable for errors in medical practice if consent can be "jointly agreed" by both parties? (d) In the event of a disagreement on a proposed care plan, what protections will be afforded to vulnerable patients who, by reason of a shortage in medical personnel (such as in rural or regional areas), cannot find an alternative careprovider? (e) Can shared decision making constitute a blanket agreement that the patient has understood and therefore consented *in advance* to all aspects of medical intervention? (f) In relation to allegations of assault and battery, does shared decision making vitiate access to legal redress for assault and battery, rendering nugatory any accountability for trespass to the person in the practice of medicine? (g) Will shared decision making develop a new (and lower standard of) legal	

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				accountability in relation to consent for the medical industry? Example: The Birth Plan The best example of the practical difficulties associated with "shared decision making" is the attempt by women to use birth plans in the provision of maternity health care. Birth plans were introduced by childbirth educators to encourage birthing persons to have an open discussion with their careproviders about the type of care they would like to receive before admission to hospital for labour and delivery. It is aimed at eliciting conversations about hospital protocols and standardised services offered by maternity health care providers and the possibilities for deviating from that standard. It recognises that women are vulnerable while in labour and are not in a position at that time to contest hospital protocols, keep track of the number of interventions being proposed and/or protect their privacy or their supporters, often all at the same time. It leads to consumer understanding and forewarning about careprovider preferences, particularly in relation to medical interventions such as pain relief, episiotomies and continuous monitoring during labour. Put simply, the birth plan is the best evidence of what a woman is willing to consider and consent to in relation to treatment options	

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				during the birth. Any change proposed to those terms requires informed consent, that is, a provider that shares information which includes an assessment of the risks and benefits and an offer of alternatives, in exchange for either agreement or refusal. To do otherwise will constitute assault or battery. In law, birth plans should carry the same weight as the stated preference of an adult Jehovah's Witness who is refusing blood products. In reality in maternity health care practice, however, birth plans are derided by providers of maternity health care. The words of one provider could not have put it more succinctly than this: “'*A steady but growing trickle of* strange *ladies is infiltrating the system and arriving in labour wards up and down the country with a familiar shopping list of demands telling doctors and midwives what to do.... These patients tend to arrive, without warning, in the Labour Ward with their lethal shopping lists.... They are not entitled to tell doctors how to do their work. They are not entitled to ask us to lower professional standards and to jeopardise babies' lives*.'	

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				It would be trite to state that this extraordinary statement is at odds with the law and in conflict with the human right to equality, freedom from discrimination, the right to the highest attainable level of health and the right to bodily autonomy and informed consent. Negative provider reactions to birth plans remain the norm to this day. HRiC receives numerous complaints, on a weekly basis, from women residing in high income countries including the UK, who sought and failed to engage their careproviders with a birth plan. Most careproviders are either unwilling or afraid to disclose personal practice preferences or standard hospital protocols. Women report that their health service or private provider either scoffed at or dismissed the notion of a birth plan, refused to even look at the birth plan or, perhaps worst of all, accepted a copy of the birth plan and subsequently either ignored or claimed to have lost the copy. By the time the woman arrives in hospital in labour and realises that her birth plan has been set aside as self-entitled nonsense, she is too vulnerable to effectively contest or, like a consumer in any other circumstance, to vote with her feet. The provider is already very much in control during this exchange. When we add economic, social or cultural disadvantages to that control dynamic,	

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				women find themselves in the perfect storm - all while delivering a baby. Conclusion In summary, HRiC submits: (h) "informed consent" is the gold standard in human rights and medical practice for protecting vulnerable patients which, in relation to the provision of maternity health services, is endorsed by the World Health Organisation, the International Congress of Midwives and the International Federation of Gynaecologists and Obstetricians; (i) "informed consent" has been developed over decades under the scrutiny of both human rights law and the national laws of countries; (j) "informed consent" takes into consideration the respective rights and responsibilities of the parties, and constitutes the best evidence of the agreement between provider and patient for the provision of medical services; (k) shared decision making, as defined in the draft recommendations, is at odds with the principles enshrined in the human and legal right to informed consent;	

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				(l) the concept of shared decision making fails to acknowledge or address the power imbalance already evidenced in the provider/patient relationship in the provision of maternity health care; (m) shared decision making assumes a health literacy that the most vulnerable amongst us – those subjected to adverse and/or hostile social, cultural and economic circumstances – will simply be unable to meet and can result in resigned acquiescence; (n) shared decision making, by its very definition, dilutes the clarity required to determine who will be ultimately held accountable for breach of the duty to inform, the right to consent, negligence and/or mistakes and, with few exceptions, assault/battery; and (o) the implications for diluting the legal concept of 'consent' in the UK are potentially far reaching and should not be dismissed until fully examined through consultation with legal professionals. Recommendation	

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				"Shared decision making" cannot and should not be used to circumvent or avoid the obligation to protect the human right to informed consent. The real problem is that the obligation to afford informed consent is poorly understood – a reflection of the education and training of, and practice by, maternity healthcare personnel. The answer to this problem is to: (a) train and educate maternity health personnel on the human rights elements of informed consent without a narrowing of the concepts or an interpretation based on provider preferences; (b) develop administrative and enforceable expectations at the institutional level for applying the practice of obtaining informed consent in relation to all treatment options as a matter of good standard practice; (c) develop new ways to record and document informed consent which does away with the practice of obtaining last-minute signatures on standardised consent forms. This should be done not simply to protect from liability and/or loss of employment but, as a	

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				minimum, to impose sound professional medical practice developed through a human rights lens.	
Keele University	Draft Guideline	005	002	'Identify existing good practice in departments or teams where shared decision making is already being practised routinely' – how is this evidenced? We are concerned that without being explicit, organisations may measure this by decision aid (DA) use. SDM is more than just using a decision aid – and use of a decision aid does not equate to SDM. A culture of SDM could be best evidenced by patient stories and feedback, or from complaints better than metrics of DA use. It would be helpful to specify how to measure or evidence SDM.	Thank you. We believe this is clear in the context of the whole guideline which explicitly makes the points you mention - that SDM is an ongoing process, that PDAs are not shared decision making and that service users should feed into service design and evaluation.
Keele University	Draft Guideline	005	007	'Identify departments or teams where shared decision making can be 8 put into practice most easily next' – as above – What does 'put into practice' mean? SDM is a culture, and created by clinician training. See our concerns in comment above. Role out of Decision aids does not equal SDM. Instead, we should encourage depts to consider the evidence they collect which demonstrates SDM – and specifying outcomes, measures and evidence would be helpful.	Thank you. The guideline notes more than once that PDAs are not the same as SDM, and this recommendation does not mention PDAs. SDM is a culture and a series of skills that can be put into practice after appropriate training and this is what is intended by putting it into practice. The evidence collected is also discussed in recommendation 1.1.9.
Keele University	Draft Guideline	005	020	Set out how people who use services will be involved in supporting 21 implementation. – implementation of what?	Thank you. This recommendation has now been clarified to refer to an "improvement plan".
Keele University	Draft Guideline	005	General	Including training on SDM as part of organisation induction for clinical staff would be	Thank you for this useful information.

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				an example of promoting a culture of SDM. We are developing brief online learning on SDM, which incorporates interventions mentioned in this guidance (pre-appointment information, health literacy interventions, use of tools, third person support etc.	
Keele University	Draft Guideline	007	001 - 002	It would be helpful if this section explicitly referenced how to achieve this in remote consultations which are becoming more common place. For example, if the consultation is conducted remotely, consider if SDM can be achieved e.g. can family members be actively involved if that is the patient preference	Thank you for your comment. The skills of SDM in remote settings are the same as in face to face settings, and this has been added to the rationale and also to a recommendation.
Keele University	Draft Guideline	009	027	Should this read lay version of clinical guidelines?	Thank you. NICE does not produce lay versions of guidance.
Keele University	Draft Guideline	010	001	Consider asking the person – should this be stronger – ask the person?	Thank you. We have amended the recommendation to "Ask people if they would like any clinical letters generated after their discussion with a healthcare professional to be written directly to them, with a copy sent to their GP, rather than just sent to their GP."
Keele University	Draft Guideline	011	007	We agree that local databases of decision aids would be helpful. However, this will be resource intensive and be best implemented if there was a SDM facilitator within organisations to lead this (a SDM champion alone may not be enough? May need administrative support?) Also, organisations could end up duplicating work. The Ottawa decision aid repository is a starting point. I wonder if specialist organisations would be better placed to collate relevant DAs in their	Thank you for your comment. There is currently no national repository for PDAs.

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				field? A repository of SDM training resources would also be helpful	
King's College Hospital NHS Foundation Trust	Draft Guideline	001	General	Who is it for? Include: - Educators and organisational development leads/teams - ICT leads - National organisations supporting the delivery of healthcare And/or, within first bullet, amend to 'Everybody who delivers *and supports the delivery of* healthcare services' In 'it may also be relevant for', consider including 'Young people'	Thank you. All of those groups are included in the delivery of healthcare services. Young people (under 18) are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents). However, please note that NICE is currently developing a guideline on patient experience of healthcare for babies, children and young people, which considers shared decision making. Please see https://www.nice.org.uk/guidance/indevelopment/gid-ng10119 for information on the development of this guideline
King's College Hospital NHS Foundation Trust	Draft Guideline	004	014	Ensure this reflects that 'practitioners' need to be multidisciplinary	Thank you for your comment. Whilst the committee agrees that a multidisciplinary healthcare professional would be useful, they acknowledge this will not be an option for every organisation and didn't want to specify as such in the recommendation.
King's College Hospital NHS Foundation Trust	Draft Guideline	005	019	Add 'Clinic templates and electronic records may need to be redesigned to capture the practitioner and patient conversations and shared decisions agreed.' Cross reference to 1.2.14 would be helpful.	Thank you. We have added a cross reference as you suggest.
King's College Hospital	Draft Guideline	005	1.1.5, line 3	After first sentence add 'Enlist support from organisational development and education	Thank you. The committee did not see any evidence on the use of organisational development and education experts.

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NHS Foundation Trust				experts within the organisation, where these are available.'	
King's College Hospital NHS Foundation Trust	Draft Guideline	006	002	Replace 'should' with 'must'	Thank you. This is a consensus recommendation from the committee. NICE only use the term 'must' in recommendations when there is a legal requirement. For information about the way NICE uses words to describe the strength of recommendations please see the box at the beginning of the recommendations section.
King's College Hospital NHS Foundation Trust	Draft Guideline	006	022	Embed this training into the organisation's training programme and formalise by keeping a record of participants. Ensure that training is concise and recurrent rather than time-intense and one-off.	Thank you. The detailed content of training is beyond the remit of NICE guidelines.
King's College Hospital NHS Foundation Trust	Draft Guideline	007	005	It would be helpful to have some examples of 'interventions' (and 'interventions' is a slightly jargon term)	Thank you. The committee chose the word interventions because of the breadth of the term. Examples of interventions are given throughout the rest of section 1.2.
King's College Hospital NHS Foundation Trust	Draft Guideline	008	001	Replace 'should' with 'needs to'	Thank you. NICE only use terms like 'must' or 'needs to' when there is a legal imperative.
King's College Hospital	Draft Guideline	008	1.2.9	This section is excellent	Thank you for your support.

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King's College Hospital NHS Foundation Trust	Draft Guideline	009	001	'intervention' is a bit jargon – how about 'treatment or test'?	Thank you. Intervention was used as a broader term which could, for example, cover prevention/prophylactic interventions.
King's College Hospital NHS Foundation Trust	Draft Guideline	009	027	In the brackets, replace 'for example' with 'including' and add 'www.nhs.uk' after NICE guidelines.	Thank you. We have added nhs.uk to recommendation 1.2.4 which outlines examples of high quality reliable sources of information, these examples would also apply to 1.2.18.
King's College Hospital NHS Foundation Trust	Draft Guideline	010	012	Add 'Organisations and' to the start of the sentence and replace 'should' with 'must'	Thank you. NICE only use the term MUST when there is a legal imperative.
King's College Hospital NHS Foundation Trust	Draft Guideline	010	014	Add a new sub-section for 'Organisations' and new lines: - Organisations need to support information-sharing, e.g. through ICT systems and joined-up (integrated care) processes. Organisations need to support clinicians to structure and record shared-decision making	Thank you for your comment. Please see recommendation 1.1.11 which deals with sharing information: "Ensure that expertise and information can be shared effectively both within and between organisations so that healthcare professionals provide people with consistent information." 1.1.7 also covers this: "Review how information systems might support shared decision-making" and mentions recording of shared decisions.

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				conversations and decisions, e.g. through structured ICT records or clinic documentation.	
King's College Hospital NHS Foundation Trust	Draft Guideline	010	023	How will practitioners know this? There needs to be a national resource for approved decision aids. See final comment below.	Thank you for your comment. Recommending a national database of PDAs is outside of NICE's remit.
King's College Hospital NHS Foundation Trust	Draft Guideline	011	003	Replace 'should' with 'need to'	Thank you. NICE only use the term must or need to when there is a legal imperative.
King's College Hospital NHS Foundation Trust	Draft Guideline	011	007	It doesn't make sense to require each individual healthcare provider to do this. The guidance needs to be 'A national organisation needs to be identified to maintain and regularly review a database of decision aids. Local organisations must provide access for staff to this resource.'	Thank you for your comment. There is currently no national repository for PDAs.
King's College Hospital NHS Foundation Trust	Draft Guideline	012	001	Replace 'should' with 'must'	Thank you for your comment "must" has a specific meaning within nice guidance and can only be applied if the recommendation is required by law.
King's College Hospital NHS	Draft Guideline	012	008	Whilst this section is excellent, there are quite a few jargon terms (e.g. pictograms, icon arrays, natural frequencies, negative framing). Difficult	Thank you. The terms used in this guideline section only defines terms that have a use specific to the guideline, not terms that are used in their general sense.

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Foundation Trust				to avoid but could perhaps be explained in the Terms Used section on page 13.	
King's College Hospital NHS Foundation Trust	Draft Guideline	012	012	'If available,' needs to be moved to the beginning of the sentence (or alternatively a comma added before 'if')	Thank you for your comment. The committee felt the current interpretation was not affected by the moving of these words.
King's College Hospital NHS Foundation Trust	Draft Guideline	012	028	A new section is required: 'Monitoring implementation of shared decision making' to include some suggested indicators that need to be reported up to the accountable Board member, e.g. patient feedback, number of staff trained, staff feedback.	Thank you. This is covered in recommendation 1.1.9
King's College Hospital NHS Foundation Trust	Draft Guideline	012	029	A new section is required: 'National support for shared decision making'. Needs to include: - Questions on shared decision making to be added to national patient surveys, staff surveys and CQC key lines of enquiry - Provision of an electronic library of approved evidence-based decision aids, regularly reviewed and updated	Thank you. This is outside of NICEs remit.
King's College Hospital NHS Foundation Trust	Draft Guideline	015	New sections	To be added for future research needed: a) Patient-reported experience measures – national work to identify what patients identify as the most important outcomes and what were the most commonly occurring short-, medium- and long-term	Thank you for your comment. The research recommendation "What are the best ways to measure shared decision making in different contexts with different populations and which reflect the complexity across encounters and people involved?" covers patient-reported experience measures also.

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				outcomes (i.e. patient-defined outcomes measures). To be undertaken with groups of patients with similar attributes (e.g. conditions, cultures). Economic analysis – cost-effectiveness of involving shared decision-making, such as costs (staff training, ICT configurations, patients choosing more treatment) versus savings (e.g. patients choosing less/no treatment).	Assessing the cost-effectiveness of SDM was out of scope for this guideline. This is largely due to the fact that an assessment of the cost-effectiveness of SDM transcends a simple comparison of the associated costs and QALYs as would be done for other interventions recommended in other NICE guidelines. QALYs are unlikely to capture the complete benefits of SDM as it's effects extend beyond health impacts. There is also an ethical imperative for SDM to be part of care, which is the primary focus to be addressed with this guideline. It should however also be noted that SDM will be used to help patients decide between treatments/care that is already provided in the NHS (and already considered cost-effective) and therefore SDM really just results in a decision between which cost-effective treatment/care the individual prefers to use.
King's College Hospital NHS Foundation Trust	Draft Guideline	General	014	New point (1.3.6): Ensure that staff have access to education and training in relation to using patient decision aids, as required.	Thank you. We have addressed this in recommendation 1.3.3
Medical Protection Society	Draft Guideline	004	General	By stating the audience for this document as 'everybody who delivers healthcare services', this guidance is very broad and fails to take into account the substantive differences in service delivery in primary care dentistry, compared with (as appears to be the assumed healthcare model), for example, large NHS trusts. Discussion of senior and middle management and patient directors is a clear demonstration	Thank you. Dentistry was represented on the committee, and the committee agreed that dentistry was an important case for SDM, given the direct cost to service users. In regards to the definition of dental practices, after discussion with committee this has been changed to accurately capture the role of local dental groups within the healthcare landscape. Healthcare professional has also been clarified more in the terms used section.

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				that the proposed operational framework does not reflect the reality of the majority of primary care dental practice. Indeed, "dental practice" appears to have been included as an afterthought: it is mentioned only once in the main guideline (Page 13 line 6) as an example of an organisation and "dentistry" is not mentioned at all in the main guideline. There are only two pieces of evidence related to dental practice included in the 5 reviews. We would be interested to understand how NICE intends the guideline to be overseen for dental practice. Senior and middle management oversight will, we presume need to be placed, perhaps, at the Local Dental Network (LDN) level. We doubt that the LDNs will relish this unnecessary additional burden. 'Embedding shared decision making at an organisational level' by appointing a patient director, making a board member accountable and responsible for the leadership and roll out of shared decision making across the organisation or system is simply not reflective of the reality of the majority of primary care dental practice. . Given the scale of dentistry and dental practices SDM practices are already effectively embedded. Because receiving dental services incurs financial costs to most patients, shared decision making is fundamentally necessary and	The recommendations have been clarified to state that if an organisation doesn't have a board, a leader at the highest level of an organisation should be made responsible for SDM embedding.

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				exercised throughout the relationship between patients, the treating clinician and the supporting team. We refer to the comment in the Evidence Reviews "93% of patients in primary care are as involved as they want to be in their care.	
Medical Protection Society	Draft Guideline	013	018 – 022	MPS welcomes opportunities where the concept of shared decision making (SDM) are discussed and attempts to embed this further in UK healthcare services are recommended. Indeed, MPS provides extensive advice and training for its members in achieving consent through shared decision making. This draft guidance appears to be aimed at large healthcare providing organisations where it may be that SDM does not always travel effectively with the patient between different departments, clinics, networks, services or teams. We would urge NICE to reconsider including dental practice without further qualification in its definition of "organisation" (Page 13 lines 4 to 8). It is important to note at the outset that for dental practices in England with NHS contracts, NICE guidance becomes mandatory. This then requires us to consider whether it has been written with all healthcare providers' environments in mind which we believe is not	Thank you for your comment. Dentistry was represented on the guideline committee, so we believe the views of dentists to be appropriately represented. In regards to the definition of dental practices, after discussion with committee this has been changed to accurately capture the role of dental practices within the healthcare landscape. Healthcare professional has also been clarified more in the terms used section.

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				the case with this guidance. Failure to do so risks regulatory challenge. We are concerned that this draft NICE guidance is in some part overly prescriptive in relation to operational direction and yet also contains only basic and selected advice on communication. We have concerns about the terminology used and the confusion arising from it. For example, the guidance refers to the 'practitioner' to include staff including reception and administrative staff. The term "Practitioner" is more commonly defined to mean one who practises a [in this instance medical] skilled profession for which special education or licensing is required. The Dentists Act restricts the practice of dentistry to those on the dental register. This means that dental receptionists (unless registrants), for example, are not practitioners. The guideline does not appear to consider the relationship between shared decision making and the consent that is required for every treatment, investigation or act that includes the disclosure of the patient's personal data. Dental registrants are already bound by the General Dental Council's Standards for the	

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				Dental Team within which Principles 2 and 3 cover, in depth, their ethical responsibilities in respect of communication with patients and the consent process. Because the intended audience for the guidance apparently extends to all patient facing roles, it speaks to a far more basic and broad understanding of shared decision making than is currently already practised by clinicians. This may be deliberate, but the unintended consequence is that clinicians will be forced, perversely by regulation, to refer to a guideline less developed than their existing understanding of the processes and normal day to day practice. This could lead to their existing culture of shared decision making to be disrupted by an overly rigid but reductive process.	
Medical Protection Society	Draft Guideline	General	General	MPS welcomes to opportunity to comment on this draft guideline on Shared Decision Making by NICE. NICE seeks to clarify the concept of SDM and describe what is needed to make the aspiration a reality in practice but has seemingly over- simplified the process. SDM is an ethical imperative that has become, particularly since Montgomery, a key aspect of the sort of gold standard health care patients expect. It is the mechanism preferred by patients to ensure they get the care they want, no more, no less. This rather process driven, prescriptive guidance,	Thank you. This guideline provides generic recommendations that can be applied in every area of healthcare. The committee saw evidence from places where SDM had been successfully implemented, and judged these were often a success due to processes that embedded SDM within standard practice, and that without these processes you could not achieve the culture and behaviour shift required to practice SDM on a large organisational scale. They thus made recommendations that focused on enabling processes that enabled these behaviour and culture shifts to occur and be sustained.

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				appears to suggest a 'one size fits all' approach which is outdated and unrealistic in practice.	
Medical Protection Society	Draft Guideline	General	General	We are concerned that the guidance appears to bring in non- practitioners such as reception staff and administrative teams into the group that this guidance is aimed at. SDM is a process for practitioners and their patients and in no way should it deviate from this. We are concerned that the guidelines may suggest to some, that SDM can encompass these groups of people who are not regulated and do not hold suitable qualifications. We do not seek to negate the value of these groups as part of the health care system, but they cannot be part of SDM save for agreed organisational tasks. It is clinicians who need to deliver the vision of SDM, and it is only they who can choose whether or not to share decisions with patients and how they will do that to best advantage.	Thank you. We have modified the recommendations to clarify that the guidance is related healthcare professionals.
Medical Protection Society	Draft Guideline	General	General	It is a well -researched fact that patients participating in SDM do infinitely better than those similar, but passive, participants. The guidance appears to rehearse SDM as it was in its infancy and we believe that it is far more advanced in practice than this guidance seems to suggest. SDM is far more nuanced than the guidance might imply and there is a consequent danger that those embracing SDM for the first	Thank you for your comment, Shared decision making is enshrined as a principle in the NHS constitution, with principle 4 stating that, 'Patients, with their families and carers, where appropriate, will be involved in and consulted on all decisions about their care and treatment'.

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				time may look at the guidance as a prescriptive, tick box exercise. We are concerned that the rigidity suggested in the guidance does not take account of, nor embrace, the strides that have already been made by the medical profession to embed SDM as underpinning a truly patient-centred delivery of care.	The committee felt the guidance was relatively flexible, taking account of organisation size (1.1.11) and the differing support needs of service users (1.2.6). Whilst the committee acknowledged some organisations practice SDM very well, the observed that this was not universal across the healthcare system, thus the guideline is intended to be a general guidance on how to best embed and implement SDM practice within a wide range of healthcare organisations. The committee also identified several evidence gaps in the field of SDM, particularly in how good SDM can be measured as seen in research recommendation 2, and felt that until there were commonly used and accepted measures for SDM it was going to be difficult to quantify its effect in an evidence review environment.
Medical Protection Society	Draft Guideline	General	General	The 'three- talk' model, whilst having its uses, is rather prescriptive as a description of what SDM should look like. There is no discussion or recommendations that explore other models of delivery of SDM. This is another example of the 'one size fits all' approach being unacceptable in modern health care. The challenge which we feel is unmet by the guidelines, is to devise effective ways for supporting SDM and ensure it is embedded into systems, processes, workforce attitudes, skills, and behaviours.	Thank you for your comment. We have amended the guideline to not explicitly refer to the three-talk model in recommendations but to refer to it as an example, and the committee acknowledged that any evidence-based model for shared-decision making. Regarding embedding shared decision making in healthcare systems, please see section 1.1, which was drawn from expert testimony of examples where shared decision making has been successfully implemented, as well as committee experience.

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Medical Protection Society	Draft Guideline	General	General	The use of Patient Decision Aids is discussed, and we welcome this as an adjunct to other methods of delivery of patient information whether that be verbal, written, or visual. We are concerned that the guidance refers to 'International PDA's' and would prefer a set of National Patient Decision Aids allowing a common, consistent approach.	The recommendation refers to standards for PDAs set by IPDAS, which are currently the most accepted standards. There is currently no national standard for PDAs.
Medical Protection Society	Draft Guideline	General	General	As a Medical Defence Organisation (MDO), MPS deals daily with many cases involving an inadequate consent process and in a lot of these cases the clinician falls down on SDM. We recognise that clinicians could do better and that they need to do better as patients crave more information and demand more involvement. We are concerned that many clinicians have made great in roads in developing their own tried and tested SDM only to be forced by a fear of abiding by these national guidelines into adopting a more rigid approach to these ever more important consultations with their patients. Might it not be preferable to include SDM into all structured training programs perhaps with incentivisation until it is a commonly held belief that all patients hold foremost the standard 'nothing for me, without me.'	Thank you. We hope these guidelines will support them in doing better. It is outside of NICEs remit to recommend training programmes. Professional training standards are set by professional bodies.

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Medical Protection Society	Draft Guideline	General	General	The guidance appears to be primarily directed at secondary care. Or at least it should be recognised that at the multitude of GP practices countrywide it would be quite unrealistic to monitor SDM by 'senior leadership'. We recognise that monitoring of the quality of SDM is however imperative so we can learn and improve.	This guideline relates to all interactions between a person and a health care professional, including physical activity discussions in primary care. The wording of the guideline has shifted towards the term "discussion" which is defined in the "terms used in this guideline" section, and is intended to clarify that SDM applies to all interactions across all settings.
Medical Protection Society	Draft Guideline	General	General	SDM and consent go hand in hand and the major enabler to patient satisfaction is the quality of doctor/ patient relationship. We are concerned that there is little made of the acute necessity to ensure high quality communication in this process: building empathy, fostering trust, emphasising a decision needs to be made but that needs to be made in partnership and with support.	Thank you. This guideline did not consider consent specifically as this is a legal process. Clearly good SDM will improve consent and therefore we hope this guidance will support practitioners dealing with consent.
Medical Protection Society	Draft Guideline	General	General	We question that NICE is not the appropriate body to publish guidance on this topic. SDM is already directed by caselaw, ethical regulatory standards, covered by undergraduate teaching and Royal College standards. It may be that NICE intends the emphasis to be on training of unregulated team members i.e. 'other staff such as reception staff and some administrative and management staff. If so, the purpose of this guideline must be more explicit about its focus.	Thank you. The guideline is for all health care professionals, though as the rationale and impact section notes, other healthcare practitioners may also be involved in SDM. NICE was asked to produce this guideline by the Department for Health and Social Care.

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Medical Protection Society	Draft Guideline	General	General	We are concerned that, especially for primary care dental practice, this guideline will create an additional bureaucratic burden: This would be contrary to recent movement by the Department of Health and Social Care and NHS England. Please refer to the consultation, 'Busting bureaucracy: empowering frontline staff by reducing excess bureaucracy in the health and care system in England', which ran from 30 July 2020 to 13 September 2020. Among the recommendations following that consultation was that system and professional regulation will be proportionate and intelligent, and we do not perceive this draft guidance to be in keeping with the spirit of this.	Thank you. Dentistry was represented on the guideline committee so we believe the views of dentists to be appropriately represented.
Medical Protection Society	Draft Guideline	General	General	Given the breadth of the types of organisations expected to comply with this guideline, we believe the recommendation to use the 'three-talk model' is overly prescriptive. We wonder why only one model is cited.	Thank you. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.
Medical Protection Society	Evidence Review A	054	042 - 049	This section reflects our concerns about the absence of discussion about consent in the context of SDM. In our medicolegal view, consent is a continuous process that involves shared decision making. Certainly, in dentistry, the two go hand in hand. It is not unusual for a patient to require immediate clinical intervention.	Thank you for your comment.

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				We are a surgical profession and we require consent to do something irreversible.	
Mencap	Draft Guideline	General	General	The guideline states that it 'may be relevant for social care practitioners. We were unclear about the reason for this and contacted NICE for more information. We were led to understand that this entailed situations where 'social workers' might need to support decision making with a healthcare professional. We are confused about whether the guideline is talking about social care staff – such as paid support staff, or PAs, or social workers in the wider sense. Assuming the intention is social care staff, we are very unclear about the rationale behind this statement and exactly how the document is relevant for social care workers and would like this to be drawn out further and stated more explicitly. Some social care workers may support people to understand information, convey how they are feeling, or by giving relevant information to support a best interests decision making process, but the role within shared decision making remains unclear. We recommend further attention is given to this issue. It is also worth noting that social care workers would not be expected to make a decision on someone else's behalf either fully or partly when it came to a medical decision.	Thank you. This guideline is aimed at healthcare providers, and not primarily at social care staff. There is a reference to social care staff in one of the recommendations as an example of someone who might provide support to a person in the SDM process.
Mencap	Draft Guideline	General	General	Much of the information and advice in the guideline is useful for supporting decision making in general, but seems really to focus on	Thank you. This guideline does not consider mental capacity. It is about shared decision making. People without mental capacity are excluded from the guideline - see section 3.1 of

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				the kinds of tools/processes clinicians might employ to meet principle 2 of the Mental Capacity Act. Therefore, we were concerned to see the rest of the Mental Capacity Act not referenced and believe this information would sit more helpfully within a framework of all principles of the MCA and relevant caselaw as pertains to decision making and consent, such as Montgomery vs NHS Lanarkshire.	the scope (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)
Mencap	Draft Guideline	General	General	There is not a clear distinction between decision making and consent in the document, both of which are important legal aspects, which we think needs to be much clearer.	Thank you. This guideline is about shared decision making. It does not cover consent although many of the skills of shared decision making are relevant to the process of consent.
Mencap	Draft Guideline	General	General	There is some content regarding advocacy, but nothing focus on supporting access to advocacy itself, and we believe this needs to be included.	Thank you. The committee looked for evidence on advocacy, but did not find enough evidence to be able to recommend it. In spite of this, recommendations 1.2.3 and 1.2.6 introduce the possibility of using advocates to support people. NICE is currently producing a guideline on advocacy. Please refer to the NICE website for details.
Mencap	Draft Guideline	General	General	We support the aim of improving how much people with a learning disability and their families are involved in decision making but believe that more focus is needed on the issues in comments 1-5 in order to enable this, and to ensure that this guideline does not create any additional risk for people with a learning disability, who are already at risk of missing out on the healthcare they need (4x more likely to die of a cause that would be treated treatable with good quality healthcare), with poor practice	Thank you for your comment.

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				around the MCA already flagged as a major contributor to this health inequality.	
Mencap	Evidence review	General	General	We are concerned that the evidence review appears to have a lack of focus on shared decision making for people with a learning disability, who may need extra support, or who may lack capacity to make some decisions for themselves. They are mentioned more as an exclusion, with only one study appearing to focus on this area.	Thank you. As detailed in the scope section 3.2, this guideline covers all settings where publicly funded healthcare services are commissioned and provided. This includes people with mental health problems and learning disabilities (except those who are legally lacking 'mental capacity' see scope section 3.1). The scope document is available at https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents
Mind	Draft Guideline	004	002	We welcome the recommendations at 1.1, to have high level leadership so as to embed shared decision-making across the organisation. We agree that patients/service users should be part of this.	Thank you for your support.
Mind	Draft Guideline	006	005	We agree with the points in 1.1.7 but it would be helpful to add something about practitioners needing to seek to understand how people view their needs/condition, what their goals for recovery are, what kinds of support they find helpful, their experience of health care so far and their hopes and/or fears regarding care and treatment. It would be helpful to be explicit about shared decision-making empowering the patient. It should also be recognised that a patient may not be able to express their views to a particular practitioner.	Thank you. This is covered in the recommendations in section 1.2, especially 1.2.9 and 1.2.11 - 1.2.13

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Mind	Draft Guideline	006	005	Training should also address equality and possible bias. The 2020 CQC community mental health survey found differences by age and sexual identity in people's experiences of mental health services across a number of aspects of care including involvement. Younger adults (18-35) reported worse experiences than other age groups and heterosexual people reported better than average experiences than people with other sexual identities. There is a substantial literature on racial disparities in mental health care and the discrimination, stigma and cultural barriers that cause or contribute to them. These inequalities need to be addressed at organisational levels and beyond, but training should also support practitioners to work effectively across cultural difference and to reflect on their decision-making from an equalities and antiracist perspective.	Thank you. We do not think this is specific to shared decision making, and is something organisations are required to do by law.
Mind	Draft Guideline	006	026	We agree with the recommendation at 1.1.10 but consider that it should go further to create an expectation of shared decision-making, as of right.	Thank you for your comment. Patients having a right to make decisions about their care is outlined at the start of the "recommendations" section and the committee agreed to emphasise this by pointing out that SDM is enshrined in the NHS constitution at the beginning of the rationale and impact section.
Mind	Draft Guideline	006	026	Mind's information resource 'Seeking help for a mental health problem' is a guide to taking the first steps, making empowered decisions and getting the right support. This section directly	Thank you for this information.

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				addresses shared decision-making - Being actively involved | Mind	
Mind	Draft Guideline	007	003	It is important that shared decision-making is seen as an ongoing process, that happens regularly throughout a person's care and treatment, so we agree with the statement at 1.2.1 but think it could be strengthened	Thank you. This is the strongest level of recommendation NICE can make. NICE can only make a 'must' recommendation when there is a legal imperative.
Mind	Draft Guideline	010	012	Working across different organisations (1.2.19) is not only about aligning messages but making shared decisions that work for the person across the different services they may use or need. In particular, people with comorbidities, whose decisions about care may need different specialist input or who are at risk of falling between services, need to be involved effectively and meaningfully in decision-making.	Thank you for your comment.
Mind	Draft Guideline	General	General	Mind welcomes this guideline. Shared decision-making should be the norm in health care but is far from being routine practice. Care Quality Commission community mental health surveys and Mental Health Act reports continue to show that too many people have too little say in their own care and treatment. In Mind's 2017 survey about discharge from hospital we found that that almost one third of respondents were not involved in their own care planning - Leaving hospital (Mind, 2017).	Thank you for your support.

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Mind	Draft Guideline	General	General	The CQC's 2019 report on monitoring the Mental Health Act showed that 20 per cent of care plans didn't take into account the patient's view of treatment, 17 per cent failed to show any involvement with the patient, and 20 per cent of care plans didn't include planning for people after leaving hospital. A key recommendation to come out of the independent review of the Mental Health Act was to give patients more choice and control over their care through shared decision making. The UK Government's response to the review, in its white paper Reforming the Mental Health Act, accepts the Review's recommendation of a guiding principle of patient choice and autonomy and commits to seek to legislate so that patients have greater control over their treatment. They propose to introduce statutory Care and Treatment Plans that "reflect the patient's preferences and, as far as possible, demonstrate shared decision making between clinician and patient". It is important that this guideline supports shifts in culture and practice that will make shared decision-making the norm for all patients and specifically for people who are under the Mental Health Act, who are hugely disempowered by their detention.	Thank you for this information.

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Motor Neurone Disease Association	Draft Guideline	001	General	There is a lack of clarity around the extent to which this guideline is relevant to or applicable in social care. Whilst it suggests that this may be relevant to social care, we would welcome greater clarity on this point.	Thank you for your comment. This section is not suggesting SDM as a concept may or may not be applicable for social care, but that the NICE *guideline* on SDM may be applicable for social care. This is based on the scope of the guideline and the evidence searched and evaluated and is not a reflection on social care practice. This guideline is for people using healthcare services. This is in line with section 3.1 of the scope (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)
Motor Neurone Disease Association	Draft Guideline	004	General	Whilst the suggestions contained in points 1.1.1 – 1.1.4 seem like good ideas, we have a couple of comments on them. First, we think due consideration needs to be given to ensuring patient representatives are truly representative. A concern we have is whether patient representatives are most likely to be those who can more readily/easily engage, meaning that those with more severe, rarer and more complex conditions are less likely to be patient representatives. Second, while appointing a patient director could be useful, it is important that the wider patient community is engaged with. We are clear that one patient cannot represent all views and experiences.	Thank you. The committee did not want to specify too much detail into which patient representatives should be assigned the roles in 1.1.1 -1.1.4 at the risk of limiting uptake of the recommendation. The committee agreed that patient engagement was important which is why this encompassed part of the monitoring and evaluation outlined in recommendation 1.1.9. The committee made recommendations that were specifically about embedding shared decision making at an organisational level. More general recommendations on representation of service users in organisation were not included because they are more wide reaching than the remit of this guideline.
Motor Neurone	Draft Guideline	005	General	We have a few extra comments to add to the suggestions contained in point 1.1.5. We think a	Thank you. The committee was clear that identifying 'quick wins' first did not mean that SDM should not be rolled out

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Disease Association				point should be added under the ideas for developing an organisation-wide plan to include engagement with patient representative organisations. Whilst we anticipate that identifying areas where shared decision making can most easily be put into practice could constitute quick wins, and that would be positive, we wonder if there should be an equal focus on areas that are more complex but where shared decision making is critical as well. When it comes to the point on identifying shared decision making trainers, it seems like a good approach but we wonder if it's success will be affected by time and capacity constraints to engage with the training. The point on reviewing information systems is a good one as we often hear issues around information sharing being an issue and concerns about data protection. On line 20, the point about setting out how people who use services will be involved in supporting implementation should perhaps also make reference to unpaid carers. The point on line 22 about monitoring and evaluation is important, but again we wonder whether time and capacity constraints might impact on the ability of this to be done routinely and effectively.	across the whole organisation. The committee was aware that there is resource impact in terms of money, time and capacity to embedding SDM in organisations, however it is a patient right enshrined in the NHS constitution. Regarding the bullet **"set out how people who use services will be involved in supporting implementation", the committee did not want to provide examples of specific people using services so as to refer to as wide a group of service users as possible, including carers.**

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Motor Neurone Disease Association	Draft Guideline	006	General	Under point 1.1.7 we feel that something could be included on the emotional skills and behaviours that professionals need around shared decision making, particularly when it comes to sensitive issues such as end of life and advanced care planning. We also think a point should be added on accessibility for those who may find it harder to communicate or understand via conventional methods. Many people living with MND experience difficulty communicating so it may be more difficult to express what their wishes and decisions are.	Thank you. The committee did not see any evidence on emotional skills and behaviours, but was not tasked with exploring the content of training. Accessibility of materials is covered in the recommendations in section 1.2 of the guideline.
Motor Neurone Disease Association	Draft Guideline	009	General	Under point 1.2.9 it should be acknowledged that some people may wish to take time to think about their options, rather than make a decision there and then. Under point 1.2.12 there should also be acknowledgement that people's views and decisions may change over time.	Thank you for your comment. Recommendation 1.2.10 states that no change is a valid option in discussions, which includes deferring making a decision. In the rationale the committee acknowledge that SDM should "be treated as an ongoing process than a one-off event" and so that decisions will inevitably have the potential to change over time.
Motor Neurone Disease Association	Draft Guideline	009	General	For point 1.2.16 we would highlight that although a high-quality resource, NICE guidelines are not always easy to understand and can be lengthy. It might be worth acknowledging that many patient representative organisations have information and resources on relevant topics that are designed with people living with that particular condition in mind.	Thank you. The recommendation also refers to NICE endorsed material, including by accredited patient organisations.

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Motor Neurone Disease Association	Draft Guideline	014	General	Under point 1, differing intervention effects in different groups, we think consideration should also be given to different types of conditions as well e.g. progressive and terminal conditions.	Thank you for your comment. This is a general guideline for SDM and does not provide recommendations for specific disease areas.
Motor Neurone Disease Association	Draft Guideline	020	General	When considering additional resources that might be required, this should include time resource, particularly in terms of time spent on training.	Thank you for your comment. Time as a resource is mentioned in the qualitative review in evidence review A, and potential effects on consultation length are also discussed in the guideline. In evidence review A, the committee discussed at some length whether SDM required more time and that allowing a larger amount of time for SDM may increase consultation length and cost. Although it did not see any quantitative evidence to reflect this, it did note that the qualitative evidence highlighted 'lack of time' as a barrier to using SDM. Overall, it agreed that any additional time needed could potentially be offset by fostering a better patient-practitioner relationship in early sessions, leading to shorter ones in the future, although they also acknowledged that many healthcare professionals only see people short term. They highlighted issues around practitioners questioning what the evidence is for more time being needed, and that more research is needed into what interventions reduce time commitment.
Motor Neurone Disease Association	Draft Guideline	General	General	We feel that there is not much mention of engaging with patient representative organisations around patient involvement and shared decision-making. It would be good to see more emphasis on working with the patient community to develop appropriate processes and resources.	Thank you. We have modified recommendation 1.2.4 to acknowledge the role of patient organisations: "When providing information and resources: only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids."

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					This would also cover information provided in recommendation 1.2.18 The committee also agreed that patient organisation representative could qualify as an example of additional support under recommendation 1.2.6. Patient feedback will also be sought as described in recommendation 1.1.9
Multiple Sclerosis Trust	Draft Guideline	007	002	It is important for the health professional to recognise that patients have different levels of knowledge and engagement with the decision and adapt their approach to reflect the patient's needs. Some patients will have studied their options carefully before an appointment and be very clear about their preferred choice of treatment (for which they may not be eligible). Others will want the health professional to tell them which treatment they should have and not be required to choose between alternatives.	Thank you. Please see recommendations 1.2.8 and 1.2.11.
Multiple Sclerosis Trust	Draft Guideline	009	023	It is vital that there is flexibility in the decision-making process, to allow patients to have further discussions after the appointment. In our experience, patients may not fully recognise the implications of the shared decision	Thank you. The committee agree and this is reflected in the recommendations for both 'during a discussion' and 'after or between discussions'.

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				until after the appointment when they have had time to reflect, carried out further research or discussed their decision with family members. However, patient access to a consultant after the initial appointment can be a significant barrier; it is often difficult for a patient to contact a consultant again to ask further questions or discuss further options outside of the initial appointment. Equally, some patients can become overwhelmed by conflicting benefits and risks of treatment options; practitioners need to recognise when a patient is struggling to make a choice and help them reach a satisfactory decision.	
Multiple Sclerosis Trust	Draft Guideline	General	General	The Multiple Sclerosis Trust welcomes the development of this guideline. We have always strongly advocated for shared decision making for people with multiple sclerosis. For people with relapsing remitting MS, there are 14 very different drugs. Decisions around treatment choice are often complex, reflecting clinical practice and NHS eligibility criteria, patient attitude to benefits and risks, and impact on lifestyle such as work commitments or plans to start a family.	Thank you for this information.

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				Questions about the choice of treatments for relapsing remitting MS are a frequent subject of enquiries taken by the information team at the MS Trust. To support people who are making decisions about MS treatments, the MS Trust has developed online and printed resources including a decision aid to ensure that people with MS are aware of their choices and can take a proactive role in discussions with health professionals. The decision aid also supports MS specialists when discussing options with patients in the clinic.	
National Axial Spondyloarthritis Society (NASS)	Draft Guideline	General	General	The guideline is welcomed. However we have found that with the introduction of biosimilars shared decision making is not always adhered to and often patients are being switched to the cheaper option without any discussion or explanation.	Thank you. We are unable to comment on specific situations, but the guideline should apply to all healthcare interactions. We agree that switching to the biosimilar should be carefully planned, taking into consideration the dose switching protocols, monitoring and the person's concerns about switching from their existing regimen, and a shared decision reached. Healthcare professionals should also refer to the summary of product characteristics for further information when considering switching to biosimilars.
National Survivor User Network and The University of Essex	Draft Guideline	001	General	1. SDM as a principle informing strategy and governance across the NHS Applying SDM in practice within health care delivery organisations is an important principle set out in the SDM guideline. However, this needs to be backed up with an approach to governance across NHS bodies that has the principles of SDM underpinning their structures	Thank you. The focus of the guideline is on the delivery of care and it is intended to be used by people delivering, commissioning, and using healthcare services. It is beyond NICEs remit to make recommendations to NHS arms length bodies.

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				and decision making processes. The principles of SDM go beyond what many NHS governance bodies refer to as PPI. NICE itself, NIHR, NHS England and other arms' length bodies embed PPI in their structures and decision making processes. Yet PPI in these contexts is mostly inadequate to genuinely empower service users and often leads to tokenism (e.g. see Madden & Speed, 2017). We suggest that the NICE guideline on SDM should explicitly state that the principles of SDM set out in the guideline apply equally to NHS delivery organisations as to NICE and other NHS arms' length bodies including NHS England and NIHR. The SDM guideline should state that the principles underpinning SDM should also underpin these organisations' decisions, structures and priorities. References: Madden, M. and Speed, E., (2017). Beware Zombies and Unicorns: Toward Critical Patient and Public Involvement in Health Research in a Neoliberal Context. Frontiers in Sociology. 2. https://www.frontiersin.org/articles/10.3389/fsoc.2017.00007/full	

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National Survivor User Network and The University of Essex	Draft Guideline	004-012 014-015	016 014-015	2. Lack of accessible information in mental health contexts We are also concerned that the SDM guideline fails to recognise and acknowledge that there is a severe lack of availability of accessible, evidence-based information required in mental health contexts in order for patients to engage in SDM. It is often assumed that people with mental health difficulties do not want to be or are unable to be involved in decisions about their care. However, a systematic review of 117 studies of service user, carer and professional views of patient involvement in mental health found that service users want more meaningful involvement but need access to better quality information (Bee et al 2015). More research is needed to explore the barriers to SDM and acceptability of SDM to practitioners in the mental health context. The SDM guideline refers to PDAs as a good example of how to provide information and enable conversations between professionals and patients. Yet there is a significant dearth of PDAs for mental health conditions relevant to the UK context. Specifically, we have found no English language PDA for depression in adults relevant to UK psychological service provision (discussed in more detail later).	Thank you. Research recommendations address specific gaps in the evidence that made it difficult for the committee to make recommendations, so recommending the development of PDAs for people with mental health problems would not be something that a research recommendation could do. The committee recognised that there is a lack of high quality PDAs in some areas and the need for this to be improved. However the committee agreed that PDAs are only one part of the process of SDM. They hoped that access to databases of PDAs might help with this.

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				We suggest that there should be a research recommendation in the SDM guideline that PDAs be developed for UK mental health contexts as a matter of urgency and that there needs to be joining up across NHS bodies such as NIHR, NICE and NHS England to prioritise and identify funding for this work and acknowledge its vital role in enabling SDM. References: P. Bee, O. Price, J. Baker, K. Lovell, Systematic synthesis of barriers and facilitators to service user-led care planning. *Br. J. Psychiatry*. 207, 104–114 (2015).	

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National Survivor User Network and The University of Essex	Draft Guideline	General	General	This new guideline on Shared Decision Making (SDM) is welcome in that it prioritises the principles underpinning SDM and emphasises that patients must have a say in decisions taken about their healthcare. The guideline clearly acknowledges that in order to be involved in decisions, patients need access to clear, evidence based, accessible information. Patient Decision Aids (PDAs) are given as a key example of how this information can be provided to patients and enable a discussion between patients and professionals. We particularly welcome the recommendations for further research in this area, as there is little evidence for the practical implementation of SDM, particularly in a mental health context. However, we have a number of concerns reflecting our joint expertise in the area of patient experience in mental health contexts. We summarise these concerns below along with suggestions around how they could be addressed. In summary, we propose: 1. That the SDM guideline should make explicit that it applies to all mental health care contexts and not just to physical health care;	Thank you. The purpose of this guideline is to be generic and applicable to all healthcare settings. This is made clear in the box at the beginning of the guideline. In response to your points raised: 1. Recommendation 1.2.6 for offering additional shared decision making support can cover those with a mental health condition, as the committee discuss in the rationale. The guideline does not apply to people who lack mental capacity as defined in the scope document section 3.1. 2.The committee agreed that patient decision aids were important for SDM but felt there were other gaps in the SDM evidence that were higher priority, which can be seen in the research recommendations. 3.NICE are currently updating their guideline methods manual in light of our new 5-year strategy 2021-26 which includes a commitment towards dynamic, living guidelines. We will feedback your response.

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				that there needs to be NHS investment in strategies to make SDM more of a reality in mental health care including research and service development work. 2. That the SDM guideline should include a research recommendation for PDA development work appropriate for a UK context to be prioritised for funding, particularly in mental health care contexts. Funding needs to be made available for this work. 3. That in light of the SDM guideline being adopted by NICE, NICE should review its Manual for developing guidelines with a view to giving greater priority to reviewing patient experiences of treatment research and incorporating this evidence into recommendations across all guidelines. 4. That the NICE guideline on SDM should explicitly state that the principles of SDM set out in the guideline apply equally to NHS delivery organisations as to NICE and other NHS arms' length bodies including NHS England and NIHR. The SDM guideline should state that the principles underpinning SDM should also underpin these organisations' decisions, structures and priorities. We elaborate on these suggestions below	4.This guideline is for everyone who delivers or commissions healthcare and public health services and we are unable to make specific recommendations to other NHS and NHS arms' length organisations.
National Survivor	Draft Guideline	General	General	3. Explicit application of SDM to mental health contexts	Thank you. The purpose of this guideline is to be generic and applicable to all healthcare settings. This is made clear in the

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User Network and The University of Essex				We are concerned that the guideline has an entirely generic focus appearing to apply to any healthcare context, without any recognition that SDM is least likely to occur in relation to mental health care including primary, secondary care and inpatient mental health settings. Mental health patients are disproportionately subject to disempowerment in the context of their care and more likely to have decisions made for them. This is largely due to the potential of the Mental Health Act (2007) to over-rule patient involvement in decision-making about their care, the principles of which extend into everyday practice regardless of whether or not someone is detained under the MHA. Evidence suggests there is poor quality patient involvement, particularly in inpatient mental health settings; a lack of input into service delivery; a general lack of control and consequent disempowerment (Abayney et al 2018); and ongoing dissatisfaction with care reported by patients (CQC, 2017). We believe that the SDM guideline should make explicit that it applies to all mental health care contexts and not just to physical health care; that there needs to be NHS investment in strategies to make SDM more of a reality in mental health care including research and service development work.	box at the beginning of the guideline. Additionally, recommendation 1.2.6 for offering additional shared decision making support can cover those with a mental health condition, as the committee discuss in the rationale. The guideline does not apply to people who lack mental capacity as defined in the scope document section 3.1.

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				References Abayneh S, Lempp H, Manthorpe J, Hanlon C. 2018. Development of programme theory for integration of patient and caregiver involvement in mental health system strengthening: protocol for realist systematic review. International Journal of Mental Health Systems, 12(1):1-9. Care Quality Commission. 2017. Adult Inpatient Survey. London: Care Quality Commission	
National Survivor User Network and The University of Essex	Guideline	General	General	4. Patient experience in NICE guidelines We are concerned that there is a significant inconsistency in the message in this NICE SDM guideline and the fact that NICE guidelines in general do not routinely prioritise or take into account patient experiences of treatment. The current guideline on SDM takes the position that SDM is important; that SDM involves prioritising patient experience and patient voice at all levels of health care delivery organisations; and that SDM relies on good quality evidence-based information accessible to patients. These principles are rarely reflected in other NICE guidelines nor, importantly, in the NICE Manual for developing guidelines which does not require that all guidelines include a review of research on patient experiences of treatments. This	Thank you. Many NICE guidelines involve reviews of qualitative research about people's experiences of care. Furthermore, all NICE committees appoint at least two lay members, who in turn are supported by a dedicated public involvement team. Please refer to the guideline on "Patient experience in adult services" which underpins all NICE guidance. https://www.nice.org.uk/guidance/cg138

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				position is not in sync with the underpinning premise of SDM. We have discussed in more detail elsewhere the reasons why it is vitally important that NICE guidelines take seriously research on patient experiences of treatment (see McPherson & Beresford, 2019), since they underpin the ethos of delivery of care. The SDM Guideline offers an opportunity for NICE to review its other guidelines and ensure that the ethos and the messages are consistent. The goal of genuine SDM in practice starts with NICE being able to acknowledge the value of experiential knowledge in their reviews: reviewing patient experience of treatments and sources of evidence that bring the patient voice into evidence reviews. We propose that in light of the SDM guideline being adopted by NICE, NICE should review its Manual for developing guidelines with a view to giving greater priority to reviewing patient experiences of treatment research and incorporating this evidence into recommendations across all guidelines. <u>References:</u> McPherson S & Beresford P. (2019) Semantics of patient choice: how the UK national guideline for depression silences patients, Disability &	

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				Society, 34:3, 491-497, DOI: 10.1080/09687599.2019.1589757	
National Survivor User Network and The University of Essex	Guideline	General	General	Depression in Adults – an example of the issues raised above We would like to particularly draw the Committee's attention to an example of the concerns we raise and suggestions put forward above. Depression is the most commonly diagnosed mental health condition, affecting millions of people in the UK and more prevalent than most physical conditions. We appreciate that the SDM guideline notes that not all conditions will have a relevant PDA. Yet a PDA for depression should, we believe, be a key priority given its prevalence and the current lack of SDM in practice. We have carried out our own work in this area recently including a wide ranging literature review and found that where PDAs in other languages or countries do exist for depression, none exist relevant to the UK context; none appear to have involved service users collaboratively in design and development nor prioritised patient-preferred outcomes in selecting and synthesising evidence. Existing PDAs for depression tend to exclude psychological treatment options (Barr et al	Thank you for your comment. The guideline does not recommend specific PDAs

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				2016), focusing on medication or medication versus a single psychotherapy option. The UK NICE guideline for depression in adults however recommends a range of evidence based psychological therapies and advocates patient choice, yet no existing PDA would be suitable to enable SDM in this context. In the absence of an appropriate PDA, people with depression are unable to engage genuinely in SDM and therefore it is not possible for the principle of patient choice referred to in the depression guideline to be implemented. During 2020, we undertook a user-led consultation on this issue involving focus groups with 28 people. We would draw your attention to our report of this work – see "Informing a Decision Guide for Psychological Therapies for Depression": https://www.nsun.org.uk/FAQs/informing-a-decision-guide-for-psychological-treatments-for-depression . The findings suggest that people seeking psychological therapy for depression have very little choice about the type of therapy or who will deliver it. People tend not to know what to expect from therapy, and want more information to help them make a decision about whether it is right for them. Issues of access and accessibility render some people's choice even more limited, and there is a need for therapies to	

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				adopt a clearly anti-racist approach if they are to address inequalities of access for Black and minority ethnic communities. Following on from this, the University of Essex and NSUN put together a team of experts including innovation designers, service users and systematic reviewers to design a PDA for adult depression and submitted a full proposal for funding. Feedback from NIHR included that such a PDA was unlikely to be used in practice. This view needs to be challenged across NHS bodies including NIHR and NHS England. The NICE guideline on SDM could play a significant role in this by making explicit that the principles of SDM should be applied at all levels of NHS provision and governance including NICE itself, NHSE and NIHR. This example of depression illustrates why the absence of a PDA for a highly prevalent mental health condition is a major barrier to SDM and should be prioritised. We would argue that addressing all of our suggestions is required because it illustrates the way in which there are more significant barriers to SDM in the context of mental health; how applying SDM principles at the level of NICE and NIHR structures could enable such a PDA to be developed; and why the principles of SDM should be applied to	

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				guideline development in order to ensure that the evidence-base on which PDAs are built also prioritises patient experience and thus empowers service users and supports recovery. Faulkner, A (2020). Informing a Decision Guide for Psychological Therapies for Depression. National Survivor User Movement. https://www.nsun.org.uk/FAQs/informing-a-decision-guide-for-psychological-treatments-for-depression P. J. Barr, R. C. Forcino, M. Mishra, R. Blitzer, G. Elwyn (2016). Competing priorities in treatment decision-making: a US national survey of individuals with depression and clinicians who treat depression. *BMJ Open*. 6, e009585 .	
NHS England and NHS Improvement	Draft Guideline	001	005	It would be helpful if this section covered all patient support resources as well as 'decision aids' (JB)	Thank you. Decision aids were identified as one of the key interventions to support delivery of SDM that had high-quality literature available (in the form of the Cochrane systematic review of PDAs) [see appendix I of evidence review B for more information], due to this high quality available evidence, NICE chose to use the Cochrane definition of patient decision aids over a wider definition of patient support resources.
NHS England and NHS Improvement	Draft Guideline	004	005	It would be useful if this recommendation was clearer as to whether this role should be vested in a clinician or a non clinical board member. NHSI view is that it is important to have clinical	Thank you. The committee did not want to dictate who the board member should be, however, in 1.1.3 they recommend the appointment of clinical champions to work with the board member or high-level organisation leader (should the

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				leadership for SDM and that that leadership should be at a very senior level (JB)	organisation not have a board): "Appoint one or more senior healthcare professionals to work with the senior leader and patient director as organisation-wide 'champions' responsible for shared decision making." Recommendation 1.1.4 also covers identifying service user champions alongside this, who could work with the board member (should the organisation not have a board): "Identify one or more organisation-wide 'service user champions' to work with the senior leader, patient director and professional champions for shared decision making. They should be recruited from people who use services."
NHS England and NHS Improvement	Draft Guideline	004	006	We would prefer that the term embedding replaces 'rolled out' (JB)	Thank you. We have changed this.
NHS England and NHS Improvement	Draft Guideline	004	014	Ideally we would recommend that the Senior Practitioner has protected time for this role? (NB this will have cost implications) (JB)	Thank you. The committee were unwilling to be specific about this because of the broad range of organisations to which this guideline applies. They did not feel it would be useful to be prescriptive.
NHS England and NHS Improvement	Draft Guideline	004	016	It would be helpful if there could be recommendation that these roles are clearly defined in job descriptions (JB)	Thank you. The committee were unwilling to be specific about this because of the broad range of organisations to which this guideline applies. They did not feel it would be useful to be prescriptive.
NHS England and NHS Improvement	Draft Guideline	004	018	We would suggest that a role description for the service user champion is developed (JB)	Thank you. This is beyond the remit of NICE.
NHS England and	Draft Guideline	005	002	We would suggest that the plan is clearly described as an 'improvement plan'. We would	Thank you for your comment. We have now included the term "improvement plan". The committee also agreed that the

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NHS Improvement				also suggest that the NHSEI baseline self-assessment checklist could be used to help develop such a plan. (JB)	baseline self-assessment checklist could be useful, and thus included a mention in the rationale, whilst stating that other tools are available.
NHS England and NHS Improvement	Draft Guideline	005	014	Would it be possible to refer to decision support tools/resources rather than simply patient decision aids? (JB)	Thank you for your comment. The committee felt "decision support tool" was too broad a term for this aspect of the guideline, and also the evidence the recommendations were made upon was based on a systematic review which specifically defined "patient decision aids", as did the protocol of the evidence review.
NHS England and NHS Improvement	Draft Guideline	005	018	We would suggest that finding out what matters to the person should be included here (JB)	Thank you. This is included in recommendation 1.1.7: "showing the person's past decisions, past preferences, values, and other information discussed during appointments.
NHS England and NHS Improvement	Draft Guideline	005	021	We would suggest 'setting this out in the in the improvement plan' (JB)	Thank you. We have added this.
NHS England and NHS Improvement	Draft Guideline	005	022	Would it be possible to suggest that internal and external monitoring is planned rather than 'or' as is currently recommended. External monitoring will have cost implications (JB)	Thank you. The committee agreed that either option was viable and meant that there were not necessarily cost implications. However it is acknowledged that external monitoring might not always be possible.
NHS England and NHS Improvement	Draft Guideline	005	022	After *'evaluation'* add using OPTION 5 (JB)	Thank you for your comment. OPTION-5 is a specific outcome measure in SDM, and the committee did not feel they were presented with enough evidence to recommend a single SDM outcome, this has led to the second research recommendation about the best way to measure SDM.
NHS England and NHS Improvement	Draft Guideline	005	025	It would be useful if the role and ToR of the support network was described more fully (JB)	Thank you. We have added a clarification on the role of the support network to the rationale.

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NHS England and NHS Improvement	Draft Guideline	006	009	We are very supportive of this recommendation but would suggest that adaptive communication techniques such as 'Chunk and Check' and 'Teach back' are also recommended for use as these are particularly helpful in ensuring clear communication takes place with people of lower levels of health literacy (JB)	Thank you for your comment. The committee agreed that "teach back" and "chunk and check" were important methods in delivering information and checking it had been understood. They agreed to add these methods as a way to implement existing recommendation 1.2.11
NHS England and NHS Improvement	Draft Guideline	006	015	We would suggest replacing the phraze *'drawing out what is important to people'* with 'find out what matters to people' (JB)	Thank you. We have changed the wording to "encouraging people to talk about what is important to them".
NHS England and NHS Improvement	Draft Guideline	006	027	We support this recommendation but would suggest that the other examples of promoting SDM to people could be via appointment letters and on web pages. (JB)	Thank you. As you note, these are examples and are not intended to be an exhaustive list. We have added your examples.
NHS England and NHS Improvement	Draft Guideline	006	027	It is unclear what 'training' is being proposed here (JB)	Thank you. Training is an example of something that might be done to support service users in engaging in SDM. See recommendation 1.1.14 for an example.
NHS England and NHS Improvement	Draft Guideline	007	004	We welcome the emphasis on supporting people before discussions with health care professionals which aligns with our emphasis on the importance of patient preparation. (JB)	Thank you for your support.
NHS England and NHS Improvement	Draft Guideline	007	010	We support the involvement of 'Family, friends or advocates'. However at different points in this guideline different words are used to describe the support that people may wish to have are used. It would be helpful if the terminology could be consistent throughout e.g. including carers (JB)	Thank you. We have aligned the terminology.

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NHS England and NHS Improvement	Draft Guideline	007	012	We suggest adding after help the person 'and to provide moral support' (JB)	Thank you. We believe that is implied by the recommendation.
NHS England and NHS Improvement	Draft Guideline	007	014	We would suggest replacing *'explain what is important to them'* with 'explain what matters to them' (JB)	Thank you. We have changed this to "explain what matters to them" as you suggested.
NHS England and NHS Improvement	Draft Guideline	008	003	We agree with this approach but would also suggest strengthening it to make it clear that "It's OK to Ask" i.e. questions and discussions are welcomed. As well as linking to NICE resources it would be helpful if there could be a link to NHSE/I Patient preparation resources (JB)	Thank you for your comment, the committee agreed preparation for consultation was important, and have reinforced this with a recommendation in the "before discussion with a healthcare professional" section.
NHS England and NHS Improvement	Draft Guideline	008	022	We suggest replacing *'important to them'* with 'matters to them' (JB)	Thank you. We have changed this.
NHS England and NHS Improvement	Draft Guideline	009	006	Checking if people understand the information often elicits a positive response even if they haven't understood. We would suggest instead that techniques such as Teach Back are used in order that the person can explain what clinicians have told them in a manner that doesn't come across as a test of patient comprehension (JB)	Thank you for your comment. NICE has added clarification that "teach back" and "chunk and check" methods can be used in recommendation 1.2.11, to ensure understanding of information provided.
NHS England and NHS Improvement	Draft Guideline	009	007	We suggest replacing *'important to them'* with 'matters to them' (JB)	Thank you. We have changed this.

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NHS England and NHS Improvement	Draft Guideline	009	010	We are very supportive of this recommendation but would suggest augmenting it by adding that people may need to defer the final decision until they have had time to think about it and discuss with family, friends and carers (JB)	Thank you. We have modified the wording of this recommendation.
NHS England and NHS Improvement	Draft Guideline	009	014	At the end of this sentence another line could be added to say that if the person makes a decision not to proceed with a procedure then they may require ongoing support. This could then be captured in a personalised care and support plan. (JB)	Thank you. This is implicit in the recommendation with the discussion of when the decision will be reviewed.
NHS England and NHS Improvement	Draft Guideline	009	024	We completely agree that people need an aide memoire with regard to decisions they have made. However, we suggest that something more akin to a Shared Decision Making Record should be made available for people to take away with them rather than a resource. Again this could be captured in a PCSP if the person has one or one is developed as part of their ongoing care. (JB)	Thank you. We have added a reference to care plans in recommendation 1.2.17 which states "When making a record of the discussion (for example, in a person's clinical notes or care plan), record any decisions made along with details of what the person said was important to them in making those decisions. Offer to share this with the person, for example in a post-clinic letter."
NHS England and NHS Improvement	Draft Guideline	009	025	We support the availability of a record '*summarising the options and decisions or plans made'.* However we would suggest that it also includes, the diagnosis, the risks and benefits of the decision and who to contact if they have any further questions or change their mind. (JB)	Thank you. We have modified the wording of this recommendation to state: "Offer people resources in their preferred format to help them understand what was discussed and agreed. This could be a printout summarising their diagnosis, the options and decisions or plans made, and links to high-quality online resources."
NHS England and NHS Improvement	Draft Guideline	010	006	We understand the rationale for this recommendation and support it but there needs to be more clarity on how people with lower	Thank you. The recommendation gives examples, but the committee did not want to be prescriptive. Some detail has been added to the rationale and impact section about the additional support that is available.

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				levels of health literacy can be provided with tailored support. (JB)	
NHS England and NHS Improvement	Draft Guideline	010	009	It might be worth stressing that a follow up may not necessarily be face to face (JB)	Thank you. We have changed the term appointment to 'discussion' and added a recommendation about remote discussions. We hope this clarifies this.
NHS England and NHS Improvement	Draft Guideline	010	012	This is very welcome because patients often report that decision making is problematic due to inconsistent information and messages from different clinicians (JB)	Thank you for your support.
NHS England and NHS Improvement	Draft Guideline	010	015	It would be really helpful if a statement could be included in this section making it clear that SDM conversations can happen regardless of the availability of a PDA. We suggest references to other forms of decision support tools such as option grids and would strongly recommend they are referred to in the final guidelines particularly as they seem to be regarded as useful tools by many clinicians. (JB)	Thank you for your comment. Recommendation 1.3.1 states to "Use patient decision aids as one part of an overall 'toolkit' to support shared decision making alongside the other skills and interventions outlined in sections 1.2 and 1.4 of this guideline." Which is to make clear that PDAs are a component of good SDM, thus SDM can continue without them. Regarding OPTION grids, the committee did not see any clear evidence of their effectiveness and could not make a recommendation on option grids specifically. .
NHS England and NHS Improvement	Draft Guideline	010	017	Please note our earlier points about references to decision support resources other than patient decision aids. (JB)	Thank you for your comment.
NHS England and NHS Improvement	Draft Guideline	011	009	We would suggest that reference is made to the decision support resource standards framework that is currently under development because this will set out how decision support resources should be maintained and updated (JB)	Thank you. As the framework was not published at the time of guideline publishing we could not include a reference to it.

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NHS England and NHS Improvement	Draft Guideline	011	011	We would suggest that this section strongly emphasises the importance of PDAs being health literate. (JB)	The NHS Accessible Information Standard (SCCI 1605) mandates that all healthcare and adult social care providers must provide information in a format their patients can read. The recommendations consistently refer to ensuring people understand and receive information in their preferred format. Please see for example recommendations 1.2.4, 1.2.5, 1.2.18. We also mention in recommendation 1.2.4 that decision aids must be "quality-assured".
NHS England and NHS Improvement	Draft Guideline	012	009	It is good to see the understanding of the challenges that people face with numerical information. We would suggest strengthening it further to make clear that population skills with regard to numeracy are significantly lower than with regards to literacy (National Skills for Life Survey 2011 BIS) which has a significant impact on people's health literacy when having risk, benefit and probability conversations. Consequently this guideline should emphasise that particular attention needs to be paid to ensuring that people understand numerical information in general and with regard to the risks and benefits of different courses of action. This applies especially to information included in decision support tools. (JB)	Thank you for your comment. The recommendations suggest using a mixture of both numerical and pictorial formats, and to be aware that risk may be interpreted differently depending on the service user. Recommendation 1.2.6 also discusses providing additional support for those who may struggle to share in decision making, including helping them understand the resources provided.
NHS England and NHS Improvement	Draft Guideline	012	Discussing numerical	This section is very clear and welcome. It provides a considerable amount of 'how to' information. We were wondering if a similarly detailed approach might be possible in other parts of these guidelines e.g. The role of Board	Thank you. The roles will need to vary by organisation and should be responsive to local need. It is not the remit of NICE to provide job descriptions for these roles.

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			information	members, the service user representatives, the support networks etc. (JB)	
NHS England and NHS Improvement	Draft Guideline	014	002	Is this the SDM definition that we want to include in this guidance as it's not the same as the NICE Collaborative definition or the one used by NHSEI? (JB)	Thank you for your comment. The definition of SDM was agreed at scoping stage including consultation. It was discussed and agreed by the committee.
NHS England and NHS Improvement	Draft Guideline	014	016-017	This is an important recommendation. Who and how do NICE recommend follows this up? (JB)	Thank you for your comment. Research recommendations are to suggest areas for future research, we do not recommend a certain organisation or body to take on this research, however research recommendations from NICE are often prioritised by NIHR.
NHS England and NHS Improvement	Draft Guideline	014	019	Evidence Review B (p55 line 17-19) suggests the tool OPTION-5 is the most valuable way of measuring SDM outcomes, yet a recommendation is made here to do more research into measuring SDM which seems to contradict the evidence. In addition patient experience measures such as CollaboRATE and SDMQ9 are being used in the system so it would be helpful to understand further why the evidence review is favouring OPTION-5. Furthermore, the use of external observers is likely to have a cost implication. (JB)	Thank you for your comment. Objective outcomes were ranked as being better than subjective outcomes due to a reduced risk of bias. There is currently a wide range of objective measures of SDM and it is unclear whether all are equally valid, or if all of them measure the same thing, since shared decision making is poorly defined and nebulous. A standardised measure of SDM would enable reviewers to compare research studies more easily to identify effective shared decision making interventions.
NHS England and NHS Improvement	Draft Guideline	015	006	We suggest using 'cohorts' rather than *'populations'* as it's more specific (JB)	Thank you. NICE strives to produce guidelines that are readable by patients and service users and where possible uses words in common use.
NHS England and	Draft Guideline	016	009	The MAGIC programme stresses the importance of clinical leadership in successfully embedding	Thank you for your comment. Clinical leadership is discussed in the "high level leadership" section of the recommendations.

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NHS Improvement				SDM. It would be useful if these guidelines also pointed out the importance of strong clinical leaderships (JB)	The importance of strong leadership was a particularly prominent theme in the expert evidence and this was supported by the committee's views. In their experience, having a commitment from senior managers and leaders to shared decision making is essential because they can make sure resources are prioritised to support it and help to instil a culture of involving people who use services across the whole organisation. This can be seen in the "rationale and impact" section of the guideline.
NHS England and NHS Improvement	Draft Guideline	017	028	(JB)	Thank you for your comment.
NHS England and NHS Improvement	Draft Guideline	018	002	We suggest using 'cohorts' rather than *'populations'* as it's more specific ' (JB)	Thank you. NICE strives to produce guidelines that are readable by patients and service users and where possible uses words in common use.
NHS England and NHS Improvement	Draft Guideline	018	009	We would suggest that this recommendation also includes the requirement to adhere to the Accessible Information Standard (JB)	Thank you for your comment. Recommendation 1.2.4 and now refers to the accessible information standard.
NHS England and NHS Improvement	Draft Guideline	019	024	We suggest adding after *'other electronic device'* 'and provide a copy of the Shared Decision Making record to the patient' (JB)	Thank you for your comment. This is covered in recommendation 1.2.18: "Offer people resources in their preferred format to help them understand what was discussed and agreed. This could be a printout summarising their diagnosis, the options and decisions or plans made, and links to high-quality online resources. Ideally, give people this material to take away, or provide it very soon after the discussion."

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NHS England and NHS Improvement	**Draft Guideline**	**020**	**013**	**We agree there is potential that appointments may need to be longer however there doesn't appear to be significant evidence that this will have a substantial resource impact. Indeed, a relatively recent Cochrane review indicated that even using a PDA only added an extra minute to consultations. We would suggest that an optimal conversation undertaken by teams trained in health coaching and motivational interviewing should not take substantially longer. We feel this is particularly important because a significant push back from the system is that SDM takes up too much time. (JB)**	Thank you for your comment. In evidence review A, the committee discussed at some length whether SDM required more time and that allowing a larger amount of time for SDM may increase consultation length and cost. Although it did not see any quantitative evidence to reflect this, it did note that the qualitative evidence highlighted 'lack of time' as a barrier to using SDM. Overall, it agreed that any additional time needed could potentially be offset by fostering a better patient-practitioner relationship in early sessions, leading to shorter ones in the future, although they also acknowledged that many healthcare professionals only see people short term. They highlighted issues around practitioners questioning what the evidence is for more time being needed, and that more research is needed into what interventions reduce time commitment.
NHS England and NHS Improvement	Draft Guideline	021	023	We agree that the term *'risk*' can have negative connotations but rather than replacing the wording would suggest in line with personalisation principles that it is made clear that this language can be tailored where it is felt that using such language may be alarming e.g. use pros and cons. (JB)	Thank you for your comment. This discussion section does not advocate for the replacement of the word risk, but broadening it to contextualise it alongside these other terms, as a form of tailoring language. The committee agreed that the patients and service users do not understand the word risk in the same way that health professionals do and therefore for the purposes of this guideline they chose to refer to risks, benefits and consequences.
NHS England and NHS Improvement	Draft Guideline	023	007	We agree that people wish to engage in conversations about their health and care at different levels at times this means 'Some people prefer not to take an active role in making decisions with their healthcare professionals'. However evidence from *Summary of Health literacy levels of British*	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.

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				adults - A cross-sectional survey using two domains of the Health Literacy Questionnaire Rebecca M. Simpson, Emma Knowles and Alicia O'Cathain of NatCen Social Research found respondents had lower health literacy in 'ability to engage' than in 'understanding information' which suggests that care must be taken to ensure that health literacy is not a barrier to participation in SDM conversations. Assuming that some people do not wish to engage in making decisions may mask that health literacy rather than personal preference is the barrier. We would suggest that this section reflects this (JB)	
NHS England and NHS Improvement	Draft Guideline	General	General	We welcome the Guidelines which will be a significant driver in the work being undertaken by NHSEI to embed SDM with in the health system. The emphasis on risk communication within the document is very welcome because this is a key part of a SDM conversation. However, we would like to see much greater emphasis placed on the importance of Health Literacy because without this the 43/61% of the English working age population who struggle to understand health information (Rowlands et al 2015, Public Health England/Institute of Health Equity 2015) may not be able to effectively engage in risk communication and SDM conversations which in turn would widen health inequalities as those people with lower levels of	Thank you. The committee did not consider specific evidence for people with learning disabilities who have mental capacity, however they agreed that they should be encouraged to participate in shared decision making, therefore they added a specific reference to people with learning disabilities. The recommendations consistently refer to ensuring people understand and receive information in their preferred format. Please see for example recommendations 1.2.4, 1.2.5, 1.2.18.We have also added reference to the accessible information standard. The committee agreed that "teach back" and "chunk and check" were important methods in delivering information and checking it had been understood. They agreed to add these

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				health literacy tend to have the worst health outcomes. In addition it would be helpful if the Guideline emphasised the importance of 'Nothing about us, without us'. It would also be helpful if the Guideline emphasised the importance of ensuring that people with disabilities are able to participate in SDM conversations and that the assumption is that they can do so rather than the opposite. (JB)	methods as a way to implement existing recommendation 1.2.11.
NHS England and NHS Improvement	Draft Guideline	General	General	The Maternity Transformation broadly welcomes this guidance which supports the need for a fundamental cultural shift in the way that organisations and practitioners work alongside people using services to deliver more person-centred care and provides valuable resources on how to achieve this. Based on stakeholder consultation, in line with Human Rights Legislation and our commitment that the woman is the ultimate decision maker, in Maternity Services we use the term Informed Decision Making. Informed Decision Making means people are supported to: • understand the care, management and support options available and the risks, benefits and consequences of those options	Thank you. The term shared decision making was agreed during the scoping of this guideline, including via stakeholder consultation. Please also note that this guideline is about shared decision making, and not about consent.

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				- make a decision about a preferred course of action, based on evidence-based, good quality, timely information and their personal preferences. The Supreme Court in Montgomery Vs Lanarkshire Health Board concluded that when seeking consent to treatment, the question of whether the information given to a patient is adequate, is judged from the perspective of a reasonable person in the patient's position. Health care providers must provide information about all material risks, that is, any risk to which a reasonable person in the patient's position would attach significance. This is also in line with the updated guidance form the GMC on decision making and consent (Nov 2020). We would therefore argue that Informed Decision Making is a more appropriate term, certainly now in maternity services, potentially to be used increasingly across the NHS, going forward. (MC)	
NHS England and NHS Improvement	Evidence Review A	054	037-041	Can the barriers and facilitators to SDM be included in the Guideline? (JB)	Thank you for your comment. Barriers and facilitators were part of the evidence review and used to inform the recommendations that are included in the guideline.

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NHS England and NHS Improvement	Evidence Review D	018	041-042	We totally agree about the importance of high quality data in risk conversations and DSRs and would hope that this will be covered by the standards framework that NHSEI have commissioned from NICE (JB)	Thank you for your comment
NHS England and NHS Improvement	Evidence Review E	014	007-008	We are very supportive of the idea that *'there should be more opportunity to assess healthcare staff's readiness to engage in SDM processes when they are being interviewed for employment'.* However, this isn't included in the Guideline which may be a missed opportunity. In addition we would suggest that SDM should be a routine element of every member of staffs induction. (JB)	Thank you for your comment. This is out of scope for NICE recommendations.
NHS England and NHS Improvement	General	005	016	It should be borne in mind that people may change their mind about decisions at any point. This is not sufficiently clear in the document. (MC)	Thank you for your comment. SDM being a changing process over time was discussed in depth with the committee, as can be seen on page 18 of the guideline under "why the committee made recommendations", and in the themes captured in evidence review A. It is also reflected in the recommendations a person "can change their mind about a decision they have made at any time" (1.2.16) and we have tried to make this clearer.
NHS England and NHS Improvement	General	005	001	It will also be important for organisations to have strong governance policies and processes in place to support staff and service users when people request treatment / intervention or no treatment where this is outside usual guidelines, and also conflict resolution procedures (MC)	Thank you for your comment.

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NHS England and NHS Improvement	General	006	017	Practitioners will also require training in understanding that different cultures or religious belief systems may impact on the way that people make decisions and decisions themselves – these should be respected (MC)	Thank you for your comment. It is outside of NICEs remit to recommend training programmes. Professional training standards are set by professional bodies.
NHS England and NHS Improvement	General	007	001	It should be made clear that the service user is the key decision maker (MC)	Thank you for your comment. Many references are made to the nature of a "shared" or "joint" decision between service user and the practitioner, and the importance of ensuring the patients voice and decision is heard. We feel this indicates that the service user is a key decision maker in the process. We have added additional text to the rationale and impact section to clarify this.
NHS England and NHS Improvement	General	007	005	… and are able to give informed consent. The document does not sufficiently reference informed consent (MC)	Thank you. Shared decision making is not a replacement for informed consent and should never be substituted for it. The skills of shared decision making may improve consenting processes by helping ensure that the patient or service user understands what they are agreeing to, but consent is not covered in this guideline.
NHS England and NHS Improvement	General	037	General	This is a really important finding particularly in view of the importance of tackling health inequalities which have been starkly illustrated by the pandemic. It would be helpful if the guidelines were offered some recommendations of how to ensure these cohorts i.e. people experiencing socio-economic deprivation and BAMER can be actively engaged in SDM. (JB)	Thank you for your comment. The committee has put together research recommendations both for the best ways to measure SDM in different contexts with different people.
NHS England and NHS Improvement	General	1.1.1	General	This is about being clear on responsibilities and not just accountability. (NP)	Thank you for your comment.

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NHS England and NHS Improvement	General	1.1.1.	General	How will you ensure that this role isn't just allocated to someone without the resource to implement? (NP)	Thank you. That is beyond the remit of NICE guidelines.
NHS England and NHS Improvement	General	1.1.10	General	This section needs further detail to show the continuous loop needed to ensure patients and service users can effect change here. Reference to the use of 'about me' type documents and resources, need to work with the persons approach and not the organisations 'style' and how a comprehensive offer of resources will be made available to people. (NP)	Thank you for your comment. The committee felt the appointment of the roles outlined in recommendations 1.1.1 – 1.1.4, couple with the training outlined in 1.1.14-1.1.15 and the monitoring and evaluation in 1.1.9, would create a feedback loop between organisations and service users to help effect change. The committee also recognised that there were challenges in sustaining shared decision making over time and across different people/departments, and thus added research recommendation 3: "What interventions are most effective at transferring shared decision making skills between people and departments, and in sustaining the implementation of shared decision making in an organisation and in clinical teams?"
NHS England and NHS Improvement	General	1.1.2	General	"consider" can be taken a number of ways, suggest being clear here about the importance of these roles and need to reflect those whom services serve to ensure decision-making isn't too medically driven and is truly inclusive. (NP)	Thank you for your comment. NICE has a specific definition for the terms "consider" and "offer" which can be seen here under "using recommendations". https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/making-decisions-using-nice-guidelines
NHS England and NHS Improvement	General	1.1.5	General	There is a need for a clear vision. Aligned to the organisations value set so that this isn't seen as tokenistic. Adding detail as to the vision will help people understand their role and place in the drive to involve, engage and collaborate with service users and will make success more likely. Also suggest effective feedback, evaluation and	Thank you for your comment. These are general recommendations for SDM and NICE wouldn't be able to reference the value sets of multiple organisations, but the committee hoped organisations would also have SDM as part of their values. In which case alignment is not an issue, or felt they should add SDM to their value set and use the recommendations in this guideline as a guide to how to implement change in line with this new value.

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				monitoring is needed to be clear here so again this becomes meaningful. Line 20 – "set out" needs to show that people need to be asked, supported and engaged with effectively well before any decisions about the direction of travel are agreed. (NP)	
NHS England and NHS Improvement	General	1.1.6	General	Are Schools of Nursing and Deaneries involved to ensure SDM is part of the curriculum and what about current professional guidelines and resources? (NP)	Thank you for your comment. Teaching of SDM at educational institutions is outside the scope of this guideline.
NHS England and NHS Improvement	General	1.1.6	General	Need to ensure the evidence bases are reflected and practitioners are encouraged to build upon these. Also suggest that this is built into reflective practice for practitioners to ensure individual learning, development and expansion of skills in these areas. (NP)	Thank you. This is not specific to shared decision making.
NHS England and NHS Improvement	General	1.1.7 and general	General	1.1.7 and elsewhere generally needs to highlight more the reasonable adjustments that need to be made and the particular skills and resources that should be drawn on in communicating with people with learning disability and with autistic people (RD)	Thank you for your comment. Empowerment of all patients with or without a disability was discussed and identified through the various evidence reviews particularly in evidence review A. Additional support for those who may find shared decision-making difficult is covered in recommendation 1.2.6 The committee have also added references to the accessible information standard.
NHS England and NHS Improvement	General	1.2.1	General	What about where people may have mental capacity assessment needs or reasonable adjustments to support them to still have the shared decision-making opportunity. Please reference best practice. (NP)	Thank you for your comment. Additional support for those who may find shared decision-making difficult is covered in recommendation 1.2.6 The committee have also added references to the accessible information standard.

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NHS England and NHS Improvement	General	1.2.11	General	In busy GP practices and outpatient clinics how will adequate time be ensured? This will be challenging and needs a considered, coordinated approach. (NP)	Thank you for your comment. The committee discussed at some length whether SDM required more time and that allowing a larger amount of time for SDM may increase consultation length and cost. Although it did not see any quantitative evidence to reflect this, it did note that the qualitative evidence highlighted 'lack of time' as a barrier to using SDM. Overall, it agreed that any additional time needed could potentially be offset by fostering a better patient-practitioner relationship in early sessions, leading to shorter ones in the future, although they also acknowledged that many healthcare professionals only see people short term. They highlighted issues around practitioners questioning what the evidence is for more time being needed, and that more research is needed into what interventions reduce time commitment. Recommendation 1.2.10 does include the option of a further opportunity to discuss options, and in the committee's view, shared decision making should be treated as an ongoing process rather than a one-off event. For organisational recommendations on how to embed and normalise SDM, see section 1.1
NHS England and NHS Improvement	General	1.2.5	General	In 1.2.5 mental health condition and sensory difficulties or English not as first language are mentioned as contributing to difficulty in shared decision making but again, not learning disability (intellectual impairment) or autism (RD)	Thank you for your comment. In order to allow "additional support for people who might find it difficult to share in decision making" to cover the broadest range of those who may need support, we have removed the examples from recommendation 1.2.6., the committee agreed learning disability and autism could be covered by this recommendation.

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NHS England and NHS Improvement	General	1.3.4	General	Query as to whether a central database for patient decision aids for access by all organisations be better to avoid duplication? (NP)	Thank you for your comment. There is currently no national repository for PDAs.
NHS England and NHS Improvement	General	General	General	I am really pleased to see this draft guideline and support its content. (CIC)	Thank you for your comment.
NHS England and NHS Improvement	General	General	General	Suggest consideration as to the current climate and Covid-19 restrictions on attending face to face and with family member/friend? (NP)	Thank you for your comment. The committee agreed that remote discussions should be considered and have also written a research recommendation that asks "How do SDM skills and techniques need to be modified for remote discussions?" They noted that remote discussions are not just limited to digital interventions, but can also cover telephone consultations which are less of a problem when it comes to digital literacy. The committee felt skills of SDM could be applied to remote settings as well as face to face settings, and this has been added to the rationale and also to a recommendation (1.2.2).
NHS England and NHS Improvement	General	General	General	Shared decision making should be an important consideration for addressing empowerment of people with learning disability and autistic people in having an active role in choices about their health care and addressing health	Thank you for your comment. Empowerment of all patients with or without a disability was discussed and identified through the various evidence reviews particularly in evidence review A. Additional support for those who may find shared decision-making difficult is covered in recommendation 1.2.6.

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				inequalities yet the process and the guidelines don't appear to have given specific consideration to this. (RD)	
NHS England and NHS Improvement	General	General	General	The membership of the guidance committee does not have representation from an individual or organisation representing learning disability / autism. (RD)	Thank you for your comment. We agree that it would have been impossible to have a truly representative committee. The best format for the committee was discussed and agreed with stakeholders at the stakeholder workshop during the scoping phase of this guideline. In addition, both the scope and the guideline have been through a process of public consultation, of which you are a part. We also complete an Equality Impact Assessment on all NICE guidelines. This documents our consideration of inequalities, including disability, during every stage of guideline development.
NHS England and NHS Improvement	General	General	General	The Equality Impact Assessment mentions people "with communication needs" and neurodiversity under the heading of people with protected characteristics but not people with learning disability or autism, (RD)	Thank you. The EIA refers to "people with learning disabilities (including autism)"
NHS England and NHS Improvement	General	General	General	A search of the Evidence Reviews only brings up one reference (in ER - A) to a source with learning disability in the title, there are no references in BCD&E. (RD)	Thank you for your comment. For each evidence review, an in depth search for literature for SDM in any setting was performed, and the relevant studies screened for at full text. Any studies looking at service users specifically with learning disabilities or autism would have been identified and included if they met the other criteria for inclusion. The protocol for each review question can be seen in appendix A and the search strategy in appendix C. The protocol is based upon the scoping document that went through a round of stakeholder consultation.

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NHS England and NHS Improvement	General	General	General	All above comments are applicable to the document as a whole. The process and the document do not appear to have specifically considered this from the perspective of enabling shared decision making with people with a learning disability (intellectual impairment) or autism. See RCN Shared decision making report 2014. (RD)	Thank you for your comment. For each evidence review, an in depth search for literature for SDM in any setting was performed, and the relevant studies screened for at full text. Any studies looking at service users specifically with learning disabilities or autism would have been identified and included if they met the other criteria for inclusion. The protocol for each review question can be seen in appendix A and the search strategy in appendix C. The protocol is based upon the scoping document that went through a round of stakeholder consultation.
NHS England and NHS Improvement	General	General	General	Overall, this is very clear and helpful in a primary care environment. I wonder whether something about the importance of cultural awareness and diversity within the team on the effectiveness of shared decision-making is missing. (CCD)	Thank you. Cultural diversity and awareness is not specific to SDM. The committee did note some gaps in the evidence that relate to different cultures and backgrounds in engaging with SDM and the perceived role of the clinician. They recommended research to better understand this.
NHS England and NHS Improvement	General	Recommendation 4	High level leadership	In this recommendation and in the guideline generally there is no reference to coproduction as a model for empowering "service user voice" in organisations - but this is a model that is high profile in learning disability settings in particular (RD)	Thank you for your comment. Many of our recommendations speak to involving patients in the decision making process at an organisation level (see recommendation 1.1.2 - 1.1.4)
NHS England and NHS Improvement	Recommendations	006	013	The option to do nothing or persevere is an important one, I wonder whether the brackets are required. (CCD)	Thank you for your comment.
NHS England and NHS Improvement	Recommendations	006	015	Feeling listened to is a positive or negative theme that recurs when patients recount their experience of health decision-making. This sentence could include something that	Thank you for your comment. General themes, including the patient feeling listened to/trusting the practitioner, was covered in the qualitative section of evidence review A, these findings

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				addresses the importance of listening and considering, as well as drawing out. (CCD)	fed into the recommendations shown here along with the other evidence reviews.
NHS England and NHS Improvement	Recommendations	008	016	In general practice a further appointment may need to be offered of an appropriate length (CCD)	Thank you for your comment. Recommendation 1.2.10 does include the option of a further opportunity to discuss options, and in the committee's view, shared decision making should be treated as an ongoing process rather than a one-off event.
NHS England and NHS Improvement	Recommendations	009	009	Which in some environments may extend to another appointment (CCD)	Thank you for your comment. The guideline makes reference to how SDM should be seen as an ongoing process not taking place at a single decision point.
NHS England and NHS Improvement	Recommendations	010	010	Or a different member of the multidisciplinary team, in general practice this could be for example, a physiotherapist, pharmacist or GP with a particular interest. (CCD)	Thank you for your comment. Since this staff member could vary as you have stated, we have left the recommendation broad.
NHS Grampian	Draft Guideline	General	General	This is an extremely welcome and valuable guideline with substantial practical content which should be feasible to put in practice over time. Adherence is likely to lead to less litigation and thus be an extremely cost-effective intervention for the NHS Trusts/Boards.	Thank you for your support
NHS Grampian	Draft Guideline	004	017	We would want to know how a 'service user champion' for shared decision making should be renumerated for their time and effort..is this an example of a voluntary role where expenses would be covered but no actual payment for their time is made? This is likely to have substantial impact on the value of this role.	Thank you. This is a decision for individual organisations.

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NHS Grampian	Draft Guideline	010	008	The recommendation that people could be encouraged to record their discussions is very understandable. It is however likely to be difficult to implement as there is considerable anxiety among health professionals that these recordings could be used out of context in medicolegal or media-reporting. It is therefore suggested that this be acknowledged and concerns allayed in the guideline in order to improve the feasibility of this recommendation being put into practice.	Thank you. Recording the discussion is given as an example only.
NHS Grampian	Draft Guideline	General	General	Given the impact of the UK Supreme Court Montgomery ruling on the perceived importance of shared decision-making in healthcare in general, but also in relation to vaginal childbirth, it would be prudent to mention somewhere that the principles of shared decision-making apply to the planning of vaginal birth in the same manner as they apply to any other aspect of medical care. We feel this is important as historical (and some current) practice has tended to exclude 'natural' processes of childbirth from those areas of healthcare where shared decision-making and informed consent are considered essential. The Ockenden report is a perfect example of how vaginal birth can be viewed by staff as a more favourable outcome and thus why substantial numbers of women are not offered a choice at all in how they give birth.	Thank you. The guideline is applicable in all settings where NHS care is delivered.

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				The consequences of this can clearly be devastating. By being explicit in the guideline that shared decision-making should be applied in the context of vaginal birth too, the prospect of realising it in real life would be hugely increased.	
North East London Foundation Trust	Draft Guideline	014	006-012	While the three-talk model is important, to the best of our knowledge it has not been validated among people from different cultures, backgrounds, and among individuals who suffer from different mental health conditions. We advise not limiting the NICE SDM recommendations to one model and would like to cite Cathy Charles et al article from 2006: *"We suggest that more research attention should be focused on exploring potential cultural variations in the meaning of and preferences for shared decision-making…".* We would also like to recommend the original SDM model by Charles et al (1997; 1999) and the integrated model by Makoul & Clayman (2006) as additional SDM models to consider. References: Charles, C., Gafni, A., & Whelan, T. (1997). Shared decision-making in the medical encounter: what does it mean? (or it takes at	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.

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				least two to tango). *Social science & medicine*, *44*(5), 681-692 Charles, C., Gafni, A., & Whelan, T. (1999). Decision-making in the physician–patient encounter: revisiting the shared treatment decision-making model. *Social science & medicine*, *49*(5), 651-661. Charles, C., Gafni, A., Whelan, T., & O'Brien, M. A. (2006). Cultural influences on the physician–patient encounter: the case of shared treatment decision-making. *Patient education and counseling*, *63*(3), 262-267. Makoul, G., & Clayman, M. L. (2006). An integrative model of shared decision making in medical encounters. *Patient education and counseling*, *60*(3), 301-312.	
North East London Foundation Trust	Draft Guideline	014	015-017	Although a range of articles from different countries have been included in the Evidence Review B (i.e., Alegria et al., 2018; Aljumah & Hassali, 2015; Hamann, 2011; Hamann et al., 2020; Ishii et al., 2017; Joosten et al., 2008; Metz et al., 2019; Raue et al., 2019; Yamaguchi et al., 2017) we were unable to identify in the draft of the Guideline document any specific recommendations that address cultural	Thank you for your comment. Evidence of this nature was included in the qualitative section of review A, and the themes were carried through into recommendation 1.2.6 and research recommendation 4.

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				differences and translate the evidence into practice.	
North East London Foundation Trust	Evidence Review A	010	013 015	Our main concern is regarding the presentation of the state-of-art evidence in shared decision making (SDM) mental health research (and practice) and specifically, in serious mental illness (SMI, e.g., schizophrenia, bipolar disorder, major depressive disorder). Several important studies were excluded due to quality of the evidence (e.g., Ishii et al., 2017; Perestelo-Perez et al., 2017; Simmons et al., 2017; Steinwachs et al., 2011; Vigod et al., 2019), study design (Lord, Livingston, & Cooper, 2017; McCabe et al., 2019; Zisman-Ilani et al., 2019), or population type of the providers (Simmons et al., 2017). SDM in mental health is NOT the same as SDM in other somatic conditions like diabetes or cancer. Several factors such as symptoms, stigma related to the capacity of the patient to make decisions, and the decision juncture/node itself lead toward a different conceptualization and practice of SDM in mental health. We have concerns that the guidelines will be less relevant for the evolving field of SDM in mental health and will interfere	Thank you for your comment. In regard to the studies excluded, reasons were given in the evidence review as to why they did not meet the PICO criteria given established before commencement of the review. For example, many studies mentioned here did not present an objective outcome of SDM and thus as per the protocol could not be included in the review. This protocol was used for an earlier Cochrane review. This guideline sought to appraise the effectiveness of approaches and activities of SDM in all settings, and in terms of specific detail of individual settings, the importance of including organisations and individuals with experience of each setting and how SDM can be applied is discussed both in barriers and facilitators and evidence review E.

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				with dissemination efforts of SDM in mental health. If the excluded studies are not considered "SDM" according to NICE, then what should be considered SDM in mental health? For example, please review the following references: Zisman-Ilani, Y., Lysaker, P, & Hasson-Ohayon, I. (2021). Shared risk-taking: shared decision making in serious mental illness. *Psychiatric Services*. Zisman-Ilani, Y., Barnett, E., Harik, J., Pavlo, A., & O'Connell, M. (2017). Expanding the Concept of Shared Decision Making for Mental Health: A Systematic and Scoping Review of Interventions. *Mental Health Review Journal, 22(3),* 191–213. We urge the NICE panel to reconsider these studies, which if included in the evidence review can provide a more accurate picture of SDM in mental health.	
North East London Foundation Trust	Evidence Review A	060	006	Although the study inclusion criteria prioritised *"randomised controlled trials (RCTs), well-designed quasi-experimental studies (quasi-RCTs), controlled clinical trials (CCTs), controlled before and after studies (CBAs) and interrupted time series analyses (ITS)"* (p.60 line 6), in mental health, only RCTs were eventually	Thank you for your comment. See appendix E of the evidence review on reasons for exclusion, relevant quasi-RCT studies would have been included had they met all other inclusion criteria, as specified in the protocol.

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				included in this review. We acknowledge the importance of RCTs as the "gold standard" for causal evidence in health research. However, in health behavioural intervention studies, quasi-experimental designs are often the preferred alternative to generate strong causal evidence when blind randomization is not feasible (e.g., due to ethical considerations, difficulty of randomizing subjects, difficulty to randomize by locations, small available sample size; Onken et al., 2014). When it comes to SDM in mental health studies, quasi-experimental designs are often the choice (except for a few examples like Hamman et al., 2007; Hamman et al., 2017; or Loh et al., 2007 studies). Therefore, some of the excluded studies could have proven invaluable when summarising the available SDM literature. Reference: Onken, L., Carroll, K., Shoham, V., Cuthbert, B., & Riddle, M. (2014). Reenvisioning clinical science: Unifying the discipline to improve the public health. Clinical Psychological Science, 2, 22–34.	
Nuffield Council on Bioethics	Guideline	General	General	We welcome this guideline as a positive contribution to the creation of healthcare environments that foster good, collaborative	Thank you for your comment.

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				relationships between patients and healthcare staff. In 2019, the Nuffield Council on Bioethics published a briefing note on the disagreements that can arise between parents and healthcare staff in the care of critically ill children (see https://www.nuffieldbioethics.org/publications/disagreements-in-the-care-of-critically-ill-children). We suggested ways to prevent protracted and damaging disagreements developing, or to resolve them more quickly. The aim should be: 1 Good communication between families and healthcare staff and an understanding of differing perspectives; 2 Appropriate involvement of parents in discussions and decisions about the care and treatment of their child; 3 Timely use of effective resolution interventions in cases of disagreement; and 4 Attention to the profound psychological effects that disagreements can have on families and healthcare staff. Taken together, the recommendations of the guideline helpfully promote collaboration, communication and informed patient choice in healthcare settings. Specifically, many of the recommendations align with the areas for action	Decisions shared between parents of sick children and practitioners were outside the scope of this guideline.

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				we set out in our document that relate to the first two aims above. For example: - "1.1.5 Develop an organisation-wide plan to put shared decision making into practice" – we suggested those responsible for national policy making in relation to healthcare practice (such as NICE) should support NHS trusts across the UK to develop processes for recognising and managing disagreements between parents and healthcare staff, such as introducing conflict management frameworks. - "1.1.6 Organisations should ensure that knowledge, skills and confidence to support shared decision making are included in the training and continuing professional development of all healthcare staff" – we suggested making ethics, communication, and conflict management training for paediatric healthcare staff more widely available, or even compulsory. - "1.2 Putting shared decision making into practice" – we suggested exploring ways in which those parents who want to can be more involved in discussions	

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				and decisions about their critically ill child. • "1.2.5 …offer to arrange additional support for them if they do not have, or do not want, support from a partner, friend or carer. Support could come from a nurse, social worker, translator or volunteer (for example, an advocate)" – we suggested making independent advocates and financial support, such as legal aid, available to parents who are in legal disputes with hospitals. We would like to suggest that NICE considers including information in the guideline on shared decision making specifically between parents of sick children and healthcare staff, given that this can differ from decisions about adult patients. Before any kind of medical intervention can be given to a baby or young child, the consent of the parents or guardians must be sought by the healthcare team (except in emergency situations where immediate steps need to be taken). This also applies to decisions to withdraw or withhold life-sustaining treatment. Parents can request a particular course of action, but there is no obligation on healthcare staff to provide treatment that they do not believe to be in the	

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				best interests of the child. In practice, this means healthcare staff and parents of young children and babies ideally should both agree to the care and treatment that is to be provided through a process of shared decision making. However, if disagreements arise that cannot be resolved, hospitals must apply to the appropriate court for an independent ruling before proceeding with a course of action that the parents do not consent to. Recent high-profile court cases in the UK have highlighted the damaging effects that these kinds of disagreements can have on everyone involved. We would like to suggest that NICE considers including some information in the guideline about when a shared decision cannot be reached. If disagreements arise, there is a range of resolution interventions that can be used. Discussions can benefit from the involvement of others such as hospital chaplains, religious and community leaders, Patient Advice and Liaison Services (PALS), and palliative care specialists. Either party can seek a second expert opinion, although care should be taken to ensure this is viewed as independent by all parties. Some hospitals have access to clinical ethics	

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				committees, which can help identify the ethical values underpinning the disagreement, but they vary widely in their membership and processes. Mediation involving a neutral mediator is increasingly recognised as an appropriate method for attempting to resolve paediatric healthcare disputes. There is a lack of evidence on the availability of different resolution interventions in UK hospitals, how often they are employed, and how effective they are in different contexts. If resolution mechanisms are discussed in the guideline, NICE might consider including the need for further evidence on their effectiveness in the 'Recommendations for research' section (p14).	
Nursing and Midwifery Council	General	General	General	We are not a provider organisation. Instead as the professional regulator of nurses and midwives across the UK and nursing associates in England we set standards that ensure that people who receive support and care are always at the centre of care and are expected to involve people in any decisions about them. We have provided links to where this is embedded in our standards and resources as we not your reference to GMC resources.	Thank you for your comment.
Nursing and Midwifery Council	General	General	General	Thank you for the opportunity to provide feedback on the draft NICE guidance on shared decision making.	Thank you for your comment.

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				Our vision is safe, effective and kind nursing and midwifery that improves everyone's health and wellbeing. As the professional regulator of almost 725,000 nursing and midwifery professionals, we have an important role to play in making this a reality. Our core role is to regulate. First, we promote high professional standards for nurses and midwives across the UK, and nursing associates in England. Second, we maintain the register of professionals eligible to practise. Third, we investigate concerns about nurses, midwives and nursing associates – something that affects less than one percent of professionals each year. We believe in giving professionals the chance to address concerns, but we'll always take action when needed. To regulate well, we support our professions and the public. We create resources and guidance that are useful throughout people's careers, helping them to deliver our standards in practice and address new challenges. We also support people involved in our investigations, and we're increasing our visibility so people feel engaged and empowered to shape our work.	

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				Regulating and supporting our professions allows us to influence health and social care. We share intelligence from our regulatory activities and work with our partners to support workforce planning and sector-wide decision making. We use our voice to speak up for a healthy and inclusive working environment for our professions. We welcome the development of new guidance in this important area of professional practice. This draft provides welcome information on how to embed shared decision making into everyday practice and in recognising that different people may need different approaches to enable them to be involved in decisions about their needs and care. We welcome the emphasis on the inclusive nature of this guidance across all professions and at all organisational levels – from those involved in the direct care of people and those who are leaders of services and organisations. Our Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates rightly emphasises the need to encourage and empower people to be involved in decisions about their treatment and care.	

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				We recently published a series of short animations to emphasise our Code in action and being person centred and shared decision making is one aspect of this campaign. Our new standards of proficiency for nurses, for midwives, and for nursing associates in England emphasise the importance of being person centred and to know and apply evidence to support people to be involved in all care decisions. It is also pleasing to see that the evidence base about what works now but also the recommendation to continue to consider what research is needed to determine what works in order to disseminate good practice, and in recognising what else needs to happen or what further research is needed. In summary we welcome the prospect of NICE guidance being published in this vital area of person centred care and would welcome an opportunity to be involved in any further research.	
Pancreatic Cancer UK	Draft Guideline	005	028	The importance of tying in with other support and information available regionally and nationally should be highlighted here. People with pancreatic cancer tell us that all too often,	Thank you for your comment. The involvement of these organisations through the roles outlined in recommendations 1.1.1 to 1.1.4 is not ruled out, but due to the range and variation in health organisations and the general nature of the

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				healthcare professionals are not aware of, and so are not in a position to offer, positive information when supporting the patient – Pancreatic Cancer UK and other organisations can help here with their wealth of resources and access to support systems for patients. It is important to mention in the guideline the importance of clinicians being aware of what is available for the patient outside of that system, so that when they have discussions with patients and families they are able to offer positive, supportive suggestions.	SDM recommendations recommending specific health organisations was not the aim of the guideline. The committee acknowledged that information from patient organisations can be useful, and added to the rationale that "Providing information is important, but the committee wanted to emphasise that it needs to be of good quality, for example NICE-accredited. The committee was aware that other quality standards exist, like the PIF TICK quality mark for patient organisations."
Pancreatic Cancer UK	Draft Guideline	006	005	The practical recommendations in this guideline are useful for clinicians including the three-talk model and the importance of sharing and discussion information clearly and thoroughly. An important addition to make is the importance of clinicians speaking to, and involving, the patient and their family in a two-way discussion, instead of simply telling them information. The importance of this two-way conversation is something those we support highlighted to us in response to this consultation document as being essential in helping people feel supported and truly involved in their care.	Thank you. We feel this is covered by "understanding the principles that support shared decision making based on an evidence-based model". It is clarified in the context section of the guideline that SDM is "a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care." And the guideline mentions throughout examples of collaborative two-way discussion (for example recommendations 1.2.7, 1.2.13, and 1.2.14)
Pancreatic Cancer UK	Draft Guideline	006	027	We would urge NICE to remove the suggestion of offering people who use services 'training' in shared decision making. This is inappropriate and unhelpful in that it places the onus on the patient. For those who are facing a pancreatic	Offering training is given as an example, and the committee felt that offering training to service users is fair and balanced if you are offering training to healthcare professionals, and helps to create a collaborative space with service users and healthcare

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				cancer diagnosis, many of whom will be palliative patients, additional training in order to receive support is the last thing that they would be wanting to spend their time on, nor should they have to feel that they need to train in order to receive appropriate, holistic and supportive care. This is the role of the healthcare professionals involved in their care. A better idea would be for the GPs to encourage and support their patients to be involved in shared decision making through readily sharing information and FAQs about shared decision making and what it is, in order to help patients build their confidence in this area. Posters in surgeries, and social media posts are also positive suggestions.	professionals on an equal footing. Both need to be involved in SDM.
Pancreatic Cancer UK	Draft Guideline	007	003	This section is useful in highlighting practical things that clinicians and other staff can do, however it does not mention, and we feel should include, the importance of continuity of healthcare professionals for the patient. It would be very helpful for many patients and especially for people with non–curative pancreatic cancer to have a named or nominated health professional consistently working with them, to provide continuity throughout the person's treatment. That person would be the conduit between the patient and their family (as often does happen in hospice care). Too often, those we support tell us the patient facing a terminal diagnosis is left unsupported at home with their	Thank you. The committee discussed this at some length, but did not see any robust evidence that continuity of healthcare professional was an effective intervention for improving shared decision making.

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				family struggling on isolated. It can very often feel that the health professionals have 'given up' on the patient as there is no treatment to be offered, so they can cease communication and patients can be bounced around a system. It is absolutely essential that all the patient's support needs are listened to and acted on where appropriate and having a consistent point of support in the healthcare system can aid with this. For some patients it is not possible or practical to be involved in shared meetings or discussions with health professionals depending on the stage of their disease, so it is even more important that they feel listened to and that their needs are met through involving any family or carers throughout.	
Pancreatic Cancer UK	Draft Guideline	008	001	It would also be useful to encourage patients to consider and prepare any questions they have before their first appointment and let them know that their questions are welcome at this and every stage. This will enable the patient and their family to feel confident in asking questions and preparing accordingly for their first appointments. People with pancreatic cancer have also told us that they would like to see included here the importance of advising the patient not to attend the appointment alone unless they choose to. A family member or friend can provide additional support and can	Thank you. We have added this.

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				take notes or ask questions on behalf of the patient if necessary.	
Pancreatic Cancer UK	Draft Guideline	008	017	Although stating how long an appointment will last can be helpful in some instances for time management, those we support feel that some patients may feel rushed by this approach and feel they need to be as quick as possible. This may lead to them withholding questions they wanted to ask and not taking in and processing information quickly.	Thank you. The committee agreed. As a result, they suggested setting priorities for discussion (1.2.7 and offering a further opportunity to discuss (1.2.10).
Pancreatic Cancer UK	Draft Guideline	009	026	The suggestion of a summary letter or follow-up call is positive, and those we support highlighted that this should be standard practice, rather than a consideration, to help patients understand and process information.	Thank you for your support.
Pancreatic Cancer UK	Draft Guideline	010	026	People with pancreatic cancer have told us that they feel positive framing should always be the priority when sharing statistical information – e.g. treatment will be successful for 97 out of 100, rather than it will be unsuccessful for 3 out or 100. Psychologically, this is easier to process for patients and helps to maintain positivity whilst also understanding that treatment will not be successful for all patients.	Thank you for your comment. The committee noted that only mentioning positive or negative framing could bias a decision, and thus both should be presented if possible
Pancreatic Cancer UK	Draft Guideline	General	General	We welcome the introduction of this guideline, which is an essential tool in helping to ensure all pancreatic cancer patients are fully involved in, and informed about, decisions surrounding their treatment and care. We believe the key to effective shared decision making for people with	Thank you for your support.

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				pancreatic cancer is cohesive, consistent communication between all involved in the individual's care, centring the patient at all times. Unfortunately, we know from the experiences of those we support that this is not always the case; each department can be siloed and detached instead of providing transparent, joined-up information and ensuring it is properly shared with all interested parties. Most of those diagnosed with pancreatic cancer report moderate to high physical and psychological supportive care needs and at least half report having moderate to high unmet. These unmet needs persist over time and increase in patients with locally advanced or metastatic disease. For these reasons, shared decision making practice when supporting people with pancreatic cancer is crucial.	
Pancreatic Cancer UK	Draft Guideline	General	General	This guideline refers frequently to the importance of patient decision aids but fails to mention the use of Patient Reported Outcome Measures (PROMs). Integration of PROMs into clinical care represents an opportunity to establish more quality of life and self-reported symptoms data, so that patients can be more aware of patient reported outcomes and bet better informed to participate in decisions about treatment. Large-scale aggregated PROMs databases that have combined patient data could illustrate patient reported outcomes for	Thank you. PROMS were used as an outcome for several of the reviews that underpin this guideline. The committee felt more research was needed and added a research recommendation: "What are the best ways to measure the effectiveness of shared decision making in different contexts (in different settings and involving different people)?"

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				different treatment approaches, with outputs based on stage, age and other individual patient characteristics allowing patients to understand the quality-of-life trajectory of specific interventions. Individualised PROM data could also be displayed and presented to patients with their own data to show symptom change over time to help guide care plans and facilitate shared treatment decisions. Only 29% of oncology clinical trials include a Patient Reported Outcome Measure (PROM) but these allow us to understand outcomes from the patient perspective and determine if interventions actually improve the life of those with a health condition. PROMs have been identified as improving care of people with pancreatic cancer through improving the shared decision-making process and should be included in this guideline as a key facet of shared decision making.	
Pancreatic Cancer UK	Draft Guideline	General	General	One important aspect that this guideline does not address in its guidance for clinicians is the need to give specific attention to older patients. The number and relative proportion of pancreatic cancer cases diagnosed in older people will rise significantly, with 74% of pancreatic cancer cases diagnosed in people over 65 by the end of the next decade. Therefore, the quality of life, supportive care	Thank you. The guideline highlights the need to give patients adequate time and support to ensure they can participate in shared decision making, whatever age they are. We believe that recommendations in section 1.2 and 1.4 adequately cover this.

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				needs and expectations of the older population will increasingly need to be considered in pancreatic cancer care. This is particularly important given that older people are more likely to have a non-curative approach and may experience higher treatment related toxicity, leading to significant deterioration in functional recovery. Clinicians should be made expressly aware of this and the need for healthcare professionals to have training in working with the older population to facilitate shared decision making.	
Parkinson's UK	Draft guideline	general	general	Clinicians we have consulted on our response to this draft guideline have given positive feedback on the document and feel that it will be useful to help improve practice in terms of shared decision making.	Thank you for your support.
Parkinson's UK	Draft guideline	general	general	We can find no mention of individuals who lack capacity or guidance on how to engage people with Lasting Power of Attorney for health. Upto 31% of people with Parkinson's have dementia at any one time (Aarsland, D., Zaccai, J and Brayne, C. (2005) 'A systematic review of prevalence studies of dementia in Parkinson's disease' Movement Disorders Journal, vol. 20, issue10, pages 1255-1263) and can experience symptoms such as psychosis that can impact on their mental capacity. We recommend that this guideline makes explicit reference to individuals who lack mental capacity and signpost to the	Thank you. People who lack mental capacity are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)

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				NICE guideline 'Decision-making and mental capacity' (NG 108) for further guidance.	
Patient Experience Library	Draft Guideline	General	General	NICE's introduction to its consultation response template says: In addition to your comments below on our guideline documents, we would like to hear your views on these questions: 1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. 2. Would implementation of any of the draft recommendations have significant cost implications? 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) We (the Patient Experience Library) would like to comment on two of these matters: • which areas will be challenging to implement, and • what would help users overcome any challenges. 1. <u>The challenge</u>	Thank you for your comment. We hope this guideline will be an important step towards shifting culture and systems towards the best practice of shared decision making.

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				The main challenge has, in fact, already been identified by NHS England on this web page: https://www.england.nhs.uk/shared-decision-making/how-to-make-shared-decision-making-happen/. It says that "Shared decision making requires shifts in culture and systems, prepared professionals and supported individuals". It goes on to say that "both professionals and patients need to become more collaborative in the way they relate to each other, giving each other mutual respect and acknowledging that both has an equal responsibility for making the 'right' decision". In this context, the NICE draft guideline on shared decision making is good. The rationale is strong, and the evidence underpinning the guideline is robust. This is a welcome contribution towards what NHS England identifies as the task of shifting systems and professional preparedness. The guideline is, however, just one piece of the jigsaw. It has to fit into a bigger picture of organisational and professional cultures, and of what NHS England describes as the need for "professionals and patients… to become more	

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				collaborative in the way they relate to each other". Here is where the challenge sharpens. 2. <u>Professional and organisational culture</u> A series of healthcare disasters in recent years has revealed a culture in medicine that is not always receptive to open and honest dialogue with patients. Ian Paterson actively misled thousands of patients, and was (eventually) jailed. But he was not a lone "bad apple". The inquiry report said "This report is not simply a story about a rogue surgeon… it is far worse. It is the story of a healthcare system which proved itself dysfunctional at almost every level when it came to keeping patients safe. Patients… complained to regulators and believed themselves frequently treated with disdain." The Cumberlege review (First Do No Harm) also revealed a healthcare system which failed many thousands of women - continuing to prescribe treatments and procedures even while patients protested about the harm that was being done. Cumberlege said "The issue here is not one of a	

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				single or a few rogue medical practitioners, or differences in regional practice. It is system-wide." Similar observations have emerged from official inquiries into large scale harm at Mid Staffordshre, Morecambe Bay, Southern Health, Cwm Taf and Shrewsbury & Telford. In 2019, the Chief Inspector of Hospitals, commenting on take-up of Learning from Deaths guidance said, "Issues such as fear of engaging with bereaved families, lack of staff training, and concerns about repercussions on professional careers, suggest that problems with the culture of organisations may be holding people back from making the progress needed". So NICE should not make the mistake of thinking that its (very welcome) new piece of the jigsaw will fit neatly into a receptive healthcare culture. Sadly, the prevailing professional and organisational cultures in healthcare have a tendency to treat patient engagement as an optional extra, to describe patient experience as "anecdotal evidence", and - when the chips are down - to go for cover-up and denial rather than truth-seeking.	

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				These are not empty assertions, nor do they represent an attack on healthcare professionals. Our comments are based on evidence from inquiries led by eminent figures - Sir Robert Francis, Bill Kirkup, Bishop James Jones, Baroness Cumberlege, Donna Ockenden. The Care Quality Commission's "Learning, Candour and Accountability" report has described "families who had to go to great lengths to get answers... who had their experiences denied and their motives questioned". These are uncomfortable truths. But if we want shared decision-making to work, we have to face the fact that there are system-wide problems in the culture of dialogue with patients. So how do we overcome this challenge? 3. Helping users overcome the challenge To have a good chance of succeeding, the NICE guideline on shared decision making needs to fall on fertile ground. NHS England is right to say that "professionals and patients need to become more collaborative". Patients should listen to and trust clinicians' expertise. But clinicians, in turn, have	

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				to recognise that patient experience carries its own validity and expertise. In the words of Baroness Cumberlege, patient experience "must no longer be considered anecdotal and weighted least in the hierarchy of evidence-based medicine". The prevailing culture, however, won't change on its own. To prepare the fertile ground for shared decision making, and for a receptive response to the NICE guideline, we must, as NHS England says, "achieve shifts in culture and systems". A good starting point would be for NHS leaders to model the behaviour that they want to see across the system. They need to show that they themselves take patient experience and engagement seriously. That it really matters to them. That they want to make it a visible part of their own organisational practice. That they want to play their part in helping to move it up the hierarchy of evidence-based medicine. It would also help if NHS leaders showed a willingness to work together on this. Cumberlege noted that "the healthcare system...is disjointed, siloed, unresponsive and defensive". Shared decision making is the opportunity to ensure that disasters such as	

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				primodos, valproate and mesh never happen again. But it relies on shared leadership at the national level. There are four ways that system leaders could model respect for patient experience and demonstrate shared leadership: • Parity of access. NHS staff should have the same access to patient experience evidence as they do to medical evidence. NICE could enable this by making patient experience evidence a dedicated part of its National Core Content. • Research prioritisation. No-one has a strategic overview of patient experience research, so time and money is wasted on duplicate studies while big gaps in the evidence base are ignored. NIHR could support a proper assessment of strengths and weaknesses in the patient experience evidence base. • Professional development. There is no qualification for patient experience work, and no consistent professional development. Health Education England could help to develop high quality accredited training for patient experience staff. • Analytics. NHS staff struggle to make sense of patient experience data. NHS England	

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				could support the development of more and better analytical tools to cut through the morass of data. These four strands would be important steps towards building a professional infrastructure for patient experience work. They would show that patient experience is not an optional extra, but a fundamental part of evidence-based practice. They would show that national organisations were prepared to take a lead on these matters, helping to break the fertile ground into which initiatives like the NICE guideline could be sown. We - the Patient Experience Library - are already working on all of this. We invite NICE to join us.	
Patient Information Forum	Draft Guideline	004	007	We suggest this line is edited to include health literacy, so it reads: 'shared decision making and health literacy across the organisation and system'. High-level leadership is required to embed health literacy and shared decision making across organisations. All organisations should have a health literacy strategy and strive to	Thank you. This guideline is about shared decision making, and whilst health literacy may be an important factor, it is not the focus of this guideline. Whilst we have not recommended this specifically, as far as health literacy and applies specifically to SDM, this is covered by the remit of the patient director, see recommendation 1.1.12 that states: "Organisations should ensure that knowledge, skills and confidence to support shared decision making are included in the induction, training and continuing professional development of all healthcare staff. This should include access

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				become health literacy friendly in all their interactions with patients and the public. Health literacy is fundamental to the success of shared decision making, it applies equally to the conduct of consultations, consultation skills and to the information provided to support decision making. Where digital tools are used to support shared decision making, the concept of digital health literacy should be used and equalities impact assessment carried out.	to clinical supervision". Health literacy resources are listed in the rationale section as an example of training.
Patient Information Forum	Draft Guideline	004	016	We suggest this line is edited to 'shared decision making and health literacy' Patients /public fulfilling these roles need training and support to do so.	Thank you. The remit of this guideline is shared decision making. Whilst we have not recommended this specifically, as far as health literacy and applies specifically to SDM, this is covered by the remit of the patient director, see recommendation 1.1.12 that states: "Organisations should ensure that knowledge, skills and confidence to support shared decision making are included in the induction, training and continuing professional development of all healthcare staff. This should include access to clinical supervision". Health literacy resources are listed in the rationale section as an example of training.
Patient Information Forum	Draft Guideline	004	017	We suggest this line is edited to' Identify 1 or more people, especially those from under-served populations'	Thank you. The committee thought this would be too prescriptive.

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				User champions are often expert patients who are well educated and not necessarily representative of the local population, equal opportunities and diversity and inclusion policies should apply when selecting user champions and appointments should be time limited.	
Patient Information Forum	Draft Guideline	005	013	We suggest this line is edited to 'Review how information systems might support shared decision making and carry out an equalities impact assessment of their use.' There is an overlay between health and digital literacy leaving some people doubly disadvantaged. Digital exclusion is a combination of access to technology and the skills and motivation to use it. It is important that the content of digital tools is health literate.	Thank you. The committee agreed that remote discussions should be considered and have also written a research recommendation that asks "How do SDM skills and techniques need to be modified for remote discussions?" They noted that remote discussions are not just limited to digital interventions, but can also cover telephone consultations which are less of a problem when it comes to digital literacy. The committee felt skills of SDM could be applied to remote settings as well as face to face settings, and this has been added to the rationale and also to a recommendation (1.2.2).
Patient Information Forum	Draft Guideline	005	016	Suggest inserting this sentence after the word 'consultation'. 'Information provided must meet recognised national quality standards for Health Information.'	Thank you for your comment. The committee added a reference to NICE quality standards in the rationale, but also acknowledged that other quality standards exist. Recommendation 1.2.4 now states "When providing information and resources, only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids."

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Patient Information Forum	Draft Guideline	005	027	Insert additional sentence, 'This is to include health literate consultation skills such as Chunk and Check and Teach Back techniques to check understanding and clarity of communication from HCP. See HEE Health Literacy Toolkit.'	Thank you for your comment. The committee agreed that "teach back" and "chunk and check" were important methods in delivering information and checking it had been understood. They agreed to add these methods as a way to implement existing recommendation 1.2.11
Patient Information Forum	Draft Guideline	006	003	Suggest this line reads 'Support shared decision making and health literacy'.	Thank you. This guideline is about shared decision making, and while health literacy is part of that, it is not the focus of the guideline.
Patient Information Forum	Draft Guideline	006	013	Suggest this line includes the BRAN method developed by the Academy of Medical Royal Colleges/ Choosing Wisely https://www.choosingwisely.co.uk/about-choosing-wisely-uk/ (In Wales. Making Choices Together) 'them using BRAN (Benefits, Risk, Alternatives, Nothing)'.	Thank you. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.
Patient Information Forum	Draft Guideline	006	028	Suggest this line is edited to 'appointment letters and notifications, EPAs, posters…'.	Thank you. We have expanded the examples.
Patient Information Forum	Draft Guideline	008	001	Insert this sentence after the word 'decision'. 'Information provided must meet recognised national quality standards for Health Information.'	Thank you for your comment, the committee agreed that providing information was important, but that the information needed to be of good quality. Examples of quality standards have been given in the rationale section.
Patient Information Forum	Draft Guideline	009	006	Insert, using 'Teach Back technique' after information:	Thank you for your comment. NICE has added clarification that "teach back" and "chunk and check" methods can be used in

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				People tend to say they understand when they don't. Use Teach Back technique to check understanding and put the onus on the healthcare professional checking they have explained clearly – i.e. so I can check I've explained your options clearly, what would you say to family and friends about your options	recommendation 1.2.11, to ensure understanding of information provided.
Patient Information Forum	Draft Guideline	009	019	Add the following to the end of this sentence 'Provide patient with a plain English Summary so they have a record of the decision to reflect on. Record decisions in personalised care plans and measure decision satisfaction.	Thank you for your comment. Please see recommendation 1.2.18: "Offer people resources in their preferred format to help them understand what was discussed and agreed."
Patient Information Forum	Draft Guideline	009	027	Insert this sentence after the NICE Guidelines. 'Information provided must meet recognised national quality standards for Health Information.'	Thank you. We believe this is covered in 'high-quality'.
Patient Information Forum	Draft Guideline	011	002	Insert additional bullet points: • Health literate Meets recognised quality standards for Health Information.	Thank you. These decisions are for NHS organisations when deciding what PDA access to provide.
Patient Information Forum	Draft Guideline	011	013	Add in Easy Read formats for people with learning disabilities.	The NHS Accessible Information Standard (SCCI 1605) mandates that all healthcare and adult social care providers must provide information in a format their patients can read. The recommendations consistently refer to ensuring people understand and receive information in their preferred format.

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Patient Information Forum	Draft Guideline	011	018	Add decision aids that meet quality standards for health information.	Thank you. The guideline specifies that PDAs should meet IPDAS standards.
Patient Information Forum	Draft Guideline	General	General	This piece of guidance is central to achieving PIF's long standing vision that everyone has access to personalised health information and support to enable them to make informed decisions about their health, wellbeing and care. There is much to welcome in the guideline, including the leadership role for shared decision making and the emphasis on consultation skills and risk communication. We have consulted our membership and member feedback has fallen into four key areas. These are summarised below and then discussed in more detail. (1) Health Literacy – we are extremely concerned that health literacy is not mentioned in this guideline. In PIF's view the availability of health literate information and support is crucial to the success of shared decision making and will contribute to tackling health inequality. This would have a major impact on practice.	Thank you for your comment. The committee acknowledged the us of pif-tick in the rationale and impact section: "Providing information is important, but the committee wanted to emphasise that it needs to be of good quality, for example NICE-accredited. The committee was aware that other quality standards exist, like the PIF TICK quality mark for patient organisations. There are also useful resources such as 'ask 3 questions' and other tools to help people prepare on the NHS England website." Regarding information quality, recommendation 1.2.4 now states: "When providing information and resources 1. only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids. 2. Take into account accessibility and the requirement to meet the NHS Accessible Information Standard. Regarding health literacy, recommendation 1.2.6 highlights some service users may need additional support, the reasons for support given were examples and this is not an exhaustive list. These have now been removed to make it clearer it is at the professional and service user's discretion regarding need for additional support. More significant health literacy needs would be an example of this.

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				(2) Information quality – while the guideline refers to IPDAS standards, it does not mention other information quality standards in place to ensure the range of information used to support shared decision making is fit for purpose. In an age of misinformation people need to know information can be trusted. (3) Long term conditions, personalised care plans, medical treatments: We are disappointed the guidance makes limited reference to personalised care and person-centred care as set out by NHS England and the Welsh Government. We would like to see much greater emphasis on the link between patient activation, personalised care and support and effective supported self-management in strengthening shared decision-making related to both medical and surgical treatment. (4) Digital consultation – We are concerned that much of the guidance is focused on face-to-face consultation skills while care is increasingly delivered in a virtual setting. We are also concerned how information is provided in virtual settings	The recommendations consistently refer to ensuring people understand and receive information in their preferred format. Please see for example recommendations 1.2.4, 1.2.5, 1.2.18. . The committee agreed that remote discussions should be considered and have also written a research recommendation that asks "How do SDM skills and techniques need to be modified for remote discussions?" They noted that remote discussions are not just limited to digital interventions, but can also cover telephone consultations which are less of a problem when it comes to digital literacy. The committee felt skills of SDM could be applied to remote settings as well as face to face settings, and this has been added to the rationale and also to a recommendation (1.2.2).

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				and about the impact of digital exclusion. Addressing these concerns will help realise the ambition of the Cumberlege report, First Do No Harm, published in 2020. *'No longer can informed patient consent be anything other than a true equality of partnership in the decision-making process between patients and their treating physicians. Their care and treatment should not be a series of events that happened to them. Rather, every patient should be able to stand back, look at their patient journey and say, 'I recognise my handwriting all over those choices.'* (1) Health literacy "Health literacy refers to the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about health." World Health Organization. Some definitions of health literacy remove the	

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				responsibility from the citizen to the healthcare system. "Health literacy occurs when a society provides accurate health information and services that people can easily find, understand and use to inform their decisions and actions." US Department of Health and Human Services. The NHS website has taken this approach and we endorse the style guide which matches UK information skills. UK information skills 9 years old is average reading age (ONS) Up to 1 million people cannot speak English well or at all (ONS) 50% of the population are at or below primary school numeracy level (DBSI) What this means in practice Many working age adults lack skills to understand and use health information. This gap between skills and the complexity of health information leaves millions of people unable to make informed decisions about health. 5 million adults cannot find data in standard health information.	

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				1.7 million are unable to explain symptoms and feelings over the phone 6.5 million cannot measure or record weight on a chart (Rowlands et al 2015) PIF's 2015 market research demonstrated the impact on shared decision-making for people with long term conditions: ● 32% of adults found it hard to find general health information on their condition ● 20% lacked understandable information to support them in having a meaningful conversation with their doctor In October 2020, PIF published the results of a survey on action on health and digital literacy. 175 cross-sector health organisations operating in the UK responded, including NHS trusts, patient groups and the voluntary and private sectors. Headline findings included ● The biggest perceived impact of low	

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				health literacy was people's lack of control over their own health (90%). ● 87% felt low health literacy led to difficulties in taking part in shared decision-making. ● 86% felt it led to problems communicating with healthcare professionals. ● Only 13% of respondents said their organisation had a health literacy strategy in place. This represented little progress from 10% in 2013. 12% said their organisation was in the process of developing a strategy. ● The biggest perceived barrier to producing health information to address low health literacy was limited understanding of how to develop resources or services (73%). ● 67% believed NICE (National Institute for Health and Care Excellence) guidelines would help support quality improvement. ● The policy area of the NHS Long Term Plan perceived to be most affected by	

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				health literacy was health inequalities (89%). The report, authored by an expert panel, made a series of recommendations: Those relevant to this guideline are listed below, and are repeated in reference to this draft guideline. 1 Organisations producing health information should aspire to become 'health-literacy-friendly.' *Health-literacy friendly organisations make it easier for people to navigate, understand, and use information and services to take care of their health. They:* • *Use clear communication (verbal, written, digital).* • *Create easy to use digital tools/websites, printed information and premises.* • *Involve people in the development of information as routine and invite feedback.* • *Train staff in health literacy.*	

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				Recommendation 2 NICE Develop guidelines on health and digital literacy to drive change and provide an evidence base. Ensure health and digital literacy is recognised in new and updated guidelines, with particular reference to shared decision-making. Recommendation 4. Shared decision-making Require the provision of 'health-literacy friendly' patient information (that conforms to standards) in planned national standards and guidelines on shared decision-making. Recommendation 7 NHS repository for health literate and translated information Create a central NHS repository for health literate information in English and other commonly spoken languages to reduce health inequality. This recommendation is made in relation to material to support shared decision-making, including formal decision aids. Information added to a central repository must meet recognised standards for health information.	

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				Recommendation 10. Equalities impact of digital tools All organisations should implement the Accessible Information Standard and, when developing digital projects, consider other reasons for digital exclusion and equalities impact including access, skills and motivation. We have made recommendations line by line where we think health literacy should be referenced in this document. In particular we recommend the leadership role for shared decision making should also encompass health literacy. High-level leadership is required to embed health literacy and shared decision making across organisations as demonstrated by our survey finding that very few organisations have a health literacy strategy in place. The draft guideline does not make it clear how high-level leadership will be monitored. We recommend a regular patient survey at service level with specific questions on SDM, whether people are given the opportunity to discuss what matters to them, what they think of information and their access to it. This could be a role for Healthwatch or PALS.	

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				In 2017, PIF and the Community Health and Learning Foundation developed a framework for the development of health literate decision support resources for NHSE. This emphasised the need to involve users throughout the development of information resources to ensure they meet users' needs and concerns. It also emphasised the requirement to train staff to use these tools effectively. PIF has since launched a Health Information Quality Scheme, the PIF TICK, which embeds the principles of co-production. (2) Information quality – while the guideline refers to IPDAS standards, it does not mention other information quality standards. Including: • The NHSE Information Quality Standard Unassessed • The Patient Information Forum's Trusted Information Creator Quality Mark (PIF TICK) – Assessed • The Health on the Net Foundation HON Code – Unassessed. • Orcha Standards for Health Apps - Assessed	

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				It should be recognised that information to support shared decision-making comes from a wide variety of sources. There are some excellent resources available but many are of variable quality and local provision is inconsistent. Some Trusts make considerable investment in information quality and have joined the PIF TICK scheme. PIF members have recently raised concern that information developed by HCPs at the local level intended to support shared decision making has included increasingly complex medical evidence as a result of new GMC guidance on consent. In some instances, it has made information unusable to many patients. This also seems to demonstrate a confusion between shared decision-making and consent. Evidence-base is a crucial element of information quality but it is only one element. The PIF TICK criteria cover 10 information quality domains, designed to ensure information is accurate, meets people's needs and is health literate. The PIF TICK criteria were co-created by an expert advisory group representing leading health organisations in the public, private and charity sector. 60 organisations have now joined the scheme..	

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				In summary the 10 criteria for trustworthy health information are: 1. Information is created using a consistent and documented process. 2. Staff are trained and supported to produce high-quality information. 3. Information meets an identified consumer need. 4. Information is based on reliable, up-to-date evidence, with clear benefit/risk communication. 5. Patients are involved in the development of health information. 6. Information is health and digital literate. 7. Print and digital information is accessible, easy to use and navigate. 8. Feedback on information is proactively sought from users. 9. Information is promoted to make sure it reaches those who need it. 10. The impact of information is measured on an ongoing basis.	

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				Consumer research by PIF found the top-rated criteria for health information by members of the public were criteria 4, 6 and 2. 80% of people said they would look for a quality mark on health information. PIF recommends that wider measures of information quality are required for the material to support shared decision making and should be a qualification of entry to a central repository of Decision Support Resources. In particular, co-production should be key criteria in the development of decision support tools. This is essential to ensure they meet the needs of the user. Users involved in co-production should represent those at risk of health inequality from a range of communities. The repository should include translated materials, avoiding the need for costly translation at a local level. (3) Long term conditions, personalised care plans, medical treatments: We are disappointed the guidance makes limited reference to personalised care and person-centred care as set out by NHS England and the Welsh Government. We would like to see much greater emphasis on the link between patient activation, personalised care and support and effective supported self-management in	

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				strengthening shared decision-making related to both medical and surgical treatment. It should be made explicit that shared decision-making covers both surgical and medical treatments and the importance of this to personalised care, particularly for those with long term conditions. Too often we see shared decision making referred to in the context of a single surgical episode only, rather than medical treatments for life-long conditions. Patients need information to make the right medication choice, otherwise the consequences can be devastating. The findings of the Cumberlege report, First Do No Harm on the use of sodium valproate by pregnant women with epilepsy make this clear. Decision support is needed in long term conditions with a range of options available. A good practice example is MS Decisions. Some Trusts have embedded this tool in care pathways. Epilepsy Action is working with Cochrane on the development of tool to support shared decision-making. PIF would like to see tools like this added to a national repository of decision support tools to	

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				improve the quality and consistency of decision support provided to patients. We believe that shared decision making should be built into the procurement process. The success of introducing new drugs or switching them should be based on a range of measures including how well SDM was realised. We are concerned that the guidance does not make the link between patient activation, personalised care and support planning and effective supported self-management in strengthening shared decision making. We would like to see specific references to all three and how they support each other. We would like to see decisions recorded in an individual's personalised care plan. The role of peer support and experience in making life changing surgical decision is crucial. For example, the IBD Standards recommends patients with IBD considering surgery should be provided with information in a format and language they can easily understand to support shared decision-making and informed consent.	

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				Gathering patient reported outcomes on treatments can also support patients to make meaningful decisions. Recording decision satisfaction would be a useful patient reported outcome measure to assess the success of shared decision-making in practice. Patient education and self-management courses should include SDM and the option of training in decision making tools. This should be made routinely and regularly available. Other questions patients may have but not fully covered by the guidance: ○ I'm not happy with the decision what can I do next? ○ What if I don't want to change the drug/service/X? ○ What if things go wrong/medicines don't work/people experience pain - how do you revisit this decision? ○ Who do I complain to? These could be dealt with by the high-level leadership role and the body tasked with scrutiny.	

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				(4) Digital consultation – We are concerned that much of the guidance is focused on face-to-face consultation skills while care is increasingly delivered in a virtual setting. We are also concerned how information is provided in virtual settings and about the impact of digital exclusion. 9 million people are unable to use digital tools unaided. (Digital Consumer Index 2020). We have recommended that health literate consultations skills such as 'teach back' and 'chunk and check' are used to check understanding in both face-to-face and virtual consultations. All organisations should implement the Accessible Information Standard and, when developing digital projects, consider other reasons for digital exclusion and equalities impact including access, skills and motivation.	
Personalised Care Institute	Draft Guideline	001	005	Question: Who is it for – The target group should include young people who are competent to give consent, and not defined solely by age.	Thank you. People under 18 are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents) However, please note that NICE is currently developing a guideline on patient experience of healthcare for babies, children and young people, which considers shared decision making. Please see

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					https://www.nice.org.uk/guidance/indevelopment/gid-ng10119 for information on the development of this guideline
Personalised Care Institute	Draft Guideline	004	006	Clarification: Leadership and influence are positive factors in sharing good practice – adding 'accountability' at the organisational level, might have negative connotations and will be difficult to define in terms of the extent of responsibility.	Thank you. The committee was clear that someone at the highest level of the organisation needed to be accountable for the implementation of SDM.
Personalised Care Institute	Draft Guideline	005	010	Comment: Does this specific role create an impression that SDM is an 'add-on' to training, rather than a central and core capability? All educators and trainers should acquire these skills.	Thank you for your comment. As this guideline is specific to SDM it focuses on best ways to plan and implement shared decision-making, and recommendation 1.1.6 is suggesting using existing good practice and the individuals performing it to help implement SDM by assigning them a specific role, this does not mean SDM should be seen as separate from other central and core skills.
Personalised Care Institute	Draft Guideline	006	012	Comment: This assumes that an assessment has been made of patient 'activation', beyond sharing information.	Thank you for your comment. This recommendation is discussing training of practitioners and is not recommended at a specific point in the shared decision making process. For recommendations at various stages of discussions see section 1.2. Ensuring patients actively partake in decision making is included in recommendation 1.2.6, 1.2.8, and 1.2.9
Personalised Care Institute	Draft Guideline	006	015	Suggestion: This phrase is rather idiomatic and might not be useful - ? 'engaging with people in order to elicit what is important to them'	Thank you. We have changed the wording to "encouraging people to talk about what is important to them".

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Personalised Care Institute	Draft Guideline	007	018	Comment: Recommending resources prior to appointments is more difficult in a 'front door' specialty / profession with undifferentiated clinical presentation when decisions are often needed at first contact.	Thank you. The committee agree. In some situations it may be just information about shared decision making, but in ongoing cases, specific information could also be provided.
Personalised Care Institute	Draft Guideline	008	016	Comment: An overly-structured approach is often impractical except for clearly pre-defined clinical contacts. The agenda might not be initially explicit to either doctor or patient, but elicited through the consultation; several problems can be presented and stipulating a time length can be damaging to the conversation – consultations often rely on flexibility and judgement.	Thank you. The purpose of the recommendation is to prioritise what the person wants to talk about. In most parts of the NHS appointment times are fixed and the committee agreed it was useful to be clear about that.
Personalised Care Institute	Draft Guideline	009	012	Clarification: This includes the right to make a technically 'unwise' decision	Thank you for your comment. Recommendation 1.2.13 states: "Accept and acknowledge that people may vary in their views about the balance of risks, benefits and consequences of treatments, and that they may differ from those of their healthcare professionals." And the committee feels this covers decisions the healthcare professional judges as "technically unwise".
Personalised Care Institute	Draft Guideline	011	002	Additional criterion: … and relevant for the individual eg. In context of culture and language.	The NHS Accessible Information Standard (SCCI 1605) mandates that all healthcare and adult social care providers must provide information in a format their patients can read. The recommendations consistently refer to ensuring people understand and receive information in their preferred format. Please see for example recommendations 1.2.4, 1.2.5, 1.2.18.

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Personalised Care Institute	Draft Guideline	012	002	Comment: Where practical, this should not be a delegated responsibility eg. asking colleagues to explain another's rationale.	Thank you for your comment. Recommendation 1.4.3 does not refer to delegation and recommends that staff presenting information about risks, benefits and consequences to people have a good understanding of that information and how to apply and explain it clearly.
Personalised Care Institute	Draft Guideline	012	011	Comment: Extreme caution should be exercised if using any promotional or sponsored resource.	Thank you for your comment.
Personalised Care Institute	Draft Guideline	015	002	Suggested addition: 'What interventions and behaviours are most effective'…	Thank you for your comment. A behaviour change in this context would fall under the definition of "intervention".
Personalised Care Institute	Draft Guideline	015	007	Suggested alternative wording: …. In populations where a power imbalance exists between professionals and the users of healthcare. (It can work both ways – authoritarian or consumer driven)	Thank you for your comment. Evidence review A identified paternalistic decision making as a key barrier to shared decision-making, as well as patient empowerment and patient's capability to participate being linked to certain cultural/social factors. This is where this research recommendation is sourced from.
Personalised Care Institute	Draft Guideline	General	General	There could be greater emphasis on the importance of developing relationship-building skills as a necessary pre-cursor to shared decision-making	Thank you. The committee did not consider any evidence that supported this.
Personalised Care Institute	Draft Guideline	General	General	From the perspective of 'Personalised Care' it would be helpful to give more details on the place of shared decision-making as part of broader approach including 'patient activation', health literacy, personalised care and support planning, and supported self-management	Thank you. This guideline is about shared decision making. It considered evidence about the effects of patient activation and health literacy on shared decision making - please see evidence review B in the project documents (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents). It is outside NICEs remit to specify what should be included in pre-registration training.

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Polycystic Kidney Disease Charity	Draft Guideline	004	005	We welcome the recommendation make a board member or equivalent responsible for shared decision making	Thank you for your support.
Polycystic Kidney Disease Charity	Draft Guideline	004	008	We welcome the recommendation to consider appointing a patient director and would recommend that nationally agreed terms of reference will be developed for this role to be published on the NICE site and widely disseminated	Thank you for your support. It is beyond the remit of NICE guideline to set out the terms of reference for any such role.
Polycystic Kidney Disease Charity	Draft Guideline	005	004	We recommend that 'existing good practice' be identified from both inside and outside the organisation. Resources undoubtedly exist. Sites such as https://fabnhsstuff.net/ have a library of best practice that could be searched for example.	Thank you for your comment. The committee felt "existing good practice" would be quite specific to each organisation and team and did not want to recommend specific sources or repositories.
Polycystic Kidney Disease Charity	Draft Guideline	005	020	We weren't sure what this recommendation means in practice for service users.	Thank you for your comment. Due to differing organisational structures and process the implementation of SDM will be different in each organisation. This guideline provides the requirements for ensuring that SDM happens but how it is implemented is for individual organisations to agree. This recommendation has now been clarified (1.1.8).
Polycystic Kidney Disease Charity	Draft Guideline	006	028, 029, 030	NB: These link with the comment below in row 7. The 'three questions' are different from the 'Ask 3 Questions' approach already used by many NHS organisations, ie: What are my choices? What is good and bad about each choice? How do I get support to help me make a	Thank you for your comment. The committee felt that the three questions within the recommendation are substantially the same as the three questions in the ask three questions tool.

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				decision that is right for me? It's not clear why NICE is recommending 3 different questions and not continuing with the 'Ask 3 Questions'.	
Polycystic Kidney Disease Charity	Draft Guideline	007	001	Links to row 6 above.	Thank you.
Polycystic Kidney Disease Charity	Draft Guideline	010	006	We are disappointed that the guideline does not include recommendations for additional support such as known, trusted charities or patient support groups.	Thank you. The committee considered that these might be 'suitable alternatives' as set out in the recommendation.
Polycystic Kidney Disease Charity	Draft Guideline	010	015	In 2012/13, a considerable amount of money was spent developing Right Care Patient Decision Aids for Established Renal Failure. They were considered poor by many and mothballed. We hope that more thought is put into the production of new Decision Aids in the future.	Thank you for your comment.
Polycystic Kidney Disease Charity	Draft Guideline	012	008	We welcome the guideline's approach to communicating risks, benefits and consequences using more modern, personalised and lay-friendly numerical methods such as pictograms, absolute risk etc.	Thank you for your comment.
Polycystic Kidney Disease Charity	Draft Guideline	General	General	We welcome the guideline in general.	Thank you for your support.

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Polycystic Kidney Disease Charity	Draft Guideline	General	General	Now that many appointments are delivered virtually, we would like to see recommendations for implementing shared decision making in these types of appointments. This could also be a recommendation for research.	Thank you for your comment. The skills of SDM in remote settings are the same as in face-to-face settings, and this has been added to the rationale and to a recommendation.
Psoriasis and Psoriatic Arthritis Alliance	Draft Guideline	007	008	Perhaps the addition of remote consultations or home settings should now be included. This perhaps could also be a research recommendation, about whether there is a detriment or benefit with remote care.	Thank you for your comment. The skills of SDM in remote settings are the same as in face to face settings, and this has been added to the rationale and to a recommendation. The committee acknowledged the changing situation with an increased reliance on remote discussions, but felt more evidence was needed to make a specific recommendation, and thus a research recommendation has been added to look at evidence for remote discussions.
Psoriasis and Psoriatic Arthritis Alliance	Draft Guideline	007	019	Preferred format. Slight concern that booklet and flyer might not be generally available in print form, as currently these are often unavailable, and potentially in future will force people towards electronic documents only, which may not be their preferred format, therefore causing some inequality of access.	Thank you. This is a risk, however it is beyond the remit of this guideline.
Psoriasis and Psoriatic Arthritis Alliance	Draft Guideline	008	003	Links to NICE resource, again may not be in an appropriate format or easily accessible.	Thank you for your comment. We have clarified that linked resources should "take into account accessibility and the requirement to meet the NHS Accessible Information Standard" and to "only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids."
Psoriasis and Psoriatic	Draft Guideline	008	005	Good to see consideration of provision for those who may have access issues, perhaps this	Thank you. We have changed the order of the recommendations.

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Arthritis Alliance				should be given higher priority in the guidance and made the first point of this section. I accept that perhaps this is not an order of priority list, but it feels that it is the lowest consideration. Assessing users need and access, would feel more appropriate as an initial opening phrase in 1.2.4.	
Psoriasis and Psoriatic Arthritis Alliance	Draft Guideline	008	016	It's implied in the title of the document, but in practice perhaps stating that it's a partnership between care provider and patient [person with condition], might be helpful, as it still feels a little like a 'directive'. Not sure people will fully understand making a choice about care, versus selecting an option offered.	Thank you for your comment. This has been defined in the "terms used in this guideline" section. The committee did not use the word partnership and agreed to use the following definition for shared decision making 'a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care'.
Psoriasis and Psoriatic Arthritis Alliance	Draft Guideline	009	014	Perhaps give greater emphasise that the person is able to control the decision about a care plan and that if an offers is made and 'declined' that is not recorded as being anti-care, but an informed choice. Our experience is that people feel seeking time to think about care or delay starting care, may be seen as lack of confidence in the provider and the offer will be removed in future or affect future offers of care (difficult patient/time waster etc.)	Thank you. Recommendation 1.2.10 states "openly discuss the risks, benefits and consequences of each option, making sure the person knows this includes choosing no treatment, or no change to what they are currently doing" and we hope this clarifies that these actions are not "anti-care" but a normal part of the SDM process and recorded as such.
Psoriasis and Psoriatic Arthritis Alliance	Draft Guideline	012	002	As mentioned above, it would be nice to see the word 'partnership' included within this statement, partnership implies greater responsibility of equal status, shared care still feels a little 'top down' where the provider still holds the options of what is offered. I accept that there are	Thank you for your comment. The committee did not use the word partnership and agreed to use the following definition for shared decision making 'a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care'.

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				constraints of NHS supply, but talking to people about shared care when the only offer is what has previously been decided to be available, is not choice, just selection.	
Psoriasis and Psoriatic Arthritis Alliance	Draft Guideline	012	008	Good to see this section, really important to understand absolute risk and benefit.	Thank you for your comment.
Reaching People	Draft Guideline	001	011	Who is it for: Adults (aged 18 and over) using … we suggest adding and any VCSEs supporting them	Thank you. This is detailed in the scope (section 3.1) "Adults (aged 18 years and over) using healthcare services, and their families, carers and advocates if they choose to involve them" We have also added “voluntary, community and social enterprise organisations” to the list of groups this guideline may be relevant for on page 1.
Reaching People	Draft Guideline	001	012	It may also be relevant for: add VCSE (Voluntary, community and social enterprise) organisations	Thank you for your comment, these organisations were added to the "who is it for" section of the guideline. We have also added “voluntary, community and social enterprise organisations” to the list of groups this guideline may be relevant for on page 1.
Reaching People	Draft Guideline	004	General	We welcome and endorse the need for organisational and system approaches. You suggest it is a Board Member where there is a Board or a senior leadership team member. We suggest, and also a senior leadership team member to support operational delivery.	Thank you. The wording of this recommendation has changed from “board member” to “senior leader” and specified that “This should be a board member or, if the organisation does not have a board, a leader at the highest level of the organisation.”

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Reaching People	Draft Guideline	005	028	Is there an existing network, how is good practice to be shared	Thank you. NICE is unaware of any of these networks that might exist. Good practice would be shared by joining up networks as suggested in the recommendation.
Reaching People	Draft Guideline	006	008	There is no indication of why the three talk model is recommended in the main text. It would be useful to summarise why it is for readers. Particularly as we note that it is not uncontested/universal, Hanna Bomhof-Roordink et al. BMJ Open 2019;9:e031763	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.
Reaching People	Draft Guideline	006	009	Teachback, is a well- tested and effective tool used in improving practitioner's health literacy practice so that they can be sure patients have understood the discussions and are able to appraise and to act /make decisions on such discussions. We suggest adoption of this use of this technique would support delivery of these aspects of SDM. There are multiple references including Shersher, V., Haines, T. P., Sturgiss, L., Weller, C., & Williams, C. (2020). Definitions and use of the teach-back method in healthcare consultations with patients: A systematic review and thematic synthesis. Patient Education and Counselling, 104(1), 118-129.	Thank you for your comment. NICE has added clarification that "teach back" and "chunk and check" methods can be used in recommendation 1.2.11, to ensure understanding of information provided.
Reaching People	Draft Guideline	006	018	Health Literacy Train the trainer training commissioned by HEE and NHSE and delivered by the former CHLF now owned by Reaching people provides a useful model which could support SDM	Thank you. This guideline is not about health literacy, however the committee have added a mention of the resources to the rationale and impact section of the guideline.

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Reaching People	Draft Guideline	006	022	Health literacy Awareness training commissioned by HEE and NHSE and delivered by the former CHLF now owned by Reaching people provides a useful model which could support SDM	Thank you. This guideline is not about health literacy, however the committee have added a mention of the resources to the rationale and impact section of the guideline.
Reaching People	Draft Guideline	006	023	We welcome the recommendation that people should be actively encouraged to ask questions to support SDM. The suggestion of providing 'training' for people seems heavy- handed and discordant with what is proposed as a partnership. Education and support to enable people to participate effectively is suggested as a more appropriate approach. As part of this, we welcome the questions proposed, which seem to be an adaptation of "Ask me three" a well-used and tested technique. There are many examples of use of this including by some of your expert witness but explicit recognition/promotion of it would enable practitioners to consult references for it such as Miller, M. J., Abrams, M. A., Barbara, M., Cantrell, M. A., Dossett, C. D., McCleeary, E. M., ... & Sager, E. R. (2008). Promoting health communication between the community-dwelling well-elderly and pharmacists: The Ask Me 3 program. Journal of the American Pharmacists Association, 48(6), 784-792. Lapiz-Bluhm, M. D., Weems, R., Rendon, R., & Perez, G. L. (2015). Promoting health literacy through "Ask me 3.". JNPARR, 5, 31-37.	Thank you. Offering training is given as an example, and the committee felt that offering training to service users is fair and balanced if you are offering training to healthcare professionals, and helps to create a collaborative space with service users and healthcare professionals on an equal footing. Both need to be involved in SDM.

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Reaching People	Draft Guideline	007	018	We welcome this but suggest also making the patient aware of local or national organisations/resources who might provide support or information, including local or national VCSEs	Thank you. We agree this is an example of what could be done.
Reaching People	Draft Guideline	008	005	Suggest wording could be perceived as pejorative/value laden, we recommend replacing with a statement that there are a number of reasons people might find it more difficult to share in decision making, for example...	Thank you. NICE recommendations are active rather than informational. We have reworded this to make clearer the committees intent.
Reaching People	Draft Guideline	008	037	We suggest RCTs/systematic reviews of RCTS to narrow a search for evidence in this field and clearly unlikely to yield results given the nature of this issue. As NICE has previously done with Public health guidance it needs to access a wider range of research evidence recognising the limitations of RCTs as a source of evidence in this context	Thank you. NICE identified substantial numbers of RCTs in this area and therefore prioritised this gold-standard methodology.
Reaching People	Draft Guideline	009	020	Ensure that notes are written in a way that complies with good practice in producing written information	Thank you. The content of medical notes is beyond the remit of this guideline.
Reaching People	Draft Guideline	010	015	Resources as well as decision aids should be evidence based and up to date. Include reference to NHS website	Thank you for your comment. Please see recommendation 1.2.4 where we have added "When providing information and resources: only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids."

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Reaching People	Draft Guideline	012	008	We suggest practitioner's attention is drawn to the high levels of adults who have difficulty with understanding and using numerical information and tailor discussions accordingly.	Thank you for your comment. The recommendations suggest using a mixture of both numerical and pictorial formats, and to be aware that risk may be interpreted differently depending on the service user.
Reaching People	Draft Guideline	016	005	We welcome the use of qualitative evidence but a summary of what it found /contributed here would be helpful	Thank you for your comment, a summary of the qualitative evidence can be found in evidence review A
Reaching People	Draft Guideline	016	018	We welcome the committee's proposals for ways of ensuring patients influence the SDM process at the highest level but suggest that other ways of engaging patients should also be explored and adopted e.g., patient participation groups, patient consultation, and experience surveys, and focus groups	Thank you for your comment. Monitoring and feedback, including service-user feedback, is covered in recommendation 1.1.9: "Plan internal or external monitoring and evaluation (including service user and staff feedback activities) and how to feed back the results to staff at individual, team and management level." This rationale and impact section is specifically focusing on embedding SDM at the highest level. The methods you mentioned could be potential ways of collecting service user feedback under 1.1.9
Reaching People	Draft Guideline	016	024	Whilst recognising that digital technology can be used to support SDM its is essential to recognise that in SDM as elsewhere it can also result in further inequalities and exclusion if this possibility is not recognised and explicitly addressed	Thank you for your comment. Recommendation 1.2.5 stated that resources should be offered to service users in their preferred format, including if this is non-digital. This also extends to 1.2.18 for post-appointment materials.
Reaching People	Draft Guideline	017	003	. The Muscat 2019 study which is referenced, used the English national Skilled for Health Resources. However, there is no reference/ signposting to the Skilled for Health resources currently hosted on the Reaching People website. https://www.reachingpeople.co.uk/training-consultancy/training-resources/	Thank you for this information.

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				Reaching People in agreement with NHS England, Public Health England and the Department for Education have been asked to host the national Skilled for Health resources temporarily whilst a long-term solution is discussed and agreed. These evidence-based resources were co-produced and extensively tested by the Department of Health, the Department for Education, and the learning charity ContinYou, the predecessor body, of the Community Health and Learning Foundation as part of a national partnership. An external evaluation of the resources showed they improved people's skills, knowledge, and confidence about their health as well as their language, literacy, and numeracy. They were subsequently updated and tested again by CHLF via funding from NHS England and the Department for Education. They are available and may be accessed and used freely. Training on their use and on Health literacy developed by the former CHLF can be accessed via Reaching People and their website as noted above.	
Reaching People	Draft Guideline	017	024	We Suggest excellent and health literate communications as the latter can be defined and has standards which can be measured and applied consistently	Thank you for your comment. Shared decision making has other facets beyond health-literate communications thus the wider term has been employed here.

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Reaching People	Draft Guideline	018	024	This fails to acknowledge the role and contribution of VCSE organisations as sources of professional information advocacy and support to which patients can be signposted or may choose to access. It suggests professional support is the gift of the health care system. The implication of this decision as elsewhere emphasises SDM as something given to patients by the system.	Thank you. Patient organisations have been added into the relevant recommendations.
Reaching People	Draft Guideline	024	006	The studies mentioned here describe teach back as a patient activity done by the patient to the practitioner. We would suggest that this is recognised as an outcome of good health literacy practice by the provider to facilitate this. It should be recognised as the responsibility of the provider to ensure that their communication enables the patient to do this.	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.
Reaching People	Draft Guideline	General	General	Whilst we welcome the recognition that Health Literacy is a fundamental component of Shared Decision Making, we are concerned that the work reviews evidence and makes recommendations consistently on the basis that health literacy is applicable only to patients/clients. However, the WHO adopted a definition of health literacy in 2015 which makes it clear that health literacy is a two-way process. It is" the personal characteristics and social resources needed for individuals and communities to access, understand, appraise	Thank you. Improving health literacy is beyond the remit of this guideline, however we believe that recommendations 1.4.1 to 1.4.4 cover the points you raise in the context of SDM.

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				and use information and services to make decisions about health". This definition highlights that Health literacy is a two- way process; practitioners need to adopt health literate good practice, tailoring the message to their client. We are concerned that without explicit two way action to improve health literacy of practitioners and people SDM cannot be successful. Evidence suggests that there is a significant gap between the levels at which information is produced and the literacy and numeracy of the population. This approach to health literacy may contribute to or why the guidance also appears to be transactional rather than relational and comes across as top down rather than partnership focused. An approach suggesting a one way process of giving the patient information which we suggest is incompatible with a process defined as 'shared' which requires working in partnership. Moreover, it needs to be recognized that there are a number of risk factors which increase the risk of low health literacy and that these are common to the experience of health inequalities more widely and also impact on SDM for example experiencing social disadvantage BAME, Long term conditions or disabilities. These challenges need to be recognized in embedding SDM	

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Reaching People	Draft Guideline	General	General	We welcome the recommendation that patient decision aids should be evidence based and up to date. We suggest that the role of other resources used to support the process should also be promoted and subject to this quality check.	Thank you for your comment: Recommendation 1.2.4 now states: "only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids." To cover other resources. This is beyond the remit of NICE and of this guideline.
Reaching People	Evidence Review A	General	General	Whilst we welcome this evidence review as collating useful information it disappointingly only looks at work done to improve the health literacy of patients (generally those with low health literacy). Failure to understand and use the WHO definition of health literacy which supports the principles of SDM provides a barrier to implementation. Even the only reference to 'teach back' recognised as an effective method for practitioners to check the effectiveness of their communication with patients by asking them to explain it, uses a study which sees it as a test of patients.	Thank you for your comment. This wider definition of health literacy is covered in other areas of the evidence reviews, for example the qualitative aspect of evidence review A, looking at the barriers and facilitators of SDM including patient empowerment. Access to information at both an organisational level and individual level is also discussed in evidence review E.
Reaching People	Evidence review B	General	General	Whilst we welcome the recognition that Health Literacy is a fundamental component of Shared Decision Making, we are concerned that the work frames health literacy as an intervention aimed solely at improving patient's literacy. It frames it as an intervention addressing a patient deficit.	Thank you for your comment. The nature of SDM as a two way process is discussed in detail throughout the guideline, including the importance of clinician attitudes and skills and their responsibilities in the SDM process. Whether an intervention was aimed at a patient or practitioner was taken into account as part of the review process (see evidence review A and particularly the qualitative analysis).

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				However, the WHO adopted a definition of health literacy in 2015 which makes it clear that health literacy is a two-way process. It is" the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about health". This definition highlights that Health literacy is a two way process; practitioners have a responsibility to adopt health literate good practice tailoring the message and format to their client . This is fundamental to embedding SDM	
Reaching People	Evidence review C	General	General	We suggest that Patient decision aids need to be checked for their readability and to be health literate.	Thank you for your comment. Recommendation 1.3.4 states that staff have access to quality-assured patient decision aids (assessed against the International Patient Decision Aid Standards)
Reaching People	Evidence Review D	General	General	We note that understanding and making decisions which require an understanding of risk requires a high level of health literacy, but this review contains no reference to health literacy even though action to support improvement in both patients and practitioner's health literacy in this is a necessary basis for understanding and participation.	Thank you for your comment. The recommendations cover both the patient's and practitioners "understanding" of the resources provided is considered. This is also covered in other sections of the recommendations outside of the risk communication section.
Reaching People	Evidence Review E	General	General	We welcome the range of evidence considered in the review and the recognition of the contribution of qualitative research and of expert witnesses,	Thank you for your comment. The recommendations cover both the patient's and practitioners "understanding" of the information/resources provided is considered.

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				In this context we are disappointed that the key role of tools and techniques demonstrated to improve health literacy in both practitioners and people is not recognised. We suggest that both are fundamental building blocks of effective SDM	
Reaching People	General	General	General	Question3 Understanding of Health Literacy as defined by the WHO; a two-way process, which is the responsibility of both individuals and practitioners and thus a fundamental building block for SDM not just an intervention aimed at a perceived deficit in patients. Access to and use of health literacy resources for professionals and people. For example, Health Education England website-hee.nhs.uk training and resources Health literacy Toolkit. Skilled for Health resources on Reaching People website https://www.reachingpeople.co.uk/training-consultancy/training-resources/ Health Literacy UK website https://www.healthliteracy.org.uk/	Thank you for your comment.
Resuscitation Council UK	Draft Guideline	004	010	We would have liked to see consistent use of plain English throughout this guideline. This bullet point is an example of wording in which the use of plain English could make it more likely to be read, understood and implemented	Thank youfor your comment, we have edited the wording of recommendation 1.1.2 to clarify the meaning.

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Resuscitation Council UK	Draft Guideline	006	009–010	We endorse this bullet point and hope that the same principle can be applied to the wording of all NICE guidelines, including this one, as we suggested in our previous comment.	Thank you for your comment.
Resuscitation Council UK	Draft Guideline	007	003–005	We are uncertain what "interventions" are being recommended here and would like to see more specific wording to make this clear.	Thank you. The committee wanted to leave the interventions broad as they are wide ranging. Specific interventions are mentioned in the subsequent recommendations in the section.
Resuscitation Council UK	Draft Guideline	007-008	018–020 001–004	It is not always appropriate to offer people "resources" before an appointment, so we suggest that this recommendation needs qualifying. There will be many instances where an appointment will involve initially informing and explaining to a person about a new diagnosis or new development in their condition, and many others in which discussion of the options for care and treatment requires firstly achievement of a shared understanding between the person and their healthcare professionals about their condition and the ways in which it may affect them. Achieving a shared understanding in this way is an essential prerequisite to then discussing options for their care and treatment to allow proper shared decision making. We would like to see inclusion of wording to emphasise this.	Thank you for your comment. Offering a person resources before an appointment to help them discuss options does not mean an appointment cannot involve informing and explaining to a person about a new diagnosis or development, and helps them further participate in this discussion. It is clear that it will not always be possible to offer people resources in advance, however where it is possible, the committee agreed that it should be done.
Resuscitation Council UK	Draft Guideline	008	017	We are concerned that the recommendation "Say how long the appointment will last" is contrary to the provision of good person-centred care, and also conflicts with some of the subsequent recommendations. Different	Thank you. The committee agreed it would be unrealistic to offer open ended appointments and recommended that further opportunities to discuss were offered (recommendation 1.2.10)

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				individuals will need different amounts of time. If the appointment is to be time-limited (i.e. service-centred and not person-centred) the health professional should make a clear offer of one or more early further discussions if needed. This is alluded to later in the guideline, but this should not be disconnected from any recommendation that discussion may be time-limited. Setting a time limit creates an immediate tension for the person and this may be an obstacle for proper shared decision making.	
Resuscitation Council UK	Draft Guideline	009	003	We concur with this recommendation, but are concerned that this conflicts with the earlier suggestion that an appointment should be time-limited, and that predicting the time required for questions cannot be achieved with confidence. Some people will have no questions, and others will want substantial time to consider and ask questions.	Thank you. The committee agreed and therefore recommended offering a follow up if people would like to discuss further.
Resuscitation Council UK	Draft Guideline	009	006	We concur with this recommendation, but would like to see a clear statement that this involves more than just asking whether they understand. Many people will answer 'yes' to that question, usually to avoid embarrassment, even if they haven't understood.	Thank you for your comment. NICE has added clarification that "teach back" and "chunk and check" methods can be used in recommendation 1.2.11, to ensure understanding of information provided.
Resuscitation Council UK	Draft Guideline	009	009–010	Again, we concur with this recommendation, but are concerned that it conflicts with the earlier recommendation that an appointment should be time-limited.	Thank you. The committee did not recommend time limited appointments, but rather were aware that most appointments are time limited in the real world. A decision need not necessarily be made in the appointment.

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Resuscitation Council UK	Draft Guideline	010	012–014	We think that the wording does not convey the intended meaning as clearly as it could. We suggest that it is edited to read something to the effect of: "Practitioners should ensure that people receive consistent information and advice by sharing expertise and information with all relevant services and agreeing how to align their messages."	The recommendation (now 1.1.11) has been modified to: "Ensure that expertise and information can be shared effectively both within and between organisations so that healthcare professionals provide people with consistent information. See recommendation 1.1.7 and section 1.4 of the NICE guideline on patient experience in adult NHS services." To clarify the intent.
Resuscitation Council UK	Draft Guideline	General	General	We wonder whether the guideline should also acknowledge the challenges involved in some aspects of shared decision making, including – for example – the importance of using sensitive explanation to help people to understand that shared decision making does not entitle them to demand care or treatments that are not being offered, because they would not benefit them in their situation.	Thank you. The committee discussed this and agreed that the term 'shared decision making' and the way it was defined (see 'terms used in this guideline') made it clear that decision making was collaborative, however they were careful to balance this with respect for patients' autonomy over their bodies and their care.
Richmond Group of Charities	Draft Guideline	004	008 - 013	We agree with the views of our member charity, The Stroke Association, that actively involving stroke survivors in discussion and decisions about stroke care is essential for developing stroke services that meet the needs of people affected by stroke. As part of the National Stroke Programme they have worked with NHS England and Improvement to appoint two Patient Voice Representatives to the National Stroke Programme Delivery Board, ensuring that the voice of those affected by stroke is central to decisions made about stroke services at the highest level.	Thank you for your comment. Recommendation 1.1.2 covers involving service users in "planning, implementing and monitoring shared decision making" which covers patient involvement in the SDM planning (and thus design) process. We also have recommendation 1.1.4 which states: "Identify one or more organisation-wide 'service user champions' to work with the senior leader, patient director and professional champions for shared decision making. They should be recruited from people who use services."

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				In the Draft Integrated Stroke Delivery Networks Specification (available in draft form on FutureNHS website and awaiting full publication), the focus on involving patient and public voice is similarly central. The guidance recommends that "Local systems should ensure that decisions around stroke services are made with effective involvement of people affected by stroke as per best practice, and service change should be done with, not to, those potentially impacted."	
Richmond Group of Charities	Draft Guideline	006	005	Training and development in shared decision making should also cover the skills required to have difficult and sensitive conversations. Macmillan research published in 2019 found that professionals sometimes lack the skills and confidence to speak about death and dying. Macmillan have highlighted how this is having a detrimental impact on professionals and on people who are approaching the end of their life, clearly impacting on the ability to make shared decisions. For example, while more than three quarters (76%) of people living with cancer have thought about the fact they may die from their cancer, worryingly only 8% of these people spoke to their healthcare team about the subject. *Macmillan Cancer Support (2019) At the*	Thank you. These skills are part of professional training and are not specific to shared decision making.

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				Crossroads: How can the NHS Long Term Plan improve end of life care in England?	
Richmond Group of Charities	Draft Guideline	006	016	There is evidence[14] that the role in SDM of carers, who may be navigating the system on someone's behalf, is a particularly challenging one in practice. The guidance as written does not give much consideration to this point and more information around how to do this well would be welcome.	Thank you. People who lack capacity are excluded from this guideline (see section 3.1 of the scope document). The guideline only covers carers and family members if the person chooses to involve them.
Richmond Group of Charities	Draft Guideline	007 09 010	020 024 006	We are concerned that this recommendation may unintentionally exclude people with low literacy levels or language challenges and therefore widen health inequalities. 16.4% of adults in England can be described as having "very poor literacy skills" [15] so it is important that alternative means are available for patients to prepare for consultation. For example, sharing information in audio format, such as voice notes, is a way to improve access. Without modification in practice there is a danger that these people will not benefit from SDM.	The NHS Accessible Information Standard (SCCI 1605) mandates that all healthcare and adult social care providers must provide information in a format their patients can read. The recommendations consistently refer to ensuring people understand and receive information in their preferred format. Please see for example recommendations 1.2.4, 1.2.5, 1.2.18.

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[14] Multimorbidity_-_understanding_the_challenge.pdf (richmondgroupofcharities.org.uk), p11

[15] Literacy Trust (2012) Adult literacy statistics: https://literacytrust.org.uk/parents-and-families/adult-literacy/

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				As above this section could be strengthened by acknowledging that written feedback may not be the most appropriate communication method for all patients and alternative options should be considered where necessary to improve access and inclusion. As above this section could be strengthened by acknowledging that written feedback may not be the most appropriate communication method for all patients and alternative options should be considered where necessary to improve access and inclusion.	
Richmond Group of Charities	Draft Guideline	008	003-004	Resources should also include links to material and guidance produced by charities.	Thank you for your comment. We have added a reference to patient organisations in the recommendation.
Richmond Group of Charities	Draft Guideline	008	005 - 014	Those providing this support should be encouraged to make use of relevant support materials developed by charities. For example, given that communication problems can be very common after a stroke, this may impact the ability of some people affected by stroke to participate in shared decision making as easily as others. Around one-third of stroke survivors have problems with speaking, reading, writing and understanding what other people say to them. To help support conversations with those affected by aphasia, Stroke Association have produced the following guidance:	Thank you for your comment. We have added a reference to patient organisations in the recommendation.

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				- SA Aphasia Team Guidance on working with people who have aphasia - SA guidance leaflet on involving people affected by stroke	
Richmond Group of Charities	Draft Guideline	009	020	The recommendation to record decisions and additional details should be strengthened. This recommendation should make clear that this information should be recorded electronically and in a shareable format, especially in order to strengthen information sharing between services. Enabling choice for all, particularly if a patient is at the end of their life, relies on professionals being able to share and access records including an individual advance care plan, which may include a decision to refuse treatment. In particular, *Macmillan Cancer Support (2019) At the Crossroads: How can the NHS Long Term Plan improve end of life care in England?*	Thank you. The content of medical notes is beyond the remit of this guideline.
Richmond Group of Charities	Draft Guideline	009	025	A printout or written account of a care plan may exclude those with low literacy levels or language challenges. It's important that all health professionals are ready and able to explain health information in ways that are easy to understand. People might be embarrassed to say they struggle with reading and writing so instead of saying, "Can you read?" we should	Thank you for your comment. The committee felt people with low literacy levels would fall under recommendation 1.2.21 which states: "Offer additional support to people who are likely to need extra help to engage in shared decision making. This could include encouraging them to record the discussion, explaining in writing the decisions that have been made, or arranging follow-up by a clinical member of staff or a suitable

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				ask, "Can I help you with this care plan?" Without modification in practice there is a danger that those people will not benefit from SDM.	alternative." Whilst printout is included here alternatives are presented if this is not an option.
Richmond Group of Charities	Draft Guideline	010	012	When sharing information between services, it should be made clear this information should be shareable with all relevant health and care professionals.	Thank you for your comment. The recommendation (now 1.1.11) has been modified to clarify this information can be shared within and between organisations: "Ensure that expertise and information can be shared effectively both within and between organisations so that healthcare professionals provide people with consistent information. See recommendation 1.1.7 and section 1.4 of the NICE guideline on patient experience in adult NHS services."
Richmond Group of Charities	Draft Guideline	014	001	The definition of shared decision-making should note the role family members or other carers can have in the process. Evidence review A (p6,I8 and p31,IL30) supports this - making clear that shared decision making involves "healthcare professionals working together with people who use services and their families and carers". The review highlights that family members/carers in the SDM process can help if patients are having difficulty expressing their thoughts and that including the patient's carer can help them feel supported. Macmillan research complements this evidence – highlighting the need to facilitate family engagement early in the decision-making process of patients. Professionals (some working in end of life care, some not) have told	Thank you for your comment. This is a brief description of shared decision making agreed at scoping stage after consultation with stakeholders, to help with a readers understanding of the guideline. The role of family members and carers has been highlighted within the recommendations (eg recommendation 1.2.3)

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				Macmillan that one of the central pillars of good patient care is open communication. This involves conversations not just with a patient but also with their carer/ family. Professionals also told Macmillan that the absence of early conversation with family members sometimes led to problems further down the line, with family members expressing different and conflicting views related to decisions about care/treatment. *Macmillan Cancer Support (2019) At the Crossroads: How can the NHS Long Term Plan improve end of life care in England?*	
Richmond Group of Charities	Draft Guideline	014 - 023	005 001	We welcome the guidance referencing advance care planning as an example of shared decision-making. These sections would be strengthened if they explained the role advance care planning has in the SDM process: enabling person-centred care through acting as a mechanism to document, and share, the outcome of decisions. *Macmillan Cancer Support (2019) At the Crossroads: How can the NHS Long Term Plan improve end of life care in England?*	Thank you for your comment. Mentioning advanced care planning in its current form is adequate as this guideline focused on SDM, not ACP. The terms used in this guideline section only defines terms that have a use specific to the guideline, not terms that are used in their general sense.
Richmond Group of Charities	Draft Guideline	General	General	We are concerned that these recommendations do not explicitly address the role of SDM in virtual consultation settings where there are different challenges to consider around how to	Thank you for your comment. The committee agreed that remote discussions should be considered and have also written a research recommendation

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				prepare, run and follow up from a session and who may / may not benefit from this type of appointment.	that asks "How do SDM skills and techniques need to be modified for remote discussions?" They noted that remote discussions are not just limited to digital interventions, but can also cover telephone consultations which are less of a problem when it comes to digital literacy. The committee felt skills of SDM could be applied to remote settings as well as face to face settings, and this has been added to the rationale and also to a recommendation (1.2.2).
Richmond Group of Charities	Draft Guideline	General	General	This guidance may be more challenging to implement for certain groups than others and doesn't distinguish between the complexity of patient need. For example, patients with multiple long-term conditions may present with complex challenges that will take more time to prepare for and talk through. Given the complexity of the decision-making process for groups of patients like this, healthcare professionals may need more time for such patients in order to have a meaningful conversation. Our evidence suggests[16] that time allotted to interactions and appointments is vital – people need sufficient time with HCPs to understand all the issues they ae facing. Currently the HCP workload is felt to	Thank you. The guideline highlights the need to give more time to people who may need it.

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[16] final_just_one_thing_after_another_report_-_singles.pdf (richmondgroupofcharities.org.uk) pp40-42

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				be too great for HCPs to provide consistently high quality empathetic care, particularly where: - There is more than one reasonable course of action and the decision involves trade-offs. - There is uncertainty or unclear evidence for one option over another. - The options have different inherent risks or benefits or where individual values are important in optimising the decision. We recommend including reference to the Ariadne principles[17] as a model to help manage this complexity.	
Richmond Group of Charities	Draft Guideline	General	General	We know from our 2019 Britain Thinks research[18] that under-resourcing was seen as impacting the care given by some parts of the system. GPs were too overburdened to provide patients with sufficient time to understand all the issues they are facing – poor communication leading some patients to feel like they were 'just a number'. For HCPs, an inability to reach existing consultants for knowledge of a patients' history / lack of shared records is likely to be a challenge. This also speaks to minimal information supplied or accessible about cancelled / moved appointments and the	Thank you. Recommendation 1.1.5 discusses a plan for SDM at organisational level, however all healthcare organisations need to be assessing the impact of practice changes on their organisation all the time. This is not an issue specific to this guideline.

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[17] Muth C, van den Akker M, Blom JW, et al (2014) 'The Ariadne principles: how to handle multimorbidity in primary care consultations', BMC Medicine, 12: 223–234.
[18] PowerPoint Presentation (richmondgroupofcharities.org.uk)

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				reasons for this which could hinder SDM. The guidance could be strengthened by recommending that providers assess the impact of any wider operational challenges on their ability to implement SDM in practice, putting appropriate mitigation measures in place.	
Richmond Group of Charities	Draft Guideline	General	General	We are concerned that this guideline doesn't address the challenge of conflicting professional advice. Specific consideration is important for people with multiple co-morbidities under the care of multiple specialists. People with multiple long-term conditions will be engaging with a range of different healthcare professionals as well as other sources of health advice (including multi-disciplinary teams) who may give conflicting advice of differing reliability, making shared decision making much more difficult. Care coordination approaches are an effective way of dealing with this issue. Specifically, we suggest a reference to the NICE quality standard [QS153][19] around coordination of care to encourage wider uptake of this model as it relates to shared decision making.	The committee agreed that avoidance of conflicting information for the healthcare user is important. They stated that any conflicting thoughts on decisions should be solved between clinicians prior to the moment where the patient is given conflicting advice.

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[19] https://www.nice.org.uk/guidance/qs153/chapter/quality-statement-3-coordination-of-care

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Richmond Group of Charities	Draft Guideline	General	General	Our Britain Thinks research[20] also points to the need to be really clear about the place of self-management in shared decision making as fears have been raised that moves towards SDM although welcome might lead to greater reliance on self-management which not everyone feels equipped to do (a concern which HCPs echo). The guidance could address this concern around self-management. Tools such as the Patient Activation Measure (PAM) can help determine which particular forms of support people may most benefit from by building on existing capabilities, reducing the risk of assumptions being made about a person's ability to self-manage The Triangle of Care approach and self-assessment tool, originally developed by Carers Trust in collaboration with mental health providers could be cited.	Thank you. This is beyond the remit of this guideline.
Richmond Group of Charities	Draft Guideline	General	General	The guidance should make clear the importance of identifying (at an early point) those key stages in a 'patient's pathway which would be likely to affect the SDM process. The assessment that a patient is in their last 12 months of life would be one such stage. Macmillan research highlights the role early identification has in supporting	Thank you. The guideline sets out the principle that SDM should be part of all healthcare decision making irrespective of where patients are in the pathway.

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[20] PowerPoint Presentation (richmondgroupofcharities.org.uk)

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				shared decision-making and thus person-centred care, finding that when patients in their last 12 months are not identified early, challenges in the system mean it can be harder to consider a person's preferences. *Macmillan Cancer Support (2019), At the Crossroads: How can the NHS Long Term Plan improve end of life care in England?*	
Richmond Group of Charities	Draft Guideline	General	General	When considering end of life care, the guidance should signpost where appropriate to *Section 1.3 Shared decision-making* of the NICE guidance "Care of dying adults in the last days of life, NICE guideline [NG31]", 2015. As the referenced guidance makes clear, there are a range of recommendations that will need to be adhered to in the SDM process for patients in their last few days of life – for instance – taking into account the dying person's current goals and wishes, a possible decision to refuse treatment, and health and welfare issues relating to power of attorney. NICE, *Care of dying adults in the last days of life, Guideline [NG31]*	Thank you. This guideline covers generic shared decision making approaches. For people at the end of their lives, practitioners would be expected to refer to the end of life guidance as well as adhering to the principles of shared decision making. This would be true of cancer, diabetes, smoking cessation etc – it would not be possible to provide links to every NICE guideline where shared decisions should be made.
Richmond Group of Charities	Draft Guideline	General	General	Question 1: Which areas will have the biggest impact on practice and be challenging to implement?	Thank you for this information.

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				We welcome the content on sharing information between services but this could be strengthened. We also know that the development of the information sharing systems used in end of life care (sometimes referred to as EPACCS) varies considerably across the country. The main challenges include clinical buy-in, functionality and data sharing. *Macmillan Cancer Support (2019) At the Crossroads: How can the NHS Long Term Plan improve end of life care in England?* Facilitating good end of life care has always been reliant on shared decision-making. When considering how to best support the implementation of recommendations in this guidance, it will be important to take account of the increased demand for end of life care in community settings. Particularly in private homes, demand for end of life has been consistently higher during the pandemic than before. Data indicates that this trend is likely to continue - when there were fewer cases of Covid-19 in the late summer (2020), excess deaths in the home remained above average, while deaths in other settings fell. At the same time, healthcare professionals have told	

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				Macmillan that that there is a lack of resource and capacity in community care, making it hard to meet demand for good quality end of life care at home; in some cases, this means family members will take on the responsibility of providing more care, but not always with the right support in place. In such situations, the ability to facilitate shared decision-making is likely to be significantly hindered. *Macmillan Cancer Support (2020) Demand for end of life care in the home: an urgent need for action, "Think. Improve. Change" Medium blogspace*	
Richmond Group of Charities	Draft Guideline	General	General	Question 3: What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) *To address challenges in the development of information sharing systems for end of life care,* Clinical Commissioning Groups (CCGs), and the Sustainability and Transformation Partnerships (STPs) and Integrated Care Systems (ICSs) they work with, must have plans in place to develop an EPACCS or an equivalent tool for coordinating palliative care.	Thank you for this information.

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				To enable the implementation in the community of recommendations in the guidance, our member charity Macmillan believes that more resource must be given to community palliative and end of life care. *Macmillan Cancer Support (2020) Demand for end of life care in the home: an urgent need for action, "Think. Improve. Change" Medium blogspace* *A number of our member charities have already developed case studies and best practice in relation to Shared Decision Making. These include:* • *Macmillan who highlight their Best Practice Case Study on 'Coordinate My Care', a London-wide information and sharing system* allowing patients with a life threatening or life limiting illness to record and share with healthcare providers, in real time, their medical details, advance care plans and wishes. *Co-ordinate My Care (p29) Macmillan Cancer Support (2019) At the Crossroads: How can the NHS Long Term Plan improve end of life care in England?* • Versus Arthritis who have led on the development of a number of shared	

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				decision making tools including a suite of 4 tools for shoulder, back pain, hip pain and knee pain (Musculoskeletal Decision Support Tools | Versus Arthritis) as well as a specific tool to support people with inflammatory forms of arthritis in making decisions around Covid-19 vaccines: msk-rheumatology-decision-support-tool-covid-19-vaccines-final-15012021.pdf (versusarthritis.org) One of our member charities, Asthma UK-British Lung Foundation Partnership, who will also be providing their own submission to the consultation, have conducted a Shared Decision Making survey involving 1,033 people with experience of a lung condition. The vast majority of people surveyed would like to be involved in making decisions about their care, with 98% finding this extremely important or very important. Furthermore, 97% agree or strongly agree that they are motivated in making decisions about their care. 97% want to be often or always involved in making a decision about their care, with 89% of respondents agreeing or strongly agreeing that they have the skills and knowledge to be involved in this process. However, only 67% of people with a lung condition agreed or strongly agreed that they had opportunities to make decisions about	

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				their care together with their healthcare professional so the guidance on how SDM can be put into practice is vital. When asked about a time where an individual or their healthcare professional had different ideas or preferences about their care, 43% said they proceeded with their healthcare professionals approach, 39% with a mixed approach and 18% reported that they went with their own preference. Furthermore, 34% of respondents said that they did not feel confident discussing preference with their healthcare professionals which may show the need for further training in SDM. Finally, respondents were asked to list the resources that they found to be most useful when making decisions about their care between appointments, as follows: 1. Links to where I can find further information (i.e. on the internet) 2. Conducting my own research on the internet 3. Information from charities 4. Notes I've made myself from the conversation with the healthcare professional 5. A printed summary sheet of what I've discussed with my health care professional 6. A letter from my health care professional after my appointment	

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				7. An app or device that helps me monitor my condition 8. An email from my health care professional after my appointment 9. Statistics and graphics 10. I don’t use any resources to help me make decisions about my care 11. Posters or information in a doctor’s waiting room 12. A text from my health care professional after my appointment	
Royal College of Anaesthetists	Draft Guideline	general	general	Nowhere does it mention that patients can refuse to participate. I'm not suggesting this is common but refusals need to be respected.	Thank you. Please see recommendation 1.2.8: “Ensure the person understands they can take part as fully as they want in making choices about their treatment or care.”
Royal College of Anaesthetists	Draft Guideline	004	1.1.1	I accept the need for leadership at Board level but there is nothing about how they relate to the 'coal face' which could be most of the trust.	Thank you. Recommendation 1.1.5 talks about having a plan to implement shared decision making at the coal face. Recommendation 1.1.3 and 1.1.4 talk about champions, who are at the coal face.
Royal College of Anaesthetists	Draft Guideline	005	2.1.1.5	Includes the heading 'Set out people who use services will be included will be involved in support implementation' This is hardly an equitable relationship!	Thank you. The committee agreed that service users being involved in implementing SDM was vital to its success.
Royal College of Nursing	Draft Guideline	002	004	Section 1.1: The board level involvement is welcomed	Thank you.

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Royal College of Nursing	Draft Guideline	002	005	Section 1.1.5: Time should be made available for continuing professional development (CPD) and there will be costs attached. Clinical supervision should also be available.	Thank you for your comment. The committee agreed to add clinical supervisions to recommendation 1.1.12
Royal College of Nursing	Draft Guideline	007	010	Section 1.2.3: The right of capacious people to make unwise decisions needs to be respected.	Thank you. Please see recommendation 1.2.13: "Accept and acknowledge that people may vary in their views about the balance of risks, benefits and consequences of treatments, and that they may differ from those of their healthcare professionals"
Royal College of Nursing	Draft Guideline	007	018	Section 1.2.4: Availability of information in easy read, dementia friendly and other languages must be in place	Thank you. We believe this is covered by 'preferred format'. We have also added a reference to the accessible information standard.
Royal College of Nursing	Draft Guideline	008	005	Section 1.2.5: If a person requires an individual to support for example a registered nurse, arrangements should be in place to ensure continuity of that individual. RCN guidance on consent may be useful: Good record keeping, consent and appropriate disclosure in occupational health nursing	Thank you for this information. The committee considered all potential signposting to guidance and decided in this case this was not necessary, as these were just examples of potential people to provide additional support, not just nurses.
Royal College of Nursing	Draft Guideline	General	General	The largest impact would be on patients with cognitive impairment and hard to reach groups whose voices were frequently unheard. Done well it may lead to more tailored care and there may be cost savings as people will not have interventions they do not wish for.	Thank you for this information.
Royal College of Nursing	Draft Guideline	General	General	There needs to be a greater embedding of mental capacity legislation and consideration for patients who have cognitive impairment or fluctuating capacity. There may also be	Thank you. People who lack mental capacity and children and young people under the age of 18 are excluded from this guideline. Please see section 3.1 of the scope document

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				opportunities to signpost people to advanced care planning as well. Shared decision making should be included in health professional's pre-registration training For shared decision making to work, consideration must be given to the organisational culture. Staff should be involved in shared decision about matters that affect them to promote an effective way of working.	(https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents).
Royal College of Nursing	General	General	General	The Royal College of Nursing (RCN) welcome the opportunity to review the NICE draft guidance for Shared Decision Making.	Thank you for your comment.
Royal College of Nursing	Questions	Question 1	1	*Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.* Health literacy is hugely complex, and this requires further clearly defined research to better understand the effects and potential inequalities in health. Correlation with Integrated Care Services (ICSs) and cross-sector working is needed to promote health literacy with professionals from health and social care and support from other sectors such as adult education and the third sector.	Thank you for your comment.

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Royal College of Nursing	Questions	Question 2	2	*Would implementation of any of the draft recommendations have significant cost implications?* We would agree that the draft recommendations will have significant cost implications to implement. The draft recommendations could potentially create or limit additional costs depending on the Sustainability and Transformational Partnership (STP) footprint or if it is an Integrated Care Service (ICS). if this is to be a cross sector and a system wide approach (i.e. - Creation of new posts for example community development workers or clinical nurse specialist roles)	Thank you for your comment.
Royal College of Nursing	Questions	Question 3	3	*What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)* • Exploring any quality improvement strategies/innovation and developments that have already happened, take validated and best practice from these initiatives to further support any recommendations	Thank you for your comment. This was a general guideline on SDM in all settings, and thus the committee did not want to make specific recommendations about staff roles that are not present in every setting. Recommendation 1.2.6 does include nurse as an example of a staff member who could offer additional support around shared decision making.

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				- To consider use of interpreting services where relevant (for example, people who are hard of hearing/ deaf/ E2L) Could not see in the draft document where the role of nurses within specialities were demonstrable in supporting people with shared decision making for example, clinical nurse specialist roles are used to act as a conduit to support communication and health literacy / other issues identified.	
Royal College of Obstetricians and Gynaecologists	**Draft Guideline**	**008**	**General**	**Section 1.2.5:** **"1.2.5 If a person might find it difficult to share in decision making, for example if they have a mental health condition, *English is not their first language or they have sensory difficulties, offer to arrange additional support for them if they do not have, or do not want, support from a partner, friend or carer. "*** **Though the guidance notes earlier to "Ask the person if they want to involve family members, friends or advocates (being aware of safeguarding)."** **This may differ from Pregnancy and complex social factors guideline [CG110] which states in section 1.3.10:** **"Communication with women who have difficulty reading or speaking English**	Thank you. We do not see these as contradictory, both are concerned with safeguarding the patient and only involving family members if that is the patient's choice. However, in order to allow "additional support for people who might find it difficult to share in decision making" to cover the broadest range of those who may need support, we have removed the examples from recommendation 1.2.6.

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				1.3.10 *Provide the woman with an interpreter (who may be a link worker or advocate and should not be a member of the woman's family, her legal guardian or her partner)* who can communicate with her in her preferred language." **The advice italicized above is mentioned three times in last week's MBRRACE report Saving Lives, Improving Mothers' Care.**	
Royal College of Obstetricians and Gynaecologists	Draft Guideline	General	General	The guideline appears to be designed mainly for non-urgent consultations. Is there any recommendation for decision making in urgent, time pressured situations such as labour care.	**Thank you for your comment, The committee acknowledged that some SDM processes are still applicable to more urgent settings, and that the recommendations could be followed from the point of "during discussions with a healthcare professional" onward into aftercare, as SDM is an ongoing process there will then be future discussions after the urgent care in which these "before discussions with a healthcare professional" recommendations could be followed. The committee were clear that if the patient was still able to participate SDM recommendations should still be followed as closely as they can be.**
Royal College of Occupational Therapists	Draft Guideline	008	009	It is limiting to give the impression that nurses and social workers are the only professionals who could provide support to individuals. Any professional who has a good relationship with the individual, and the necessary skills to support their needs, would be well placed to	Thank you. This list gives examples of where support 'could' come from and is not exhaustive.

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				offer assistance – for example occupational therapists, sensory rehabilitation officers etc.	
Royal College of Occupational Therapists	Draft Guideline	008	021	Suggest change of wording to 'tests, treatments *and interventions'* which better represents the work of some health professionals e.g. occupational therapists and other Allied Health Professionals	Thank you. We have added this.
Royal College of Occupational Therapists	Draft Guideline	009	010	Suggest change of wording to 'tests, treatments *and interventions'* which better represents the work of some health professionals e.g. occupational therapists and other Allied Health Professionals.	Thank you. We have added this.
Royal College of Occupational Therapists	Draft Guideline	009	024	Information should be provided in the person's preferred format, suitable to their communication needs.	Thank you. We have added a reference to the accessible information standard.
Royal College of Occupational Therapists	Draft Guideline	010	006 - 010	This does not go far enough to demonstrate the additional support that people may need, or the different type of communication methods that may be necessary. Some people – for example individuals with learning disabilities or cognitive impairments, may need considerable support to participate in shared decision making and understand / remember the outcomes of decision-making sessions. It is important that these people (many of whom are already at higher risk of health inequalities) are not disadvantaged or treated inequitably because services have not sufficiently prepared to support them.	Thank you. This list of additional support is not exhaustive, and there is an earlier recommendation that goes into more detail on supporting people before the discussion begins who might find it difficult to share in decision making (1.2.6). The committee agreed this would include those with learning disabilities and cognitive impairments.

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Royal College of Occupational Therapists	Draft Guideline	014	013	Suggest additional research recommendation – Equitability of shared decision making. How is shared decision making applied with groups at risk of health inequalities.	Thank you for your comment. This is covered as an aspect of research recommendation 1: "How do the same shared decision making interventions differ in effectiveness between different groups of people and different care settings?"
Royal College of Occupational Therapists	Draft Guideline	General	General	Some of the vocabulary used throughout the document e.g. 'treatment and care' reinforces a traditional, paternalistic approach to health – focusing on 'doing to' the person rather than 'doing with', which is at odds with the ethos of shared decision making. This language (though necessary in some cases) should be balanced by terms such as 'support and intervention' which are more collaborative.	Thank you for your comment. The committee felt these terms were not inherently paternalistic. The guideline as a whole has been written with the aim to encouraging a more collaborative and less paternalistic view of decision making in healthcare.
Royal College of Occupational Therapists	Draft Guideline	General	General	The guidance could go further to make clear that everyone has the right to be involved in shared decision making, and that all reasonable steps should be taken to allow people with additional needs to participate – especially individuals and groups who are at greater risk of experiencing health inequalities. There should be clearer explanation on how additional communication needs could be met to ensure that all individuals have equitable opportunities to engage.	Thank you. Please see recommendations 1.2.2 to 1.2.6 which address this issue.
Royal College of Physicians and Surgeons of Glasgow	Draft guideline	001	005	Another noted the section on "Who is it for?" does not mention people under the age of 18 specifically. It is unclear whether the guidelines do not apply to minors and their parents/carers or whether it is this just not mentioned? As this is read by lay people there needs clarity.	Thank you. People under 18 are out of scope for this guideline and thus were excluded. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)

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					For information on decision making in children and young people see information at https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/0-18-years/making-decisions NICE also has this guideline currently in development - Babies, children and young people's experience of healthcare which includes the following question 'How do children and young people like to be involved in planning their healthcare and making shared decisions about their health? This new guideline should address the concerns you've raised.
Royal College of Physicians and Surgeons of Glasgow	Draft guideline	004	017	It is unclear what is being meant by "people who use services as organisation-wide 'service user champions' for shared decision making".	Thank you. We have clarified this as "Identify one or more people who use services as organisation-wide 'service- user champions' to work with the senior leader, patient director and professional champions for shared decision making. They should be recruited from people who use services."
Royal College of Physicians and Surgeons of Glasgow	Draft guideline	006	008	The "three talk" model is not widely known in clinical medicine. Our reviewer did a limited search on the internet possible suggesting that the model is controversial and/or in flux (https://www.bmj.com/content/359/bmj.j4891). A s George Box said, all models are wrong, some are useful. It would be helpful to know how it has been used in practice. What is it about the model which practitioners and patients need to know and, by using it, do differently?	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.

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Royal College of Physicians and Surgeons of Glasgow	Draft guideline	008	005	This paragraph lacks mention of those who are unable to read or write. Illiteracy is commoner in those particularly from a BAME background whose first language is not English. When identifying what additional support is required for those with sensory impairments it would be useful if such support was actually available. The reviewer attempted to get hospital appointment letters in large print for an elderly lady with macular degeneration. While this is a national requirement and has been a local standard for at least the last ten years, no such facilities exist because the centralised computer system is incapable of providing such facilities.	Thank you. The examples given were examples and this is not an exhaustive list. These have now been removed to make it clearer it is at the professional and service users discretion regarding need for additional support, but of course it would be expected that those with illiteracy would fall under this offer of additional support. Regarding printing capabilities, NICE cannot make recommendations over accessibility of NHS computer systems.
Royal College of Physicians and Surgeons of Glasgow	Draft guideline	General	General	The Royal College of Physicians and Surgeons of Glasgow although based in Glasgow represents Fellows and Members throughout the United Kingdom. While this report is related to England, many of the recommendations are applicable to all devolved nations including Scotland. They should be considered by the relevant Ministers of the devolved governments. The College welcomes this Guidance although it considers it aspirational and giving an ideal. This may not be entirely practical given the considerable constraints within the NHS (exacerbated by the COVID-19 crisis). There	Thank you. We agree that it would have been impossible to have a truly representative committee. The best format for the committee was discussed and agreed with stakeholders at the stakeholder workshop during the scoping phase of this guideline. In addition, both the scope and the guideline have been through a process of public consultation, of which you are a part. The resource impact of the majority of the recommendations outlined in this guideline are expected to be minimal (e.g., small increases in printing costs as a result of using decision aids or because only minor updates were made to existing recommendations on communicating risk and benefits and therefore should already be part of existing care). For

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				appears to be no evaluation of the full financial consequences of this guideline. The College notes the committee comprised of lay people (4-5), palliative care consultants (2), GP (2), mental health professional (2), psychologist (1), orthopaedic trainee (1), pharmacist (1), primary care palliative care advisor (1), primary dental care professional (1), ethicist (1), academic in epidemiology and public health (1) (three others listed have academic posts). While it is impossible to have every speciality recognised on the committee, there appears no representative from specialities which have a long-term practice of shared decision making such as surgery, oncology, respiratory medicine, elderly health, rheumatology, rehabilitation or pain management (other than palliative care). While there were five lay members of the committee, for such an important issue wider consultation may be necessary. It perhaps would have been helpful to consider focus groups for professionals and the public in the methodology.	recommendations where there is an expected resource impact this is discussed in the short version of the guideline. For example, to limit the potential resource impact the recommendation on arranging third party support was limited to only people who might need additional support to engage in SDM, rather than a recommendation for third party support for all people. It is also noted that some recommendations might result in longer appointments/consultations, but that this resource impact could be offset by fewer subsequent appointments and potential benefits in people making the right decision upfront in their care pathway.
Royal College of Physicians	Draft guideline	General	General	A lay reviewer felt "it is ironic that the ends and means (ie the purpose) of this document, despite careful reading, are not readily apparent.	Thank you. All of the stages of the development of this guideline are detailed on the NICE website in the 'project documents' section of the SDM guideline page

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and Surgeons of Glasgow				It is, of course, a consultation document. But to what end? NICE is obviously part of the way through its project (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents), which has been operational since mid-2019 and which it expects to conclude in June this year. Is this document aspirational or a consultation on likely proposals (or a mixture)?" The structure of the document is unhelpful to this reader; while the table of contents on page 3 does give some clues about what is to come, a summary of where this consultation has got to, where it is, and where it is going would be most useful. Some of the links are weblinks and some indicate that a defined term is being used. There are references to documents which contains research that is unintelligible to this layperson. The research may be highly pertinent. How is the layperson to know? Diagrams, tables, illustrations, and explanations (rather than a link) would be useful. Without being able to understand what has been researched, the reviewer did not know the answer to such basic questions as:	(https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents) including the public consultation on the scope. Additionally, all of the evidence considered by the committee is on the website. We appreciate that the documents are often complex, but their aim is to guide the discussions of an expert committee.

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				1. Assuming that shared decision-making is capable of *quantification*, what metrics are being used? 2. Is shared decision-making partly (or wholly?) *qualitative*? What means should be used to investigate that aspect of decision-making? 3. Might parallel longitudinal studies of patients and doctors be useful?	
Royal College of Physicians and Surgeons of Glasgow	Guideline	009	010	The suggested process for carrying out discussions during appointments is fine. It contains all the elements expected except that "conflict resolution" is not mentioned anywhere. There just seems to be an expectation that discussions will go as planned and a mutually acceptable course of treatment will be agreed. What happens when the patient/carer/advocate completely rejects to options presented and proposes a course of action that is either not acceptable or available to the medical professional. This needs to be discussed. The reviewer also pointed to the issues raised in https://casereports.bmj.com/content/bmjcr/14/1/e237942.full.pdf where a seriously ill patient had different priorities to his medical team.	Thank you for your comment. The committee agreed it was important to clarify a pathway in cases where SDM is not occurring. They identified three different scenarios where SDM is impeded: 1. SDM cannot be performed (e.g. In an emergency): In these cases this is out of the scope of this guideline 2. Service user is asking for a treatment that is unavailable (e.g. due to CCG/ funding) 3. Clinician does not believe treatment preferred by service user would be in best interests of patient, or vice versa In the event of number three, the committee recommended a three-step pathway to resolve this conflict: 1. Further discussion between patient and clinician

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					2. Seeking of a second opinion to help support the shared decision-making process and get another perspective 3. A grievance/complaint process The committee also noted that starting SDM as early as possible should help avoid situations like the ones outlined above from occurring as frequently.
Royal College of Physicians and Surgeons of Glasgow	Guideline	009	024	All output information and letters should be in a format that can be easily read and understood. Although NICE documents are quoted as an example, many are in a form which cannot be understood by the lay public. Consideration needs to be given to lay versions of NICE documents and compliance with readability standards such as the "crystal clear standard" of the Plain English Campaign.	Thank you. NICE strives to be clear in its language in its guidelines, however we acknowledge that guidelines are underpinned by complex technical evidence. NICE do not produce lay versions of guidelines.
Royal College of Physicians and Surgeons of Glasgow	Guideline	General	General	Our lay reviewer concluded "in summary, there are some useful observations in the document about organisational, cultural, and individual approaches to shared decision making. Top-down initiatives may not work, particularly when the culture is not receptive to a strategic initiative. This Guideline needs to define what are the most effective tasks that patients and practitioners might adopt to make measurable (quantitatively/qualitatively) improvements in	Thank you. The committee found from expert witness testimony and their own experience from both a healthcare professional and service user background that SDM can only be successfully implemented if it is driven from the very highest levels of the organisation, and has buy in from all staff members.

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				shared decision making with efficient use of time".	
Royal College of Psychiatrists	Draft Guideline	008	005	It is unhelpful to offer "mental health condition" as a generic reason for a person not be able to share in decision making. It would be much more accurate to talk about mental capacity and vulnerability. Most people with mental disorders are perfectly capable of making decisions and engaging in shared decision-making.	Thank you. The reasons for support given were examples and this is not an exhaustive list. These have now been removed to make it clearer it is at the professional and service user's discretion regarding need for additional support.
Royal College of Psychiatrists	Draft Guideline	008	General	This section is entirely generic and does not recognise that for a significant minority of people, issues such as lack of capacity and detention under the Mental Health Act will be issues.	Thank you. People who lack capacity are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents).
Royal College of Psychiatrists	Draft Guideline	009	General	It needs to be made clear that no clinician is obliged to prescribe or make available a treatment or intervention for which there isn't sufficient evidence.	Thank you for your comment. The committee added some consideration of this to the rationale: The committee noted that some people may not want to be involved in shared decision making. They also noted that not all decisions can be shared. People have a right to refuse any treatment, and similarly, healthcare professionals are not obliged to provide any treatment that in their clinical opinion is medically futile (this may require a second opinion or discussion with a senior colleague). Healthcare professionals cannot provide access to treatments that are not available.
Royal College of Psychiatrists	Draft Guideline	010	General	Can this be reworded to clarify that a letter will be sent to their GP (exceptions may be services like termination of pregnancy I think), and that the person has the option to have the letter written to them and copied to GP not vice versa.	Thank you. We have clarified this in recommendation 1.2.17: "In secondary or tertiary care, consider asking the person if they would like a letter detailing the information from their appointment to be sent to them and copied to their GP. Letters should be written in line with Academy of Medical Royal

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				Otherwise this suggests that there is an option of not having the GP written to.	Colleges guidance on writing outpatient clinical letters to patients."
Royal College of Psychiatrists	Draft Guideline	011	General	This is far too generic. The implications of the Montgomery judgement really need to be distilled and added.	Thank you for your comment, the implications of the Montgomery judgement are fully understood and were taken into account by the committee. For more context on the judgement see the context section.
Royal College of Psychiatrists	Draft Guideline	012	General	This statement is unclear.	Thank you for your comment. It is unclear to which statement you are referring.
Royal College of Psychiatrists	Draft Guideline	General	General	There is a danger in recommending a patient director. For patient representatives to be effective, they should fulfil two requirements: 1. A recent experience as a patient 2. A connection to other patients. The first of these argues against a fixed appointment for longer than a year. The second is usefully supported by the idea of 'patient leaders' later in the document. Patient directors should have a close relationship with a representative patient body.	Thank you. Organisations would need to take this into account if they chose to appoint a patient director.
Royal College of Psychiatrists	Draft Guideline	General	General	The use of the word 'service user' is not supported by research. When asked, patients often prefer the term 'patient'. The document alternates between these two terms. Most patients outside mental health are unlikely to know what the term 'service user' means.	Thank you. The terms are not used interchangeably. The guideline uses the term patient when the interaction is likely to be a clinical one and service user in broader contexts. This is standard NICE style.

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Royal College of Psychiatrists	Draft Guideline	General	General	This is an immensely simplistic approach – whilst I can see the appeal as it is meant for all patients in all services and specialties, it really does need to acknowledge much more explicitly issues such as capacity, advance decisions, the role of families/carers (no proxy consent), clinical duty, the issue of risks to others and therefore limits to one's choice, the issue of children and adolescents and the role of parents, etc. I cannot see what this guideline will add otherwise?	Thank you. People who lack capacity (and children under 18) are excluded from this guideline. Please see section 3.1 of the scope document. The recommendations in the guideline are applicable to all of the other scenarios you present.
Royal National Institute of Blind People	Draft Guideline	001	005	The box at line 5 does not include patients under the age of 18 but does not say where to find guidance for those under 18.	Thank you. People under 18 are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents). However, please note that NICE is currently developing a guideline on patient experience of healthcare for babies, children and young people, which considers shared decision making. Please see https://www.nice.org.uk/guidance/indevelopment/gid-ng10119 for information on the development of this guideline
Royal National Institute of Blind People	Draft Guideline	005	002	'Develop an organisation-wide plan to put shared decision making into practice.' There are instructions about what this should contain but no requirement to involve patient groups, also no mention of this document being published or available to the public, these would seem to be appropriate requirements for the preparation and use of joint decision making documents.	Thank you. There is a requirement to "Set out how people who use services will be involved in supporting implementation" (recommendation 1.1.8).

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Royal National Institute of Blind People	Draft Guideline	005	013	Information systems should also record if a person has a preferred format in which information is provided to the patient. In August 2016, the NHS Accessible Information Standard (SCCI 1605) came into force. It mandated that all healthcare and adult social care providers must provide information in a format their patients can read.	Thank you for your comment. Please see recommendation 1.2.4 which has been amended to refer to the NHS accessible information standard.
Royal National Institute of Blind People	Draft Guideline	006	011	When sharing the information it should be in the appropriate format. In August 2016, the NHS Accessible Information Standard (SCCI 1605) came into force. It mandated that all healthcare and adult social care providers must provide information in a format their patients can read.	Thank you for your comment. The guideline now references the accessible information standard.
Royal National Institute of Blind People	Draft Guideline	007	018	'Before an appointment where a decision will be discussed, offer the person access to resources in their preferred format (for example a booklet, flyer or app).' This action should be stronger than 'offer', it should be 'provide'. The requirements of the Equality Act 2010 and the Accessible Information Standard should be explained as being mandatory rather than a guideline or recommendation. In August 2016, the NHS Accessible Information Standard (SCCI 1605) came into force. It	Thank you. We recommend providing information in accessible formats and have added a reference to the accessible information standard.

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				mandated that all healthcare and adult social care providers must provide information in a format their patients can read. Importantly, the Standard reinforces the existing obligation under the Equality Act 2010 on service providers (including the NHS) to provide information in accessible formats. The Standard has come about because the Government recognised that more needed to be done by the NHS to address the lack of accessible information provision.	
Royal National Institute of Blind People	Draft Guideline	008	005	Reference to someone helping a patient understand the resources supplied. There are other resources that can supply this help, for example in Eye clinics there are often Eye Clinic Liaison Officers (ECLOs) who can supply the help and support required.	Thank you for your comment. The list of people able to help support the service user is not exhaustive
Royal National Institute of Blind People	Draft Guideline	008	007	'offer to arrange additional support'. This should not be an offer additional support should be provided. As written, this is an offer within a recommendation within a guideline. It needs to be stronger.	Thank you. We do not believe additional support should be provided against peoples will, but rather that it should be offered to them.
Royal National Institute of Blind People	Draft Guideline	009	015	There is a reference to 'writing up' the consultation. Most healthcare professional will make a record of the consultation, writing up sounds archaic and unsuited to 21st century health care.	Thank you. We have changed this as you suggest.

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Royal National Institute of Blind People	Draft Guideline	009	016	' At the end of an appointment, state clearly what decisions have been made to make sure the person agrees with and understands what has been decided, what happens next, what the timescales are, and when it will be reviewed.' RNIB do not think that this goes far enough, this should be part of the plan not something stated at the end of an appointment. In talking with patients RNIB have been told that patients want also to know when the items in the plan should take place and what to do if they do not take place at the appropriate time.	Thank you. This is all covered within the recommendation. It is not possible to make decisions about next steps until shared decision has been made.
Royal National Institute of Blind People	Draft Guideline	009	024	'Give people resources to help them understand what was discussed and 25 decided in their appointment.' It is a requirement that this be done in an accessible format. The requirements of the Equality Act 2010 and the Accessible Information Standard should be explained as being mandatory rather than a guideline or recommendation. In August 2016, the NHS Accessible Information Standard (SCCI 1605) came into force. It mandated that all healthcare and adult social care providers must provide information in a format their patients can read. Importantly, the Standard reinforces the existing obligation under the Equality Act 2010 on	Thank you. We have added a reference to the accessible information standard.

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				service providers (including the NHS) to provide information in accessible formats. The Standard has come about because the Government recognised that more needed to be done by the NHS to address the lack of accessible information provision. This is also where further support should be signposted, for example to local authority rehabilitation services, to any benefits that might be claimed. In eye clinics ECLOs can provide this service.	
Royal National Institute of Blind People	Draft Guideline	010	017	'Use patient decision aids as one part of an overall 'toolkit'' It is not clear what patient decision aids exist. If practitioners are recommended to use these aids, they need to know whether an aid exists and where to find it. It would be useful here to signpost where patient decision aids can be found. The guideline at page 20 line 24 under the heading Rationale and Impact refers to having a library of decision aids, why is this not a recommendation?	Thank you for your comment. Recommendation 1.3.4 now states that staff have access to quality-assured patient decision aids. This could be by maintaining a database of decision aids that are regularly reviewed and updated, or signposting staff to decision aids produced by national bodies such as NICE.
Royal National Institute of Blind People	Draft Guideline	General	General	These are Guidelines and as such are not mandatory (although in answer to a PQ the Government has said it expects NICE guidelines to be followed - see below). Why then are there 'recommendations'. Only recommending in what	Thank you. NICE makes recommendations based on the best available evidence in all of it guidelines. Where the evidence is strong, the recommendation is strong. Where the evidence is less strong the committee make a recommendation to 'Consider' a course of action. This is detailed in the box at the

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				are already guidelines will reduce compliance with the guidelines. Within the guidelines there are 'recommendations' to 'consider' actions. Again, this is a further diminishment of the impact of the guidelines and compliance is less likely. The Government's response to a Parliamentary Question concerning ophthalmology was as follows; 'Clinical commissioning groups are responsible for commissioning secondary care ophthalmology services to meet local need. We would expect services to be commissioned in line with National Institute for Health and Care Excellence (NICE) guidance where it is available or best available evidence and for patients to receive treatment, in line with their clinical priority, without any undue delay at any stage of their referral, diagnosis or treatment.'	top of the recommendations section and has a hyperlink to a fuller explanation.
Royal National Institute of Blind People	Draft Guideline	General	General	The relationship between shared decision making and consent is not adequately addressed. For Consent users of the guidelines are referred to the General Medical Council's advice on consent. This is meant for doctors although it says that 'it may be of interest to	Thank you. This guideline does not consider consent specifically. Consent is a legal framework; however the skills of shared decision making may be a useful part of the consent process.

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				others'. Given the guidelines apply to 'all healthcare settings' then consent should be addressed within the guidelines as part of the shared decision process.	
Royal National Institute of Blind People	Draft Guideline	General	General	At various points in the guideline it mentions the provision of information in an appropriate format however the requirements of the Equality Act 2010 and the Accessible Information Standard should be explained as being mandatory rather than a guideline or recommendation. In August 2016, the NHS Accessible Information Standard (SCCI 1605) came into force. It mandated that all healthcare and adult social care providers must provide information in a format their patients can read. Importantly, the Standard reinforces the existing obligation under the Equality Act 2010 on service providers (including the NHS) to provide information in accessible formats. The Standard has come about because the Government recognised that more needed to be done by the NHS to address the lack of accessible information provision.	Thank you. As you say, all organisations must by law comply with this. The committee have added reference to the accessible information standard in the appropriate recommendations.
Royal National	Draft Guideline	General	General	The approach regarding making a joint decision or plan about treatment and care should extend to giving patients further support beyond	Thank you. This guideline is about shared decision making, if these interventions were raised by either service user or

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Institute of Blind People				treatment and care. This holistic approach could include support on how patients can help themselves, for example lifestyle, diet, exercise. Support should also include psychological support at the point of diagnosis where appropriate. Also consider non-medical support such as social prescribing, signposting to physiotherapy, rehabilitation services and welfare support.	healthcare professional as part of the shared decision making process they could form part of the discussion.
Royal Pharmaceutical Society	Draft Guideline	General	General	We agree with the overall points and direction of the guideline, but it is difficult to see how this would be applied in small individual practices such as an independent community pharmacy. The guidance outlines many roles and actions at an organisational level which would not directly apply to an independent contractor. The section about high level organisation support only applies to big organisations such as Hospital Trusts. It is not helpful for primary care practitioners such as community pharmacies, GPs, dentists etc as they do not have this type of hierarchy. PCNs could be useful in helping raise profile of SDM within primary care and perhaps that role should be further explored. We also think it would be helpful if there was a national repository of helpful resources to	Thank you. It is a challenge to write a guideline that is relevant to all healthcare settings and each organisation will need to adapt the guideline to suit their setting. The decision to create a national repository of resources is not within the remit of NICE.

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				support this guidance e.g., decision aids that smaller organisations could easily access, and this should be considered.	
Royal Pharmaceutical Society	Draft Guideline	General	General	The focus seems to be very much on process rather than achieving the desired outcomes. Within an organisation, however big or small, it needs to be made easy for the patient voice to be heard and listened to and to show you have responded appropriately ('you said, we did' approach). The guidance does not really capture the overall gravity and shift that is required in pretty much the entire healthcare work force in terms of cultures and behaviours. We believe that SDM starts with understanding the person and their expectations/beliefs and values and preferences and then the practitioner offers suitable option (s) and they have a conversation together to come to a final decision.	Thank you. The committee saw evidence from places where SDM had been successfully implemented, and judged these were often a success due to processes that embedded SDM within standard practice, and that without these processes you could not achieve the culture and behaviour shift required to practice SDM on a large organisational scale. They thus made recommendations that focused on enabling processes that enabled these behaviour and culture shifts to occur and be sustained.
Royal Pharmaceutical Society	Draft Guideline	General	General	In terms of training, it would be prudent to signpost people to training that has been accredited by the Personalised Care Institute at a national level which includes training on Shared Decision Making	Thank you. NICE does not signpost to accredited training providers.

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Royal Pharmaceutical Society	Draft Guideline	General	General	For older people, there are a number of difficulties, the absolute risk of any treatment/ stopping treatments is not known as they are often excluded from clinical trials, tend to have multiple long-term conditions and take multiple medicines. Decision aids often do not work very well in this age group for the same reasons so it might be useful to add a section specifically about older people/ frail older people and explaining risk as well as possible risks even if the absolute risk is not known.	Thank you. We believe the guidance is clear that decision aids are not always useful and that they are one part of the SDM process. We believe your point is covered by recs 1.4.1 – 1.4.4.
Royal Pharmaceutical Society	Draft Guideline	General	General	Within this guidance there does not appear to be guidance on shared decision making in the context of co-morbidity and the complexity that this brings with it. This should be included.	Thank you. The committee made recommendations that apply universally. The principles of SDM are not different in the context of co-morbidity.
Society of British Neurological Surgeons	Draft Guideline	General	General	There should be a section to include patients who lack capacity or too ill to engage	Thank you. These groups are excluded in the scope for this work. Please see section 3.1 of the scope document on the NICE website.
Society of British Neurological Surgeons	Draft Guideline	General	General	We agree with the principle and there is a need for patients to have shared decision making and to be provided with all facilities and time required	Thank you.
Society of British Neurological Surgeons	Draft Guideline	General	General	We also emphasise the need to have a balanced approach to avoid compromising efficiency of clinical services.	Thank you.

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Society of British Neurological Surgeons	Draft Guideline	General	General	The title should include the word clinical e.g. Shared Decision making in Clinical settings	Thank you. We would expect the guideline to be relevant in all settings where services are delivered by the NHS, including non-clinical settings.
Society of British Neurological Surgeons	Draft Guideline	General	General	A pre-set allocation of time is best avoided. The time required will be variable and not predictable.	Thank you. Most NHS run services book appointments on a specific time schedule and would be unable to function otherwise.
Takeda UK Ltd	Draft Guideline	005	013	Ensure both the service user and healthcare professional have access to or can be directed to available patient decision aids or tools that have been adopted for use by the organisation. This could be facilitated through hosting materials on a designated central online shared decision-making platform.	Thank you. Please see the recommendations in section 1.3 about decision aids.
Takeda UK Ltd	Draft Guideline	005	022	The NHS Improving Value in Specialised Services: Menu of Opportunity publication outlines the need for Key Performance Indicators to measure quality and efficacy of shared decision making. We consider this to be an important aspect of organisational implementation to ensure provider compliance and enable continued organisational governance through audits against KPIs.	Thank you for your comment. The committee considered any suggested documents for reference in the guideline and decided a reference to the menu of opportunity was not necessary, Recommendation 1.1.9 states: "Plan internal or external monitoring and evaluation (including service user and staff feedback activities) and how to feed back the results to staff at individual, team and management level." and the committee felt this adequately covered the need for monitoring of SDM.
Takeda UK Ltd	Draft Guideline	005	023	We consider that if the organisation is using decision aids which have been developed by partners, they are able to feedback considerations for improvement, using information gathered through evaluation	Thank you for your comment. Improving decision aids through feedback was not seen in either expert witness testimony or PDA reviews and thus is not included in recommendations, however recommendation 1.3.3 does state: "Ensure the

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				processes. Contact details of partners should be accessible to enable feedback.	database [of PDAs] is maintained so that decision aids are regularly reviewed and updated."
Takeda UK Ltd	Draft Guideline	005	029	An online best practice forum, hosted on a central shared decision-making platform, will enable practitioners to share best practice examples, particularly regarding their area of expertise. It is important that speciality practitioners have the opportunity to learn from peers, considering the diverse needs and requirements across therapy areas.	Thank you for your comment.
Takeda UK Ltd	Draft Guideline	006	015	It is important that training of the practitioner involves consideration of individual service-user circumstances, needs and ambitions for care. Practitioners should be trained on how to use relevant shared decision-making tools and aids appropriately, which will prompt them to ask questions to the patient which considers what is important to them. Such training should involve insights from service users, where possible.	Thank you. We believe this is adequately covered in the recommendation.
Takeda UK Ltd	Draft Guideline	006	026	We believe it is equally important for practitioners to champion and promote shared decision making and it should not be limited to those who are involved in the direct consultation and prescribing. Training on the importance of shared decision making should form a part of the core organisational training, to enable it to be a practice that is encouraged at all levels of care and a patient's care pathway.	Thank you. The committee agreed and have acknowledged this in the rationale and impact section.

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Takeda UK Ltd	Draft Guideline	008	004	Resources should also include links to relevant tools which have been developed and approved to support the shared decision-making process, which could be housed on the dedicated shared decision-making platform.	Thank you for your comment. We have now clarified further resources and tools in the recommendation: "only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids."
Takeda UK Ltd	Draft Guideline	008	022	The service user should be given time to consider what is important to them and their needs and preferences before the appointment; any prior communication should direct the patient to the appropriate tools and resources to prompt this thinking, which will enable the service user to enter the consultation feeling prepared.	Thank you. Please see recommendation 1.2.5 which covers offering the person access to resources in their preferred format to help them prepare for discussing options and making shared decisions. Recommendation 1.2.4 has been added which clarifies what information and resources are appropriate to use.
Takeda UK Ltd	Draft Guideline	008	General	It will be important to ensure that there is a mutual understanding of the service user's ambitions, needs and aims of treatment at the start of the consultation, before exploring therapy options, to enable consideration of these requirements throughout the consultation.	Thank you for your comment.
Takeda UK Ltd	Draft Guideline	009	007	Consider using visual materials to explain risks and benefits, which may support decision making, for example the use of Cate's Plots. Visuals are important to ensure tools developed are accessible and inclusive.	Thank you. Please see recommendation 1.4.5 which states: "Think about using a mixture of numbers and pictures (for example, numerical rates, and pictograms or icon arrays) to allow people to see both positive and negative framing at the same time." We would not be able to provide an exhaustive list of numerical and pictorial formats in the recommendations.
Takeda UK Ltd	Draft Guideline	010	023	Patient decision aids should be developed in collaboration with patient representatives or patient organisations, or at least piloted with these groups. This will enable development of	Thank you for your comment. Development of PDAs is outside of the scope of this guideline.

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				materials that put the patient choice first, and will address considerations around language, ensuring the language used is appropriate for the patient community.	
Takeda UK Ltd	Draft Guideline	010	General	We consider that there should be clear guidance around how the tools, which support shared decision making, will be developed. There should be considerations around who will be accountable for their development and an understanding of the process flow, exploring how to involve patient representatives or patient organisations, to ensure the patient voice is considered in development of materials.	Thank you. That is beyond the remit of this guideline.
Takeda UK Ltd	Draft Guideline	011	007	We are concerned that the guidelines do not clearly indicate which version of IPDAS standards or publications it will be using for decision aid assessment. It will be important to clarify exactly what the standards are and make sure they are easily accessible, to ensure that all tools developed are of the required standard and quality.	Thank you. We would expect organisations to use the most up to date version of the standard.
Takeda UK Ltd	Draft Guideline	011	General	There is a lack of clarity around who will be responsible for assessment of the decision aids and if they will be assessed at a national or regional level. If it is a regional level, this may have the potential to lead to a disparity in care across regions. A central database, hosted on an online platform, of approved decision tools would support standardised care and improve ease of review and maintenance.	Thank you for your comment. There is currently no national repository for PDAs.

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Takeda UK Ltd	Draft Guideline	General	General	Takeda welcomes and fully supports the NICE consultation on shared decision making as the NHS works towards its ambition to make personalised care business as usual across the health and care system. We believe shared decision making is a central component to ensure the patient voice is heard and considered in decisions around their care. COVID has propelled the health and care system to reconsider existing care pathways and explore digital routes to optimising patient care. It is essential that, as the system moves to new and improved ways of working, the patient voice is central to the conversation and involved in development processes. As such, we recommend patients should co-create material around shared decision making and that NHS England should create a central digital platform to maximise implementation of shared decision making across organisations and to allow clear signposting for service users. Further to the specific comments below, in general terms, we consider that development of a dedicated online platform for shared decision making would support its implementation and allow for clear signposting for both practitioners and service users. We suggest that NHS England could host such a platform on the dedicated Personalised Care section of its	Thank you for your support. Your suggestions are beyond the remit of NICE and should be referred to the appropriate agency.

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				website. An online platform would allow for a central repository of materials developed and approved for shared decision making; enable practitioners to share best practice specific to their speciality through dedicated online forums; offer a central support hub to support organisations with implementation and training of shared decision making, and offer a portal through which potential partners could submit material or ideas developed to support shared decision making, for consideration by NHS England. As shared decision making should form a part of everyday care, we consider that there should be a clear mechanism for both accountability and progress measurement which can be integrated at an organisational and departmental level. Organisations should be mandated to evaluate their performance against key performance indicators, to support continued governance, delivery and improvement of processes. Furthermore, it will be important to outline who has ownership of the tasks described in the guideline, for example the development and assessment of materials to be used to support shared decision making. Creation of a central digital platform would enable centralised governance, headed by NHS England. It will be important to monitor geographic access to NICE	

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				approved therapies as a key component of centralised governance, ensuring patients have access to all approved therapies for their disease area, which is a key aspect and enabler of successful shared decision making.	
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	004	004-018	Could recommendations on high level leadership be strengthened to include embedding shared decision-making in each organisation's values and strategy, mission statement, and expected behaviours?	Thank you For your comment. The current strength of recommendations does not exclude these things from happening, and NICE is aware many organisations have differing methods of describing values/strategy/mission/behaviours and would not want to limit application of guideline by specifying one structure in particular. However, the rationale does state that high level leadership should "help to instil a culture of involving people who use services across the whole organisation."
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	004	008-013	A "patient director" would be helpful, but carers should also be represented. The patient director would need to understand there is a range of service user voices and would need to be able to hear and represent the differing views.	Thank you for your comment. Recommendation 1.1.2 states that the patient director would be responsible for "raising the profile of the service-user voice in planning, implementing and monitoring shared decision making, especially from those in underserved populations." We feel this covers the patient director understanding the variety of service user views.
Tees, Esk and Wear Valleys NHS	Draft guideline	004	014-018	Using champions can be seen as a soft approach; shared decision-making should ideally be written into all care professionals' roles.	Thank you. Appointing champions is only one aspect of the recommendations for embedding shared-decision making, and NICE recognise the need for an organisation wide plan for

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Foundation Trust				If using champions, a significant number would be needed across a large organisation. Champions would need to have the role written into their job plans with protected time to ensure that this important work is prioritised and not lost when workloads are increased. All leadership roles need to be aligned and embedded in operational structures. Shared decision-making needs to be reflected in policies and pathways, team meetings and care planning structures.	implementing SDM. For more information on planning and implementing SDM please see recommendation 1.1.5
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	004	017	It is unlikely that 1 service user would be enough: There are too many varying views and perspectives.	Thank you. This guideline needs to be relevant to a wide range of healthcare organisations. In a small rural primary care practice (for example), one service user champion might be appropriate.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	005	004-009	Starting with teams where change is most easily implemented is likely to be supported by organisational change models. However, there may be more variation between professions than between teams. There is an argument for focusing practice change efforts on the professional groups with the greatest potential for positive impact. For example, the biggest improvement for people using mental health services may come from sharing decision-making with psychiatrists, but psychiatrists may	Thank you. The committee discussed this at length and chose to recommend departments rather than professions. Training individual professionals in SDM rather than teams did not fit the committees view of an "organisation-wide plan" for SDM. Expert evidence suggested that SDM is embedded best when the practice is taught and performed across a whole team/organisation, rather than individual professions in different teams.

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				share decision-making less readily than nursing staff. In this case, it would make sense to prioritise working with psychiatrists to improve their shared decision-making practice.	
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	006	001-030	Need to have training embedded in staff job plans to ensure it is prioritised. Training is a good introduction but staff report they need practice to change behaviour. It would therefore be helpful to embed shared decision-making in structures for meetings, supervision and care reviews. It would be helpful to add a bullet point to the list in this section recommending that organisations reflect shared decision-making principles in relevant policies and procedures. Training could include example service user stories, or include Experts by Experience as trainers. Shared decision-making should be part of pre-registration courses for all care professionals. Assessment of mental capacity should be a key part of training. Organisations need strong materials (such as story boards, easy-read	Thank you. It is not the committee's role to dictate what should be in job descriptions, the content of training or the curricula for pre-registration training. Other bodies are responsible for this. Assessment of mental capacity is outside the remit of this guideline.

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				materials, comics etc.) to help support decision-making.	
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	006 - 008	015	Drawing out what is important to the person should be at the top of this section as we cannot weigh up the evidence and best options without first knowing what is important to the person and what their goals are. These priorities should frame the discussion. This is a core component of the three step model but local experience suggests this must be presented at the beginning to ensure care professionals take this angle in practice.	Thank you. We have moved this to the top of the section as you suggested, though the list is not in order of priority.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	007	003-005	It would be helpful to strengthen the wording to make it clear that shared decision-making needs to be continuous throughout care and is not a one-off event.	Thank you. The recommendation contains the phrase "so that they are fully involved throughout their care". We believe this conveys the point you raise.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	007	006	Could the guidance be more specific about "methods" that support shared decision-making?	Thank you. This refers to all methods, not specific ones. Any kind of SDM will most likely need to be tailored to the environment in which it is being delivered.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	007	010-012	Could the guidance state explicitly that service users have a right to have someone accompany them to appointments?	Thank you for your comment. The recommendations are phrased in the context of an action, and whilst we agree that service users should be able to have someone accompany them to appointments, this requirement is not an action or specific to SDM and thus is not included in the recommendation.

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Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	007	016	Information given should be documented – not just remembered.	Thank you. See recommendations 1.2.15 to 1.2.21.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	007	018	The recommendation implies shared decision-making is reserved for big decisions and that we know before an appointment that a decision is to be made. In practice, we need to use shared decision-making in every interaction (acknowledging that the support and follow up information provided will vary in line with the complexity of the decision and how far reaching it is, i.e., decision aids and letters etc. are not needed for every decision).	Thank you. The committee agree that shared decision making should be used in all interactions, and we have edited the text of the recommendation to clarify this.. The definition of "discussion" in terms used in this guideline, states a discussion is "any interaction between a healthcare professional and a person using services. It refers to all appointments and consultations (in person or remotely) in which a healthcare decision might be made" In the rationale and impact section, the committee stated "In the committee's view, shared decision making should be treated as an ongoing process rather than a one-off event." To clarify this process is not just for big individual decisions.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	008	005-006	This recommendation categorises people with mental health conditions as a whole as finding it difficult to share in decision-making. This suggests a low expectation of people with mental health conditions and is not accurate. Many can and want to engage in shared decision-making. It would be more accurate to mention those with mental capacity issues but, even then, we need to be mindful that mental capacity should be judged for each individual decision and people should be engaged in shared decision-making wherever possible. The	Thank you. We have amended the wording of this recommendation.

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				guidance should also acknowledge the difference between shared decision-making and informed choice.	
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	008	006-010	Recommend replacing the term “sensory difficulties” with something more specific: Does it refer to sensory impairments (e.g. visual impairment) or sensory processing differences? Should also include people with communication impairments and differences such as autism or ADHD. The list of those who can support should include Speech and Language Therapists. May be helpful to mention reasonable adjustments; the person may have a hidden disability such as dyslexia. Written information should be made available in other languages.	Thank you. The reasons for support given were examples and this is not an exhaustive list. These have now been removed to make it clearer it is at the professional and service user’s discretion regarding need for additional support.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	008	009-010	Being able to choose who provides support before appointments would be helpful. This would allow the service user to choose someone they have a good relationship with. Having an opportunity to discuss shared decision-making with chosen others ahead of appointments, and record views/wishes with a copy given to the care professional, could help service users give their perspective during the appointment.	Thank you. Parents are family members and would be included under this recommendation. This list gives examples of where support 'could' come from and is not exhaustive.

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				Having a list of professions here is limiting because it excludes various people who could be very helpful (e.g. parents). Could replace the list with "appropriate person".	
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	008	015	Could this section use more recovery focused, less medicalised language?	Thank you. The section refers to tests, treatments or other healthcare services. We believe this covers all NHS services.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	008	016-017	It is not always possible to agree a timescale for appointments. Need to acknowledge that this is a gold standard to work to, but care professionals have time constraints.	Thank you. This recommendation (1.2.7) serves exactly that purpose, to make sure that everyone understands the time that is available in the appointment. The committee agreed. As a result, they suggested setting priorities for discussion (1.2.7 and offering a further opportunity to discuss (1.2.10).
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	008	021-023	This recommendation is very important to service users. Some medications have side effects that can make it very difficult to work or get on with activities of daily living. Similarly, some psychological therapies can be very distressing leaving people unable to function day to day. The timing of such interventions needs to be considered in the context of what else is going on in the person's life, including work and caring responsibilities. Could this recommendation be included in the definition of shared decision-making, highlighted in the	Thank you for your comment, the committee agreed on the importance of this point, and agreed placing this action within a recommendation was the mechanism by which to give it the most importance, particularly in the section regarding "during discussions with a healthcare professional", which is the core section where a shared decision making encounter is described .

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				guidance and/or listed as a 'key priority for implementation'?	
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	008	027-029	Could the guidance include "impact" as well as "consequences"? Need to acknowledge that in some circumstances, choosing no intervention can cause anxiety for service users; it may mean they are discharged from mental health services (e.g., from IAPT); it may also lead to detention under the mental health act for treatment.	Thank you. The committee discussed this at great length and agreed that the best way to refer to what is traditionally described as 'risk' as 'risks, benefits and consequences'.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	009	009-010 016-019	It is not always possible or sensible to make a decision by the end of an appointment. Service users may need a few days to digest the information and discuss with family/carers (particularly if they are unwell at the time), before making a decision. In learning disability services, 3 or 4 appointments may be needed to get to a position where a decision can be made. Memory clinic appointments can take 2 hours; need to consider whether the person can engage for that length of time.	Thank you. We believe this is adequately covered by the recommendations.

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				The three step model advocates for a pause before acting; the NICE guidance should make that link.	
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	009	009-013	Need to consider harm minimisation alongside allowing time for consideration and accepting others' views. The person's mental health could deteriorate rapidly and/or there may be a risk of harm or admission, meaning a decision needs to be made more urgently.	Thank you. Urgent decisions are outside the scope of this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	009	016-019	Paragraph could be perceived as coercive: Could amend wording to 'clarify what decisions have been made…' Note this is not always an option when detaining a patient; in these circumstances we must document why shared decision-making was not possible. However, even when someone is being detained, there may be some decisions that can be shared.	Thank you. We have reworded this.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	009	020-022	Practitioners should record how the decision was reached.	Thank you for your comment. Please see recommendation 1.2.17 which states: "When making a record of the discussion (for example, in a person's clinical notes or care plan), record any decisions made along with details of what the person said was important to them in making those decisions. Offer to share this with the person, for example in a post-clinic letter."
Tees, Esk and Wear Valleys NHS	Draft guideline	009	023	This section could also include giving people contact details so they know who to contact for additional support.	Thank you for your comment. The committee agreed this should be clear, and we have added 1.2.19 which states

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Foundation Trust					"Ensure that information provided after discussions includes details of who to contact with any further questions."
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	009	024-028	Other formats such as video or audio recordings of the appointment may be helpful for some people.	Thank you. We have amended the recommendation.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	010	001-005	Letters should be for opt out, rather than opt in.	Thank you. We have amended the recommendation to "Ask people if they would like any clinical letters generated after their discussion with a healthcare professional to be written directly to them, with a copy sent to their GP, rather than just sent to their GP."
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	011	015-	Could this section include 'quality of life' specifically as well as benefits and consequences? Risks and benefits should be considered in the context of what is important to the person (e.g. a mother who wants to take her children to school may not want a medication that will cause sedation in the morning).	Thank you for your comment. This section is primarily focused on communication of risk, benefits and consequences. Quality of life concerns would be incorporated into appointments as discussed in Recommendation 1.2.9 "When discussing decisions about tests and treatments, do so in a way that encourages people to think about what is important to them, and to express their needs and preferences."
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	012	009	Refers to "numerical and pictorial formats". Could it say "consider use of numbers, symbols and pictures to support the person's understanding"?	Thank you. We have amended this.
Tees, Esk and Wear Valleys NHS	Draft guideline	014	010	It would be helpful to rephrase the guidance to underline that shared decision-making is a two way process e.g., replacing clinicians	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its

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Foundation Trust				"describing options" with both clinician and patient "sharing the full range of options", acknowledging that not all options are available in all areas.	effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	014	013	TEWV has started implementing the three step model and alongside this we have been working on human rights. Understanding human rights and taking a rights-based approach to decision-making is a requirement in the public sector and also provides a legal framework for considering decisions. Future research into how human rights legislation supports shared decision-making would be of benefit.	Thank you for your comment. Research recommendations allow the committee to address specific gaps that they found in the evidence that affected their ability to make recommendations. The committee was not tasked with looking at the evidence for human rights legislation and its relationship to SDM.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	General	General	Both staff and service user focus group participants recommended this guidance should be aimed explicitly at mental health, learning disability and social care services as well as physical healthcare services. Shared decision-making is expected by people using mental health and learning disability services, and can be a therapeutic intervention in itself. Failure to provide opportunities for shared decision-making in this setting may be detrimental to service users because it can leave them feeling powerless.	Thank you. As detailed in the scope section 3.2, this guideline covers all settings, including people's own homes, where publicly funded healthcare services are commissioned and provided. This includes people with mental health problems and learning disabilities (except those who are legally lacking 'mental capacity' see scope section 3.1). The scope document is available at https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents
Tees, Esk and Wear	Draft guideline	General	General	Mental health services may have two roles in relation to this guideline: to support shared	Thank you for your comment.

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Valleys NHS Foundation Trust				decision-making in our own services, and to support people with mental health conditions accessing physical healthcare. This is how our Health Facilitation Teams work and is part of the integration agenda. Physical health services should consider the mental health their patients, even if they are not currently accessing mental health services.	
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	General	General	Question 1 re recommendations that would be challenging in practice • In Improving Access to Psychological Therapies (IAPT) services, the scope for choice is limited in line with NICE guidance and the assessment is short with rapid decision-making. Reasonable adjustments are made for those who need them but it would be difficult in terms of capacity and process to give people time to go away and consider their options. What would be the recommendation for shared decision-making in this situation? Question 2 re cost implications: • There are restructuring and cost implications for implementing this guidance well. Organisational infrastructure is needed.	Thank you for this information. The committee felt that shared decision making recommendations could still be mostly followed with limited time, as it is a continuous process there will always be time after one decision to go away and consider options, which includes reviewing a previous decision. This is easier where more time is available but unless emergency situations as set out in the scope should always be possible to some degree. There will also always be options to make decisions on, even if these are limited by guidance, as no decision or no treatment are always options.

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				- A large organisation would need a significant number of trainers; this role would need to be added to job plans and not added on to current roles. Question 3 re overcoming challenges: - Sharing stories about the positive impact for individuals who have benefitted from shared decision-making. - Online courses. - Promotion explaining why it is important. - Sharing good practice so shared decision-making is done meaningfully and does not become tokenistic. - Making shared decision-making a transparent part of processes, setting out that this is an expectation and challenging if it is not delivered.	
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	General	General	Could summary care records and/or hospital passports be used to record preferences/priorities (such as a preference for quality of life over length of life), for use as a starting point for shared decision-making discussions? People's preferences re how they receive information should also be documented.	Thank you. We believe this is covered by rec 1.2.17: "When making a record of the discussion (for example, in a person's clinical notes or care plan), record any decisions made along with details of what the person said was important to them in making those decisions. Offer to share this with the person, for example in a post-clinic letter."

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Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	General	General	The terms "treatment" and "healthcare" do not reflect psychological therapies and therapeutic engagements – could the guidance use the terms "interventions" and "therapies" as well/instead? Could the term "healthcare professional" be replaced with "care professional" to reflect the fact that the guidance is applicable to social care and other sectors? • Might also include chaplains. Staff may be unsure how much information they can share with chaplains which can make it more difficult for them to support service users. Could the term "assessments" be included alongside "tests"?	Thank you for your comment.. The guideline is for settings where NHS services are delivered so healthcare professional is the correct term. We feel "test" and "assessment" are synonymous and can be used interchangeably.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	General	General	The definition of shared decision-making should specifically include service users and their carers, and should cover professionals in the voluntary sector, social care and learning disability services as well as mental and physical healthcare professionals. The definition in the guideline includes 'healthcare professional' (singular), which does not support the MDT philosophy.	Thank you. The definition used for this guideline was 'a person and their healthcare professional'. This was defined during the scoping process and agreed during the consultation on the scope.

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Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	General	General	Need to clarify that advance directives/decisions are used in mental health, learning disability, and physical health services.	Thank you. Shared decision making applies to all situations in which people are making decisions about their health.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	General	General	Could the guideline include an expectation that shared decision-making is documented in the care plan?	Thank you. Recommendation 1.2.17 covers the documentation of decisions. See also 1.2.18 - 1.2.21
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	General	General	The guidance does not discuss the person's ability to retain information or their capacity to make decisions. However, it is noted that NICE makes reference to other guidance that does address mental capacity. Could the shared decision-making guidance include prompts to consider mental capacity?	Thank you. People who lack capacity to make decisions are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	General	General	The guidance does not discuss recovery goals.	Thank you. This guideline is about shared decision making but recovery goals could be discussed as part of a treatment choice, whilst the specific term isn't used, recommendation 1.2.1o talks about what the service user hopes to gain from a treatment or intervention.
Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	General	General	The NICE guidance refers to General Medical Council guidelines re decision-making and consent; it appears to be supplementing existing guidance and this should be clearly stated.	Thank you. This guideline does not consider consent or supplement existing guidance on consent.

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Tees, Esk and Wear Valleys NHS Foundation Trust	Draft guideline	General	General	People may not be optimally well when discharged from mental health wards making this a difficult time for planning and decision-making. It would be helpful if decisions recorded in discharge plans/letters could be given a short review date so all care professionals involved, including GPs, are aware that a follow-up discussion with the patient will be needed at a set time.	Thank you. Please see recommendations 1.2.14 - 1.2.21, as well as 1.1.11 regarding sharing information between services.
The British Pain Society	Draft Guideline	007-008	018-004	In the 'before appointments' section, they would need to send information about having their info in different formats or languages. What if the patient's first language isn't English and they send letters in English or if a patient needs large size text formats?	Thank you for your comment. The NHS Accessible Information Standard (SCCI 1605) mandates that all healthcare and adult social care providers must provide information in a format their patients can read and has been added to recommendation 1.2.4. The recommendations refer to ensuring people understand and receive information in their preferred format. Please see for example recommendations 1.2.4, 1.2.5, 1.2.18.
The British Pain Society	Draft Guideline	008	005-010	Where a patient has "apparent" cognitive ability it may be difficult to gain permission for a partner, family member or advocate to be allowed to participate. Example of an elderly person with late onset dementia who is perfectly credible in many respects but who would not have been able to remember what they had been told and had not understood that their permission was required.	Thank you. We hope the guideline will make this easier.

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The British Pain Society	Draft Guideline	008	009-010	Also include other organisations such as charities - Many charities can help to provide information and support, who may well be able to explain resources to patients. Organisations may also be able to offer impartial advocates. Although advocates are mentioned, it isn't clear if charities or support organisations could be involved.	Thank you for your comment. This list gives examples of where support 'could' come from and is not exhaustive. The committee agreed that advocates could be applicable to patient organisation advocates.
The British Pain Society	Draft Guideline	009	024-028	Are they going to provide this information to patients? Is there sufficient appointment time?	Thank you. This section is for recommendations after or between discussions.
The British Pain Society	Draft Guideline	010	001-005	Should it be suggested where patients don't need to request the copy and should be sent a copy as standard?	Thank you. We have amended the recommendation to "Ask people if they would like any clinical letters generated after their discussion with a healthcare professional to be written directly to them, with a copy sent to their GP, rather than just sent to their GP."
The British Pain Society	Draft Guideline	010	007-010	If a patient can record the appointment- what kind of recording would be allowed? Video, voice recorder, notes? This needs to be stipulated (this is talked about on page 19 lines 20-25) but it just says about electronic devices, does it include videoing on the patient's phone?	Thank you for your comment. These are given as examples of ways an appointment could be recorded.
The British Pain Society	Draft Guideline	010	008-009	Will all follow up materials be available in different languages and formats for accessibility reasons	The NHS Accessible Information Standard (SCCI 1605) mandates that all healthcare and adult social care providers must provide information in a format their patients can read. The recommendations consistently refer to ensuring people understand and receive information in their preferred format. Please see for example recommendations 1.2.4, 1.2.5, 1.2.18.

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The British Pain Society	Draft Guideline	018	025-027	The offering of bringing an advocate should be included on documents as many people may not realise they can do this	Thank you for your comment.
The British Pain Society	Draft Guideline	019	012-015	Having the no treatment option and agreeing when to schedule the next review should be included during the appointment. People need to be given all the options including no treatment. It's also important to know when you would next be reviewed so you're not waiting for a letter telling you that. It's crucial that patients and their caregivers where appropriate should be given all the necessary information to make a fully informed decision as to their course of treatment. It is also important that patients feel fully listened to especially with any fears they may have or concerns they may have about their decision or the treatment. This has been reflected in page 23, but it is important to highlight this.	Thank you for your comment.
The British Pain Society	Draft Guideline	023-024	030-004	It mentions that patients should be told about risks and potential benefits that the patient 'would consider significant for any reason'. If a patient is worried, is shy, or doesn't like to question anything how would the practitioner make the determination of what is important that is 'revealed during your discussion with the patient about what matters to them'? It's crucial to provide all the necessary risks including	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.

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				serious risks and any potential benefit instead of waiting for anything to be 'revealed'?	
The British Pain Society	Draft Guideline	024	012-014	We understand the value of quantifying risks accurately. Similarly patients have access to performance statistics in many instances. How do patients know what numbers are considered low, medium, high risk? Risks can be significantly affected by other factors such as co-morbidities, family history and genetic make-up.	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.
The British Pain Society	Draft Guideline	General	General	Equality - not everyone can assimilate masses of text. Having images, pie charts etc as part of the communication is something that should be considered.	Thank you. The recommendations consistently refer to ensuring people understand and receive information in their preferred format. The recommendations consistently refer to ensuring people understand and receive information in their preferred format. Please see for example recommendations 1.2.4, 1.2.5, 1.2.18.The committee have also added reference to the accessible information standard.
The British Pain Society	Draft Guideline	General	General	Where there are co-morbidities, there are examples where a prior case conference between the different Clinicians would have helped significantly in selection and offers of the best options for treatment.	Thank you. Please see recommendation 1.1.11 regarding "sharing information".
The British Pain Society	Draft Guideline	General	General	There have been examples where a clinician has asked a patient which option they would wish to follow and the patient has not been willing to decide either through lack of intellect and understanding or through	Thank you. The committee agreed this was a concern and made recommendations to encourage and enable people to participate as much as they wanted to.

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				uncertainty regarding the best course of action.	
The British Pain Society	Draft Guideline	General	General	Unclear on how treatment is determined by someone incapable of acting for themselves. How is pain relief on request possible for someone who is not fully conscious or capable of indicating a need for assistance? for example.	People unable to act for themselves are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)
The British Pain Society	Draft Guideline	General	General	We applaud the ideas for structured discussions and for planning but would contend that stating a time to be spent is not necessarily easy to achieve in the average outpatient appointment due to constraints on clinicians' time.	Thank you for your comment. The committee felt that shared decision making recommendations could still be mostly followed with limited time, as it is a continuous process there will always be time after one decision to go away and consider options, which includes reviewing a previous decision. This is easier where more time is available but unless emergency situations as set out in the scope should always be possible to some degree. There will also always be options to make decisions on, even if these are limited by guidance, as no decision or no treatment are always options.
The British Pain Society	Draft Guideline	General	General	The matter of medical confidentiality is an important one , but there are examples when a long-term partner, sibling or advocate has been excluded from being made aware of important medical information through the constraints of confidentiality and a lack of a suitable document providing permission.	Thank you. The committee discussed this. It was clear that people should have a choice about whether anyone else was part of their care. It was aware of the potential for coercion and control, but also that carers or family member could be facilitators of the SDM process and great supporters of the patient or service user.

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The Challenging Behaviour Foundation	Draft Guideline	004	General	Any high-level leaders responsible for embedding shared decision making should have sufficient understanding of the decision-making needs of people with learning disabilities and those who support them. For example, they should be mindful of inclusive approaches to communication and the relevance of the Mental Capacity Act	Thank you for your comment. The appointed leaders should be following the other recommendations in this guideline when it comes to the embedding of high quality SDM, and ensuring support is available for those with learning disabilities is covered in recommendation 1.2.6 and the rationale.
The Challenging Behaviour Foundation	Draft Guideline	005	020	Any plans for how people who use services will be involved in supporting the implementation of shared decision making (including through participation in evaluation processes) should be accessible to people with learning disabilities. Particular efforts need to be made to gather the views of adults with severe learning disabilities. Additional efforts should be made to include family carers and others who support the individual in implementation of shared decision making.	Thank you. Due to differing organisational structures and process the implementation of SDM will be different in each organisation. This guideline provides the requirements for ensuring that SDM happens but how it is implemented is for individual organisations to agree.
The Challenging Behaviour Foundation	Draft Guideline	006	005	In addition to the topics outlined, training and development for practitioners should include additional training on communication aids such as Talking Mats and a range of communication support individualised to personal needs, which may include symbols, photographs, Makaton signs, gestures, Now & Next charts and others. This will help to ensure that the goal of clear communication is met in respect to young people and adults with learning disabilities who	Thank you. This guideline is intended to be applicable to a broad range of organisations and each will need to identify its specific requirements, including for training in different communication skills.

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				have additional communication needs. There is a wide spectrum of learning disability- ranging from mild/ moderate to severe and profound. Different methods will be required according to need- for example, easy read materials for people with mild learning disabilities, whereas objects of reference may be more suited to someone with complex needs – but it needs to be individualised.	
The Challenging Behaviour Foundation	Draft Guideline	007	010-016	Practitioners should be aware of their obligations under the MHA and MCA in terms of involving family, friends and advocates in a patient's care where the patient may lack relevant capacity to express their desire to include these persons	Thank you. People who lack capacity are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents).
The Challenging Behaviour Foundation	Draft Guideline	008	005	Young people and adults with severe learning disabilities whose behaviours challenges should be included among the examples of groups who may find it difficult to share in decision making. This should encourage relevant professionals to ensure they communicate effectively with this group.	Thank you. The reasons for support given were examples and this is not an exhaustive list. These have now been removed to make it clearer it is at the healthcare professional and service user's discretion regarding the need for additional support.
The Challenging Behaviour Foundation	Draft Guideline	008	009	If a person with learning disabilities requires additional support to help them share in decision making, this support should be provided by someone with sufficient expertise in learning disabilities and/or autism and if possible, someone who knows the individual well. This could be an advocate of family members. Family carers often know the individual best and should	Thank you for your comment.

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				be included in discussions around additional support an individual might need.	
The Challenging Behaviour Foundation	Draft Guideline	008	021	A clinical/unfamiliar environment is stressful for many people and it can be especially stressful for someone with a learning disability and/or autism. Therefore, proactive measures should be taken to record an individual's preferences for tests and treatments in advance of their exposure to new environments and people which might make it more difficult for them to communicate their preferences at a time of stress.	Thank you. Please see recommendations 1.2.3 and 1.2.6. The committee agreed those with learning disabilities and/or autism can be included in this group of those who "might find it difficult to share in decision-making" but did not want to specifically define groups of people in case this excluded a particular group or assume a group of people could never competently share in decision making.
The Challenging Behaviour Foundation	Draft Guideline	009	024	All resources and information should be available in accessible formats and be prepared to cater for any additional communication requirements of patients.	Thank you. We have added a reference to the accessible information standard.
The Challenging Behaviour Foundation	Draft Guideline	010	011	We would recommend that family carers and support workers of people with learning disabilities and/or autism be included in this information sharing to ensure consistency of support. Family carers often know the individual with learning disabilities best, and therefore will also have useful expertise and information to share with practitioners and services.	Thank you. People with learning disabilities who have capacity will choose whether they want family carers and support workers involved. People who lack capacity are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents).
The Challenging Behaviour Foundation	Draft Guideline	011	011	Facilities and systems must also be prepared to provide patient decision aids in formats appropriate for those with additional communication needs. For example, through the use of Talking Mats and a range of communication support individualised to the	Thank you. This would be a matter for decision aid repositories.

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				person's needs, which may include symbols, photographs, Makaton signs, gestures, Now & Next charts.	
The Challenging Behaviour Foundation	Draft Guideline	012	005	People with learning disabilities often have health conditions that may make them more clinically vulnerable than the rest of the population. Data from the Learning Disability Mortality Review (LeDeR) shows that on average, people with learning disabilities die 15-20 years younger than the general population. We are concerned that generic advice on risk vs. benefits may not accurately reflect the risk vs benefits for this group and therefore extra efforts should be made to personalise information on risks and benefits for this group. Evaluation of the risks and benefits for individuals with learning disabilities should also include consideration of the impact of testing and treatment.	Thank you for your comment. The NHS Accessible Information Standard (SCCI 1605) mandates that all healthcare and adult social care providers must provide information in a format their patients can read. The recommendations consistently refer to ensuring people understand and receive information in their preferred format. Please see for example recommendations 1.2.4, 1.2.5, 1.2.18.
The Challenging Behaviour Foundation	Draft Guideline	014	015	We welcome the recommendation for further research 'How do the same decision making interventions differ in effectiveness between different groups of people and different care settings' and insist that people with learning disabilities and/or autism should be included in this study should it be conducted. The pandemic has exposed the extent of the health inequalities suffered by people with learning disabilities and	Thank you for your comment.

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				more research is needed to better understand how guidance can be made more inclusive. There is a wide spectrum of learning disability- ranging from mild/ moderate to severe and profound. Different methods will be required according to need- for example, easy read materials for people with mild learning disabilities, whereas objects of reference may be more suited to someone with complex needs – but it needs to be individualised.	
The Challenging Behaviour Foundation	Evidence review C	Gene ral	gene ral	We are concerned that the aids outlined in this guide would not be appropriate for people with complex communication needs. These individuals have the same right to be involved in decision-making related to their care. The guidance should be clear as to how practitioners can adapt this information and share it in a more accessible format to include young people and adults with learning disabilities in decisions. There is a wide spectrum of learning disability- ranging from mild/ moderate to severe and profound. Different methods will be required according to need- for example, easy read materials for people with mild learning disabilities, whereas objects of reference may be more suited to someone with complex needs – but it needs to be individualised.	Thank you. We believe the guidance is clear that decision aids are not always useful and that they are one part of the SDM process. The guideline has recommendations to provide extra support in cases where it is needed (1.2.6) which the committee agreed could include those with learning disabilities, and to provide information in an accessible format in line with the accessible information standard (1.2.4)
The Haemophilia Society	Draft Guideline	004	016	The guidelines should more strongly suggest that at least one service user representative should be on the board (if one exists) or directly	Thank you for your comment.

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				working with the responsible board member. Their role should be greater than simply a 'service user champion' and should have more direct input and responsibility.	Recommendation 1.1.4 outlines the role of service user chamions to "work with the senior leader, patient director and professional champions for shared decision making." They should be recruited from people who use services.
The Haemophilia Society	Draft Guideline	005	013	The recommendation should go further and suggest that organisations seek out disease-specific decision aids by approaching relevant patient-groups, such as The Haemophilia Society and clinician groups (e.g UKHCDO, The United Kingdom Haemophilia Doctors Organisation and the HNA, Haemophilia Nurses Association)	Thank you. Regarding seeking out decision aids, recommendation 1.3.4 states that staff have access to quality-assured patient decision aids. This could be by maintaining a database of decision aids that are regularly reviewed and updated, or signposting staff to decision aids produced by national bodies such as NICE.
The Haemophilia Society	Draft Guideline	006	009	Organisations should look to use tool and guidance created by patient-groups to aid in communication with patients and supporting shared decision-making.	Thank you for your comment.
The Haemophilia Society	Draft Guideline	006	018	We would welcome a stronger recommendation that service-users should be involved in training design and delivery.	Thank you. The committee did not see specific evidence relating to this, but it could be one way that service users are involved in implementing shared decision making (see recommendation 1.1.6) Service users are recommended to be involved at higher organisational levels and should be able to make decisions on how training for SDM is implemented alongside other senior organisational staff. (see recommendation 1.1.4)
The Haemophilia Society	Draft Guideline	008	003	Rather than suggesting linking to NICE guidance and information the guidelines should encourage linking to more accessible information such as information provided by patient organisations such as The Haemophilia Society.	Thank you for your comment. We have added a reference to patient organisations in the recommendation.

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The Haemophilia Society	Draft Guideline	008	017	The guideline should recommend that appointments should be long enough to allow full consideration and discussion of the available tests and treatment options.	Thank you. The committee agreed this would be unrealistic within current resources. Instead, they recommended offering further opportunities for discussion (recommendation 1.2.10)
The Haemophilia Society	Draft Guideline	008	027	The guideline should explicitly recommend that theoretical or potential risks are mentioned and the clinician explains what is known and to what extent the risk is quantified and understood.	Thank you for your comment. It is anticipated this should be addressed in the discussion of risk, which is outlined in section 1.4. Discussing risks when offering tests, treatments or other interventions is also mentioned in recommendation 1.2.10
The Haemophilia Society	Draft Guideline	009	027	Relevant information should include factsheets and guidance produced by patient organisations such as The Haemophilia Society.	Thank you. We have modified recommendation 1.2.4 to acknowledge the role of patient organisations: "When providing information and resources: only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids." This would also cover information provided in recommendation 1.2.18
The Haemophilia Society	Draft Guideline	General	General	To reach an appropriate decision in terms of treatment, it is critical to consider what outcomes matter most to the patient and that they have full and accurate information. Effective decision making requires that both NICE and NHS England provide information about available treatments and commissioning decisions. NICE should encourage and work with NHS England to ensure this information is published, accessible and highlighted to patients. All information, guidance and decisions should be published in plain English explaining technical terms to ensure accessibility.	Thank you. In the context of this guideline we believe this is covered in the recommendations in section 1.2. It is beyond NICEs remit to make recommendations to NHS England.

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				The Haemophilia Society's 2019 survey showed that many people with bleeding disorders are entirely unaware of what treatments and types of care they should be able to access. The survey also showed that only half of people with bleeding disorders felt able to influence decisions about which treatments are prescribed to them. Personalisation and co-decision-making should become the norm. However, this can only occur if clinicians take the time to fully understand their needs and objectives and provide them with full details of available treatments and their advantages and disadvantages.	
The Medical Technology Group	Draft Guideline	004	004-007	Shared decision making should be instituted as a standard form of best practice in everyday clinician-patient relationships. Whilst making a board member responsible for shared decision making is worthwhile, the guideline will only be effective if all board members lead by example. The accountable board member's responsibilities should focus on championing wider culture change that puts patient choice at the heart of decision making.	Thank you for your comment. The committee acknowledged this in the rationale: "In their experience, having a commitment from senior managers and leaders to shared decision making is essential because they can make sure resources are prioritised to support it and help to instil a culture of involving people who use services across the whole organisation."
The Medical Technology Group	Draft Guideline	004	011-013	Embedding the patient voice at the highest level of organisations through the creation of a patient director role is a positive step. However, the role cannot be merely symbolic and should go	Thank you. The role has been left open so that organisations can implement the role in such a way that best suits their own organisational structures and requirements. The role is

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				beyond "raising the profile of the service-user". The patient director should be in a position to co-produce solutions with his or her peers that impact patients. A description with more detail around how this could work in practice would be welcome.	intended to be a director level role and it's anticipated they should be in a position to effect change.
The Medical Technology Group	Draft Guideline	005	001-009	All teams, whether or not they work in a patient facing role, must have an understanding of the value of shared decision making as the bedrock of best practice in the delivery of care.	Thank you. The committee agreed.
The Medical Technology Group	Draft Guideline	007	018-020	Before an appointment where a decision will be made, patients should be provided with information in their preferred format to help them prepare for the discussion. The MTG welcomes the outline of this process in the guideline.	Thank you for your support.
The Medical Technology Group	Draft Guideline	008	001-004	There should be a recognition that NICE guidance is not an accessible resource for patients in and of itself. NICE guidance should be given to patients in addition to other more accessible kinds of information.	Thank you for your comment. We have now included "only use reliable, high-quality sources such as NICE-accredited information, links to NHS.uk, information from appropriate patient organisations or relevant NICE guidelines and quality-assured patient decision aids" and "take into account accessibility and the requirement to meet the NHS Accessible Information Standard" as part of recommendation 1.2.4.
The Medical Technology Group	Draft Guideline	016	024-025	Given the new ways of working which have come out of the Covid-19 pandemic, more could be said about digital consultations in the guideline. In a recent patient survey, the MTG found that 40% patients rate technology as less effective than face to face contact with their clinician. It is essential that digital tools	Thank you for your comment. The skills of SDM in remote settings are the same as in face to face settings, and this has been added to the rationale and in a new recommendation and research recommendation. The committee acknowledged the changing situation with an increased reliance on remote discussions, but felt more

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				incorporate and allow for shared decision making. For example, online tools that prioritise convenience, may inadvertently make patient interactions overly transactional.	evidence was needed to make a specific recommendation, and thus a research recommendation has been added to look at evidence for remote discussions.
The Medical Technology Group	Draft Guideline	General	General	The Medical Technology Group (MTG) welcomes the development of this guideline. The group believes that the NHS must ensure that patients are able to make an informed decision about the best treatment for them. A practice of shared decision making will help to create a culture that listens to the voice of patients.	Thank you for your support.
The Patients Association	Draft Guideline	004	004-007	We agree that making a board member or senior leader accountable and responsible for shared decision making may often be helpful. However, shared decision making must be presented throughout this guideline as an approach and a way of working, and not reduced to the status of a formal process: this risks making it appear as something that can be done mechanistically – a set form that is followed – or, at worst, as something that can optionally be done or not done. It must be explicitly clear that shared decision making is the way in which clinicians and professionals are expected to go about their jobs, not merely a process to add to their work. Phrases such as 'roll-out' risk giving the latter impression, as does any suggestion that individual staff members are exclusively responsible for it and therefore, implicitly, others	Thank you. We have changed the word 'roll-out'. The committee agreed that buy in from leaders was critical and therefore made the recommendations in section 1.1. The committee agreed that senior management buy-in is essential, this is captured in the rationale: "The importance of strong leadership was a particularly prominent theme in the expert evidence and this was supported by the committee's views. In their experience, having a commitment from senior managers and leaders to shared decision making is essential because they can make sure resources are prioritised to support it and help to instil a culture of involving people who use services across the whole organisation."

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				do not need to concern themselves with it (although clear responsibility for oversight and training is of course desirable). A clear statement is also required at this stage that buy-in across all leaders and senior clinicians is essential.	
The Patients Association	Draft Guideline	004	008	Appointing a patient director is a welcome recommendation, though not sufficient on its own, for the same reasons as in comment (4): shared decision making must clearly be a required approach for everyone, and not seen to be siloed as the responsibility of one person or team but not others.	Thank you for your support.
The Patients Association	Draft Guideline	004	010-011	We agree that a focus on securing greater involvement from under-served populations is desirable, and this might be addressed more thoroughly throughout the guideline as a whole (see also comment 11). However, we are unsure what is meant by 'raising the profile of the service-user voice in shared decision making'. By definition, if the patient voice is absent or inadequately heard, shared decision making cannot be taking place. This language verges on jargon and the intended meaning here should be stated more clearly.	Thank you. We have clarified that this means planning, implementing and monitoring SDM at an organisation level.

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The Patients Association	Draft Guideline	004	012-013	We support embedding shared decision making at the highest level of the organisation; this needs to be a central recommendation in its own right, not just something that the appointment of a patient director can do (although that will be helpful).	Thank you. The first recommendation requires organisations to make a senior leader level member responsible for SDM in the organisation. We kept the term broader so as to include organisations that do not have aboard. There are also further roles for embedding decision making (recommendation 1.1.2 – 1.1.4) the initial recommendation is to ensure that a senior leader is involved in the shared decision making embedding process, not to ensure that they are the sole responsibility for it.
The Patients Association	Draft Guideline	004	017-018	Appointing patients as 'service-user champions' may be helpful, but will not be sufficient; anything that gives the impression that shared decision making is an extra or add-on in any way could be counter-productive to embedding it as the default way of working. The guideline could perhaps be phrased more in terms of numerous champions being appointed: in most organisations, it will be too big a task for one person, or even a limited handful of people as suggested by 'one or more'. Also, we suggest the term 'patient' rather than 'service-user': our research suggests that as a general term, 'patient' is well understood and broadly accepted. As currently drafted the guideline switches back and forth between different terms. See our report 'Being A Patient': https://www.patients-association.org.uk/blog/being-a-patient.	Thank you. The committee agreed, which is why service user champions are one small part of the overall strategy. NICE uses the term service user to reflect a broader population than patients, for example people using maternity services are not patients, people using mental health services do not prefer to be called patients, and many public health services do not have patients. Since the guideline if for general embedding of SDM across all settings, NICE cannot recommend a certain number of patient or healthcare professional champions.

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The Patients Association	Draft Guideline	004	General	The guideline would benefit from a clear opening statement of what is meant by shared decision making, and why it is important to practise it. This material exists elsewhere in the guideline (for instance on page 14 rows 1-5, page 22 rows 27-20 and page 23 rows 1-10), but for clarity, and to ensure readers approach the rest of the guideline with a common understanding, it should be stated at the beginning. This material would also be helpful in making clear that shared decision making is an overall approach, and not a formal process (see next comment).	Thank you. Shared decision making is defined in the 'terms used in this guideline' section and hyperlinked from each section where it is used.
The Patients Association	Draft Guideline	005	001-003	Shared decision making needs to be embedded across whole pathways of care, and systems, not just within organisations. Particularly in light of the NHS's proposed shift to more integrated, system-based working, these recommendations could usefully be couched in those terms.	Thank you. The guideline aspires to shared decision making being embedded across the NHS.
The Patients Association	Draft Guideline	005	001-009	All teams across an organisation (or that work across a system or pathway) must have a shared understanding of the value of shared decision making, as well as appropriate knowledge of ways of delivering it. This shared understanding could in part be developed by identifying good practice already taking place and promoting it across the rest of the organisation, as suggested here. However,	Thank you. That is what this guideline aims to do. There are a series of recommendations on what good SDM looks like (Section 1.2).

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				the current text offers no criteria for assessing what constitutes good practice. We recommend that the need to develop a common understanding of shared decision making should be re-stated here, and clearer guidance given on how to identify existing good practice, perhaps with reference to appropriate key points elsewhere within this guideline.	
The Patients Association	Draft Guideline	005	001-009	This section in particular risks presenting shared decision making as a process rather than a way of working. This risks procedures being followed by rote or in form only, creating auditable box-ticking that purports to show that shared decision making is taking place, but in fact implements none of its practice, and secures none of its benefits for patients. We accept there is a tension here: without some kind of formal standing, it is difficult to implement shared decision making, or to show that it has been implemented. Assessing and measuring whether it is 'being practised routinely' is difficult, as research into the question has repeatedly shown, and as the recommendation for further research (page 14, lines 18-20) acknowledges. But on balance we advise against presenting it simply as a matter of form and process, which risks giving an unhelpful steer to clinicians and professionals.	Thank you. As you suggest, the committee was mindful that SDM needs to be built into the organisational structure as well as being part of a culture. The committee agreed that cultural change needs to start at the top and made recommendations at organisational level to encourage this.

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The Patients Association	Draft Guideline	005	001-029	Marginalised groups could have the most to gain from being empowered to participate in decisions about their care, as is implicitly recognised on page 4, lines 10-11. This could be clarified in this section on organisational planning: it must be done in such a way as to ensure this benefit is realised, which will mean a requirement to engage with all patient populations, including those that an organisation might have found harder to engage with previously.	Thank you for your comment. The committee recognised the importance of engaging with these groups, and this is why t the very highest level recommendation 1.1.2 states the directors role is "raising the profile of the service user voice in planning, implementing and monitoring shared decision making, especially from those in under-served populations".
The Patients Association	Draft Guideline	005	001-029	Patients vary in the extent to which they want to be involved in decisions, but even those who want to leave it to their clinician's judgement still usually value clear information about what's happening with their care. This benefit, and the close relationship between shared decision making and communication might usefully be outlined in this section, or elsewhere in the guideline.	Thank you. Please see the recommendations in section 1.2, especially 1.2.9: "When discussing decisions about tests, treatments and interventions, do so in a way that encourages people to think about what matters to them, and to express their needs and preferences." We have also added further detail about this to the rationale and impact section of the guideline.
The Patients Association	Draft Guideline	005	020-021	It is unclear what is meant by, "Set out how people who use services will be involved in supporting implementation." The guideline should explain what activity, or what sort of activity, should be undertaken in this respect, and for what purpose.	Thank you. Due to differing organisational structures and process the implementation of SDM will be different in each organisation. This guideline provides the requirements for ensuring that SDM happens but how it is implemented is for individual organisations to agree.

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The Patients Association	Draft Guideline	005	022-024	The question of evaluation and feedback returns to the issues relating to how to identify when, and how well, shared decision making is being practised. Can the guideline say more about how the practice of shared decision making can be identified, and its efficacy evaluated, albeit that more research is needed?	Thank you. As you note, more research is needed in this area and the committee made a priority research recommendation (research recommendation 2 - measuring shared decision making).
The Patients Association	Draft Guideline	005	027	We are unsure what is meant by 'practitioners' of shared decision making. This ought to be all clinicians and professionals, so what distinction is this point attempting to make?	Thank you. The recommendation has been reworded to use the phrase "healthcare professionals" to match your comment and is hopefully clearer.
The Patients Association	Draft Guideline	006	001-024	Research suggests that there are gaps between both clinicians' and patients' views of the value of involving patients in decisions, and their perceptions of how effectively this has been done – clinicians can sometimes feel they have involved the patient more meaningfully or effectively than the patient does. The guideline might usefully emphasise the importance of ensuring consistent, shared understanding on both of these issues.	Thank you. Please see recommendations in section 1.2, especially 1.2.10
The Patients Association	Draft Guideline	006	001-024	The guideline might usefully address concerns that some clinicians and professionals are known to have about shared decision making. For instance, it is sometimes thought that it is only of interest to educated, middle class	Thank you. The Montgomery ruling is discussed in the context section of the guideline. The committee agreed that communication skills are vital to SDM and envisaged that these would be the kinds of skills that training would cover.

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				patients; it might usefully be made clear that people from all backgrounds and walks of life can be engaged if done well. Similarly, some fear that complying with the Montgomery ruling can only be done by overwhelming patients with information, in turn wasting time and leading patients to make poor decisions; the guideline might usefully mention the ruling directly in its main body, and make clear the link between shared decision making and informed consent. A common thread through these concerns, and the answers to them, is that communication skills are a core part of the clinician's toolkit, and must be recognised as such. It might also be emphasised that there still comes a point when clinicians must exercise their clinical judgement: deciding what information to provide to a patient, for instance, still ultimately rests with the clinician, and the onus is on them to make efforts to avoid consciously or unconsciously biasing or skewing the shared decision making process when they decide what information to provide. Shared decision making still requires clinicians to use their judgement, and clinicians who are sceptical of it should be reassured that the involvement of	

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				patients is a way to deploy their clinical judgement to improved effect, not to supplant or override it.	
The Patients Association	Draft Guideline	006	005-017	In this list of elements to be included in training, the item 'drawing out what is important to people' should be placed higher. Probably the only item that should come ahead of it is an understanding of the importance and value of shared decision making, which should feature prominently in training materials. The sequencing of a list of this sort can be important, and readers can take cues from it consciously or unconsciously. Given how far there is to go to embed shared decision making as a standard way of working, a clear understanding of why it matters and the need to understand what matters to patients should be the top items.	Thank you. We have moved this to the top of the list.
The Patients Association	Draft Guideline	007	003-004	Generally we would expect that material that has been produced by patient charities or other organisations, and endorsed by NICE, might be more directly helpful to patients than NICE guidelines themselves, which are both thorough and somewhat technical. The emphasis could perhaps be adjusted here to recommend that patients be directed towards helpful patient-focused information and material, and allowing for the possibility of them reading NICE guidance rather than putting its first on the list.	Thank you. We have reversed the order so that NICE endorsed information is first and added a reference to patient organisation materials.

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The Patients Association	Draft Guideline	007	003-009	We are unsure what is meant by 'interventions that support shared decision making'. Making an offer to people at all stages of discussions with professionals may well be desirable, but it is unclear what the guideline is proposing they should be offered. If shared decision making has been embedded as everyday practice, what more needs to be offered? The jargon-heavy terminology used here is unhelpful in making clear to patients what they should expect. Similarly, the intended meaning of the term 'methods that are best suited to support shared decision making' is obscure and should be clarified.	Thank you. The committee wanted to leave the interventions broad as they are wide ranging. Specific interventions are mentioned in the subsequent recommendations in the section.
The Patients Association	Draft Guideline	008	016	The guideline should expand on what is meant by the term 'agenda'. Clearly the use of the term is awkward in some way, as the draft text already puts it in inverted commas: explanation should be given of exactly what is meant. Should the 'agenda' be a formal document? Probably in many situations this would not be suitable; perhaps the intended meaning is that clinicians and professionals should agree items to be discussed with patients at the outset, and use their judgement about the individual situation to determine whether to capture this in writing or less formally, including by asking the	Thank you. The agenda is to prioritise what to discuss, the recommendation does not specify that the agenda needs to be a formal document, but simply an agreement on what each party wants to focus on in the discussion. Regarding recording the outcomes of these discussions, this is addressed in recommendation 1.2.15 and 1.2.17

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				patient what they would prefer (unless there is a good reason not to).	
The Patients Association	Draft Guideline	008	024-029	As with comment 19 above, the sequencing of this list should be considered. The item on clarifying what the person hopes to gain (in fact listed on page 9) should probably come first.	Thank you. We think the order currently reflects the order in which an appointment might address them.
The Patients Association	Draft Guideline	009	020-026	Point 1.2.15 usefully recommends that at the end of an appointment the clinician or professional should record what was decided, as well as what the patient said was important to them. This note should be shared with the patient immediately if this is possible, or shortly afterwards if not: point 1.2.16 recommends giving patients resources to help them understand what was discussed and decided, including a summary of plans made; this could more usefully be tied in with the previous point, making clear that notes should be shared as fully as possible and as promptly as possible with the patient.	Thank you. We have amended recommendation 1.2.16 to state "Give people resources to help them understand what was discussed and decided in their appointment. This could be a printout summarising the options and decisions or plans made, and links to high-quality online resources (for example, relevant NICE guidelines). Ideally, give people this material to take away, or provide it very soon after the appointment."
The Patients Association	Draft Guideline	010-011	017-023, 001-005	This material on using patient decision aids is presented before the explanation of what they are on page 13 (lines 9-17). This sequencing is likely to be unhelpful to the reader and should be reconsidered, with the overview of patient decision aids placed earlier. It could also usefully be emphasised that there is	Thank you for your comment. These recommendations are linked to the relevant sections of the guideline that the reader can jump to, should they require further information.

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				considerable variety in the aids that are available and the scope of what they do: some may be simple guides to help patients take part in discussions with clinicians, while others may be in-depth resources for particular conditions or treatment options. This understanding will be useful in equipping staff to seek out appropriate aids to use, at appropriate points.	
The Patients Association	Draft Guideline	016	009-017	This is a useful discussion of why effective leadership is essential to delivering shared decision making; this could be stated more directly in the guideline itself, in addition to the procedural recommendations for possible board appointments and so on.	Thank you for your comment. The recommendations provide actions to be taken to achieve embedding of SDM, whilst the rationale and impact explains why this should be done.
The Patients Association	Draft Guideline	016	024-025	More could be said about digital healthcare tools, both here and in the main body of the guideline. For instance, it is important that newly developed digital tools incorporate and allow for shared decision making: some online tools that prioritise convenience, for instance, may inadvertently make patient interactions overly transactional, and become a barrier to securing the benefits of shared decision making.	Thank you for your comment. In terms of digital technologies for the patient and practitioners interaction specifically, see our recommendations for PDAs and risk communication tools that clearly state these digital tools must be of a high standard.
The Patients Association	Draft Guideline	020	019-022	The discussion is right to say that patient decision aids, while helpful, do not on their own deliver shared decision making. This could usefully be stated in the guideline itself. Tools for	Thank you for your comment. Please see recommendation 1.3.1 that clarifies to "use patient decision aids as one part of an overall 'toolkit' to support

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				use by patients must be accessible in language and style.	shared decision making alongside the other skills and interventions outlined in sections 1.2 and 1.4 of this guideline”. This shows that PDAs should be considered alongside other SDM interventions, not as a sole solution.
The Patients Association	Draft Guideline	023	007-010	This stipulation that patients may sometimes prefer not to take an active role in decisions is helpful, and could usefully be included in the main guideline. Clinicians must, as part of their shared decision making skill set, be able to respond to patients’ preferences about the extent of their involvement, and be able to provide appropriate information and support to patients who genuinely don’t wish to take an active role in decision-making, without attempting to force the issue. (See also comment 12, above.)	Thank you for your comment. Recommendation 1.2.8 states “Ensure the person understands they can take part as fully as they want in making choices about their treatment or care. Which the committee feel covers those who do not wish to take part in SDM.
The Patients Association	Draft Guideline	023	022-027	This pithy discussion of the implications of the Montgomery judgment for informed consent and shared decision making could usefully be included in the main guideline.	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice.
The Patients Association	Draft Guideline	General	General	We welcome the development of this guideline and support its aims. We believe that the NHS needs to develop a culture of listening to patients and valuing what they say, and that embedding shared decision making will be an important step in achieving this. It will require buy-in throughout the NHS to the idea that	Thank you for your support.

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				shared decisions are beneficial; in individual organisations, this needs to come from senior leaders. There is a long way to travel: we know that some clinicians and professionals doubt the value of patient input, and this is particularly corrosive to an organisation's culture when it comes from senior clinicians.	
The Patients Association	Draft Guideline	General	General	The guideline might usefully make clear when patients will get the opportunity to initiate discussions or review decisions already made; or, even better, make clear that clinicians and professionals should be prepared for the patient to make a request to discuss or review choices at any time.	Thank you. We believe this is inherent in recommendations 1.2.7, 1.2.14 and 1.2.15.
The Royal College of General Practitioners	Draft guideline	001	Box	The guideline is stated to apply to over 18 year olds. Can the committee consider adding young adults who are Gillick competent to ensure young adults are also included within the shared decision making guidance.	Thank you. People under 18 are excluded from this guideline. Please see section 3.1 of the scope document (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents) However, please note that NICE is currently developing a guideline on patient experience of healthcare for babies, children and young people, which considers shared decision making. Please see https://www.nice.org.uk/guidance/indevelopment/gid-ng10119 for information on the development of this guideline
The Royal College of General Practitioners	Draft guideline	004	002	Can the committee add the definition of shared decision making at the beginning of the guidance for clearer understanding?	Thank you. Shared decision making is defined in the 'terms used in this guideline' section and hyperlinked from each section where it is used.

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The Royal College of General Practitioners	Draft guideline	004-005	002-018; 001-029	Can the committee consider the organisational structure within general practice when talking about high level leadership changes, planning and implementing shared decision making? Currently the guidance appears to only refer to large organisations such as trusts. It is essential to consider where shared decision making leads would fit within the structure of primary care, and how leads would work with practices if appointed at a system level.	Thank you for your comment. This guidance is a general guideline aimed at all organisations, and individual organisations should be able to adapt the guidance to their own organisation size, setting and context.
The Royal College of General Practitioners	Draft guideline	005	013-019	Can the committee consider adding the recommendation of the regular use of the SNOMED "Shared decision making" code within primary care in order to show that shared decision making has occurred or been declined or considered inappropriate. This would then enable auditing of notes and improvement in practice through audits and random case analysis	Thank you for your comment. The committee felt recommending SDM as a code in primary care would just create a "box-ticking exercise" and that the real way to encourage SDM is a shift in culture and the recommendations seen in this guideline.
The Royal College of General Practitioners	Draft guideline	008	015-022	Can the committee consider adding a section on the limits and boundaries of shared decision making, including recognition of the following: • There may be situations where shared decision making is inappropriate or unsuitable. Shared decision making and potential information overload can upset and be a burden for some patients, particularly those who are naturally risk averse and/or unprepared to challenge healthcare professionals. This is	Thank you. People who lack capacity are excluded from this guideline, everybody else should be involved in shared decision making to the extent that they wish (see recommendation 1.2.8

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				especially true with regard to life or death decisions such as around cancer treatment or the withdrawal of treatment as well as potentially controversial ethical topics such as termination of pregnancy or aesthetic plastic surgery procedures. See Montgomery v Lanarkshire (2015). - Some patients may be poorly motivated or have impaired capacity which limits their ability to engage with shared decision making. - Some patients may have unrealistic expectations of what can be offered and achieved. There may be conflicting values between the clinician and the patient which would need to be managed with care.	
The Royal College of General Practitioners	Draft guideline	009	009-010	Can the committee add that giving "enough time to make decisions and tests and treatments" may mean the decision needs to be made later in the day or on different day, rather than during the individual consultation.	Thank you. The wording of this recommendation has changed.
The Royal College of General Practitioners	Draft guideline	009	020-022	It is important to note that good quality documentation of discussion and decisions can be time consuming especially if the discussion is complex or challenging and this will increase time and resources required to implement shared decision making	Thank you for your comment.

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The Royal College of General Practitioners	Draft guideline	010	001-005	Can the committee consider making this recommendation more implicit. Patients should *always* be asked if they would like information to be sent to their GP. The sharing of information between secondary, tertiary and primary care is crucial for continuity of care.	Thank you. We have amended the recommendation to "Ask people if they would like any clinical letters generated after their discussion with a healthcare professional to be written directly to them, with a copy sent to their GP, rather than just sent to their GP."
The Royal College of General Practitioners	Draft guideline	020	007-014	Can the committee consider adding that a system wide change may be required to accommodate shared decision making, to ensure the additional time required and increased length of appointment are considered. For shared decision making to be implemented in general practice which standardly has only 10 minute appointments, the consultation length will have to be increased or become more flexible.	Thank you for your comment. In evidence review A, the committee discussed at some length whether SDM required more time and that allowing a larger amount of time for SDM may increase consultation length and cost. Although it did not see any quantitative evidence to reflect this, it did note that the qualitative evidence highlighted 'lack of time' as a barrier to using SDM. Overall, it agreed that any additional time needed could potentially be offset by fostering a better patient-practitioner relationship in early sessions, leading to shorter ones in the future, although they also acknowledged that many healthcare professionals only see people short term. They highlighted issues around practitioners questioning what the evidence is for more time being needed, and that more research is needed into what interventions reduce time commitment. There are also recommendations and evidence for normalisation of SDM at an organisational level in section 1.1 of the guideline and evidence review E. Recommendation 1.2.15 covers the fact that decisions will be reviewed at follow-up discussions: "1.2.15 At the end of a discussion, state clearly what decisions have been made to make sure there is a shared understanding between the person and their healthcare professional about what has been

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					agreed, what happens next, what the timescales are, and when it will be reviewed."
The Royal College of General Practitioners	Draft guideline	General	General	Can the committee consider the cultural and behavioural changes needed to implement shared decision making which are currently not included in the guidance. This applies to systems, organisations, individual clinicians and patients. In order to embed shared decision making we consider that organisational culture will need to encourage an increased equality between clinicians and patient, with patients supported and empowered to gain confidence and willingness to engage in new styles of communication and consultation.	Thank you. We believe this is adequately covered in the organisational level recommendations (section 1.1 of the guideline)
The Royal College of General Practitioners	General	General	General	The draft guideline appears to take on-the-job training within career grades as its sole focus for achieving additional capacity for shared decision making. There are other ways of achieving this aimCan the comiteee consider undergraduate, postgraduate or equivalent training as a key lever for introducing new ways of working, such as shared decision making, at a large scale. The RCGP Curriculum, Being a General Practitioner, includes shared decision making in the "Communication and consultation" section. We believe the explicit inclusion of shared decision making in all medical training curricula and, importantly, examinations would help to drive its more widespread adoption.	Thank you for your comment. Recommending training is outside of the scope of this guideline.

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The Royal College of General Practitioners	General	General	General	Can the committee consider add a section relating to the ethical aspects of shared decision making? Communication and the sharing of information and responsibility for health care decisions can be considered interventions which, as a result of the intervention may have negative impacts. This section could include: • Autonomy, which is generally enhanced by Shared Decision Making when patients have capacity and health literacy • Non-maleficence: patient unconscious bias of the practitioner or practitioners overloading patients with information could cause harm and this must be taken into account • Justice: Resource implications, in particular the increased time spent when undertaking shared decision making Key literature here includes: • Gillick MR, Re-engineering shared decision-making, Journal of Medical Ethics 2015;41:785-788. This article puts some perspective into Shared Decision Making, Stiggelbout A M, Van der Weijden T, De Wit M, Frosch D, Légaré F, Montori V, et al. Shared decision making: really putting patients at the centre of healthcare. BMJ 2012;344: e256. The responses tease out some of Shared Decision	Thank you. This is not the role of a NICE guideline. This is adequately covered in most pre-registration textbooks.

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				Making's limits including ethical aspects referring to the experience of doctors as patients	
The Royal College of General Practitioners	General	General	General	The draft guideline makes no reference to patient competence which is a potential limitation to shared decision making. Can the committee consider adding a recommendation regarding decisions made by patients which practitioners do not feel to be in their best interest ? The potential harm of these decisions is both to the practitioner and to the patient in terms of conflict and potential harm through under, over or inappropriate treatment.	Thank you for your comment. There are recommendations covering those who may find it difficult to share in decision making (1.2.6). The committee also added further detail about this to the rationale and impact section.
The Royal College of Radiologists	Draft guideline	General	General	<u>Recommendation</u> We recommend that a reference is inserted into the final guideline outlining that registered healthcare professionals, including doctors, must adhere to their professional codes, eg the General Medical Council's (GMC) Good medical practice guidance. This would allow for the draft guideline to be aligned with the professional requirements as far as possible and reduce the risk of confusion or inadvertently creating competing requirements. <u>Rationale</u> We are fully supportive of patients and service users being able to access and communicate information in a way suited to their needs, and	Thank you. NICE guidelines must always be considered alongside professional codes. It is not intended to replace them.

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				which fosters shared decision making where possible. We also appreciate that the draft guideline is written to be applicable to everybody who delivers healthcare services, commissioners of health and public health services, and adults using healthcare services, their families, carers and advocates, and the public (p.1 of the draft guideline). However, in our view the overall ambition of the guideline is already covered by the GMC's Good medical practice guidance. The guidance outlines the professional values and behaviours the GMC expect from any doctor on its register. By aligning this guideline to the existing professional requirements, we believe it would reduce the risk of inadvertently creating competing requirements. It would also be beneficial as the draft guideline is referencing the GMC's guidance on decision making and consent for advice on how to deal with uncertainty. This guidance in turn is specifically referencing the Good medical practice guidance and making this link more clearly would reduce the risk of confusion around the requirements for both healthcare	

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				professionals, patients and service users as well as on an organisational level. Examples of the Good medical practice guidance, and in particular domain 3: Communication partnership and teamwork, that interplay with this draft guideline are: • You must listen to patients, take account of their views, and respond honestly to their questions. (section 31); • You must give patients the information they want or need to know in a way they can understand. You should make sure that arrangements are made, wherever possible, to meet patients' language and communication needs (section 32); and • You must work in partnership with patients, sharing with them the information they will need to make decisions about their care, including: a) their condition, its likely progression and the options for treatment, including associated risks and uncertainties b) the progress of their care, and your role and responsibilities in the team c) who is responsible for each aspect of patient care, and how information is	

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				shared within teams and among those who will be providing their care d) any other information patients need if they are asked to agree to be involved in teaching or research (section 49).	
The Royal College of Surgeons of Edinburgh	Draft Guideline	General	General	Shared Decision making is a key concept in modern medicine. It is vital that the patient, and whoever forms part of their support mechanism, understands the diagnosis, the different treatment options available to them (and this will include doing nothing), together with the risks and benefits of each. The document lays out these principles well. Perhaps more emphasis could be given to highlighting that it is what matters to the patient which is most important. For these principles to be adopted it is essential that there is organisational buy in; the culture must change to allow the necessary time and resources to be available. In this regard, it is good to see that embedding shared decision making at an organizational level is the first section. The suggestions of specific board member responsibility and having a patient representative, together with front line staff and patient champions, are to be commended. The inclusion of the healthcare service user at the	Thank you. We recognise that NICE guidance is only one piece of the jigsaw and that implementation will be a challenge in many areas, however that is beyond the remit of this guideline. The guideline is clear that 'practitioners' refers to the wider healthcare team and has included a glossary term to describe this. Please see the 'Terms used in this guideline' section. NICE will be reviewing the text used on its website and how this relates to shared decision making. The resource impact of the majority of the recommendations outlined in this guideline are expected to be minimal (e.g., small increases in printing costs as a result of using decision aids or because only minor updates were made to existing recommendations on communicating risk and benefits and therefore should already be part of existing care). For recommendations where there is an expected resource impact this is discussed in the short version of the guideline. For example, to limit the potential resource impact the recommendation on arranging third party support was limited to only people who might need additional support to engage in SDM, rather than a recommendation for third party support for

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				organisational level is vital so this is a highly welcomed recommendation. It is beholden on the healthcare professional counselling the patient to ensure that they pass on all of this information honestly and in a manner that the patient understands; good evidence for the merits of each option is not always available and it is important that they are clear when this is the case. It is also important to note that the value of the intervention can only be decided by the patient not the clinician – this needs to be emphasized more clearly in the document. Both parties (patient and healthcare professional) are subject to biases and heuristics – conscious and unconscious. Those biases are temporal and subject to concurrent external factors. While these principles discussed in the last paragraph are key it is not always easy to do this well. It takes considerable expertise to do this. Significant resources are required, both in time, healthcare professional training, appropriate systems within the healthcare setting and the availability and correct implementation of decision aids.	all people. It is also noted that some recommendations might result in longer appointments/consultations, but that this resource impact could be offset by fewer subsequent appointments and potential benefits in people making the right decision upfront in their care pathway.

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				While the document highlights some of these, very little guidance is provided on how these can be successfully implemented. For example, there is no statement that increased resource is essential to make this work, no specific advice on how decision aids can be introduced/used, no specific advice on how a service could be run to achieve the goals outlined. At present patients usually receive a 10 minute single outpatient appointment to make a diagnosis and fully discuss the options for treatment. This is woefully inadequate if the decision making principles outlined in the document are to be followed. While agreeing these principles is a vital first step, it MUST be followed up with sufficient resources to allow proper implementation. It is important to recognise that for some diseases, two or more treatment options may be offered by different specialties/teams. It is important that all healthcare providers have a working knowledge of the alternative procedure - the extent of that knowledge will vary depending on the procedure and should be defined, assessed and maintained at a specialty/departmental level. The importance of 'teams' should be noted here. There should be a low threshold for, and an ease of referral to the sister pathway (documented pathway), to	

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				appropriately facilitate discussion of the alternate procedure. For example, it is important that the patient is counselled by both the oncologist and the surgeon if both options for oesophageal cancer management are all able to be discussed fully. It is also important to mention the impact of misinformation on patients' decision making - patients should be directed towards reliable sources of information and there is a role for the development of a list of these resources and their inclusion in patient information literature, by each organisation. Training in these principles is vital so it is good to see a section on Supporting Practitioner Skills and Competencies. In my view, this could have had even greater emphasis. Evidence of care providers personal development plan, including training in recognising and understanding their biases and the cognitive process, heuristics and behaviours involved in decision making, along with communication, should be included in appraisal and revalidation. It should also be an essential part of the curricula in all undergraduate and postgraduate healthcare professional training.	

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				It would also be beneficial to have a shorter key summary/key-principle document that could be shared with patients and their carers; perhaps this could form the basis of a contract between the patient and the healthcare professional. The document should acknowledge that the wider healthcare team (including nurse practitioners) are often at the forefront of patient information. Explicit reference to these roles should be included.	
The Somerville Foundation	Draft Guideline	009	016	1.2.14 – We believe patients should be offered copies of the tests that are available at that stage to take away. E.g. copies of the ECG, pacing check report, X-Ray on disk, ECHO report etc. – patient held records is an important aim to ensure educated patients as they can then avoid risks in other health environments especially A&E.	Thank you. Patient held records are outside the scope of this guideline.
The Somerville Foundation	Draft Guideline	009	024	1.2.16 – copies of test results unavailable at the consultation should be sent to the patient (pt) as soon after the consultation as possible	Thank you for your comment. The committee felt this was captured by updated recommendation 1.2.18, which now states: "1.2.18 Offer people resources in their preferred format to help them understand what was discussed and agreed. This could be a printout summarising their diagnosis, the options and decisions or plans made, and links to high-quality online resources. Ideally, give people this material to take away, or provide it very soon after the discussion"

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The Somerville Foundation	Draft Guideline	010	001	1.2.17 – We think it is totally inappropriate to "…consider asking the pt. if they would like a letter…" This should not be open for consideration by the health professional, it should be mandatory that they either offer a letter or much more preferable a letter is always sent to the pt. with the GP copied in (although it is actually sent to the GP with the pt. copied in generally)	Thank you. We have amended the recommendation to "Ask people if they would like any clinical letters generated after their discussion with a healthcare professional to be written directly to them, with a copy sent to their GP, rather than just sent to their GP."
The Somerville Foundation	Draft Guideline	General	General	Not sure where to fit the comment. Continuation of care is of huge importance to the pt. It should be standard practice that pts. see the same medical professional on-going rather than different people. A very important part of care is confidence in the medical professional	Thank you. The committee did not identify any evidence to suggest that this was the case.
The Somerville Foundation	Draft Guideline	General	General	This may not be the document to deal with this, but there should be a mechanism where the medical professional is open to the request for there to be a second opinion. This should be discussed between the pt. and the medical professional with the medical professional making it clear it is not taken as a slight on them but part of the shared discussion over what is best to be done for the good of the pt.	Thank you. The committee added some consideration of this to the rationale: The committee noted that some people may not want to be involved in shared decision making. They also noted that not all decisions can be shared. People have a right to refuse any treatment, and similarly, healthcare professionals are not obliged to provide any treatment that in their clinical opinion is medically futile (this may require a second opinion or discussion with a senior colleague). Healthcare professionals cannot provide access to treatments that are not available.
University of Exeter	Draft Guideline	005	018	Explaining what is meant by a person's 'values'. The single word 'values' doesn't seem to convey enough meaning here, although from the rationale it seems it is intended to refer to the persons' priorities in a holistic sense. Could this sentence have its own separate bullet point	Thank you. Please see the recommendations in section 1.2, especially 1.2.9. Values was defined as what matters to the service user, or what they "value".

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				and/or be reworded to increase emphasis on using the patients' notes to record and understand the context of the decision to be made, in terms of the patients' wider life values?	
University of Exeter	Draft Guideline	006	028	Question 3, overcoming challenges: Some patient groups, including the elderly, may benefit from being invited to convey the level of involvement or degree of information sharing that they feel comfortable to start the conversation with. This will be unique to each individual and may change depending on the decision to be made. Certain patient groups have beliefs that the doctor should make the decision for them. This should not exclude them from participating in shared decision-making that explores their values and priorities, however both practitioner and patient will need to understand the starting position, and the recommendation could usefully state that patients should be invited to convey this.	Thank you. The committee agreed this was an important point and made recommendation 1.2.8 and research recommendation 4 "What influences the acceptability of shared decision making in populations that predominantly believe in the authority of the healthcare professional?"
University of Exeter	Draft Guideline	007	004	Question 2, cost implications: This point describes offering shared decision-making at different stages. However, it is also important to acknowledge, at this point in the guideline, that shared decision-making can be an ongoing process, carried out across multiple consultations with the same practitioner or by utilising more than one member of a multi-	Thank you. We agree that implementing good shared decision making will have cost implications and that it is unclear whether these costs will be offset by the outcomes of SDM.

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				disciplinary team, for example. Decisions can be reviewed at a future timepoint, or people may make a delayed decision following provision of information at an earlier timepoint for example. Recommending multiple appointments and/or continuity of care will have cost implications, however these costs may be offset by achieving positive outcomes associated with the facilitation of effective shared decision-making.	
University of Exeter	Draft Guideline	007	010	Question 3: Overcoming challenges. At the time of asking the person if they want to involve family, friends or advocates, it would be important to establish the degree of involvement that the person themselves is expecting to have in the decision-making process. The aim of involving the advocate should be to empower the patient. The practitioner should aim to avoid diminishing the person's decision-making role within the conversation by involving a third party, unless this is the person's wish, or they do not have the capacity to make the decision for themselves. These messages could be stated more clearly here.	Thank you for your comment. This recommendation is placed here as the committee noted you need to establish the need for additional support to actively engage in discussions before beginning those discussions.
University of Exeter	Draft Guideline	007	014	'Explain what is important to them' does not convey that it is the person's fundamental life values that need to be established first. This in turn will help inform priorities regarding the	Thank you. We have modified the wording to "explain what matters to them".

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				specific decision to be made. We suggest that the wording here is reviewed.	
University of Exeter	Draft Guideline	008	018	Question 3: Overcoming challenges – patient empowerment. We feel that information about participating as fully (or not) in decision-making about their care should come earlier, prior to the appointment, in order to nurture the person's confidence and prepare them for optimal engagement during the consultation. The practitioner can also repeat these messages at the 'choice talk' stage, during the appointment (as currently recommended in the guideline).	Thank you for your comment. We believe this is covered in the 'before a discussion' section as 'whether you want to participate in SDM' would be covered in SDM resources that are reliable and of high quality (see recommendation 1.2.4 and 1.2.5)
University of Exeter	Draft Guideline	008	026	"Explain the healthcare aims of each option and how they align with the person's aims" Consider replacing 'aims' with 'wider life goals/priorities'. Changing the wording here may help to convey the message behind this point more clearly.	Thank you. We have added this.
University of Exeter	Draft Guideline	009	010	Question 3: Overcoming challenges – perceptions of having/being given enough time. Perceptions of having enough time are closely associated with perceptions of effective shared decision-making, with patients' trust in the practitioner and with their satisfaction with the care provided (Croker et al. 2013). Providing continuity of care, or at least a follow-up consultation, could be highlighted here as a means of ensuring that people have 'enough	Thank you for your comment.

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				time to make decisions about tests and treatments'. Croker, J., et al. (2013) Factors affecting patients' trust and confidence in GPs: evidence from the English National GP patient survey, BMJ Open, 3, e002762.	
University of Exeter	Draft Guideline	009	012	Question 3: Acknowledging and managing individualised perceptions of risk. It may be important here to acknowledge that people's perceptions of risk should be considered holistically, and that evidence-based risk calculations, for example, should be set in context, by taking a personalised approach to address the priorities of each individual.	Thank you. Please see the section on communicating risks, benefits and consequences (section 1.4)
University of Exeter	Draft Guideline	009	018	Question 3. Overcoming challenges - Follow-up planning. 'What happens next, what the timescales are, and when it will be reviewed.' This should not be set in stone, the person should be aware that they can bring the review date forward if needed or, if feasible, that they can change their mind about the decision that has been made. The practitioner needs to empower the person to feel confident that they can approach the practitioner to review the decision-making – this message is not clear in the current text.	Thank you. We have made this clearer in the recommendations.

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University of Exeter	Draft Guideline	010	006	Question 3. 'People who need extra help' - Mental Capacity Act. Consider linking to information regarding the Mental Capacity Act and decision-making guidance here, as well as elsewhere in the guideline, as the information is relevant when considering 'people who are likely to need extra help to share in making decisions'.	Thank you. People who lack mental capacity are excluded from this guideline. Please see section 3.1 of the scope document. (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents)
University of Exeter	Draft Guideline	010	008	Question 1. Implementations challenges - Additional support for vulnerable groups. Whilst this recommendation, 'to record the discussion during their appointment', seeks to improve access to shared decision-making for those who may need extra support in the process, we are concerned that it may not represent equality of access to support. For example, it is likely that the frail elderly may not have the means or ability to 'record' their consultation. It may be appropriate to highlight that the 'additional support' should be individualised. It might also be appropriate to re-evaluated the outcomes of the appointment at a later date, to ensure that the support was effective and that shared decision-making has been successful. Question 1. Implementation challenges - Recording the discussion. Could there potentially be issues of data protection if this recommendation is perceived to be advocating the 'recording' of patient consultations? It is not	Thank you. Recording the discussion is given as a suggested example only and is for the personal use of the patient using their phone or other electronic device. We therefore don't think data protection issues apply in this instance.

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				clear what type of recording is meant here – audio/video or written?	
University of Exeter	Draft Guideline	010	012	Sharing information between services. The recommendation appears tagged-on here and as such seems vague in its meaning. Should this point come under the 'embedding shared decision-making at an organisational level' heading and perhaps use examples related to the points within that section?	Thank you for your comment. This recommendation was moved to "embedding shared decision making at an organisational level" as suggested.
University of Exeter	Draft Guideline	011	012	<u>Question 2.</u> Cost impact - 'Provide patient decision aids in multiple ways'. These are important messages for the developers of decision-aids and for those commissioning them/ advocating their use. This may be an avenue for future research – to understand how decision-aids can be developed and provided in different formats, whilst ensuring equality of access and cost-effectiveness in their delivery.	Thank you for your comment.
University of Exeter	Draft Guideline	011	017	<u>Question 3.</u> Overcoming challenges - Communicating 'consequences'. In the rationale for this section the committee acknowledge that 'some implications are neither risks nor benefits, but are still important for decision-making (for example, whether a particular treatment option will affect the person being able to drive)'. We feel that this explanation, of why 'consequences' has been added to 'risks and benefits', should	Thank you for your comment. The reasoning for adding consequences is covered in the guideline under "Why the committee made the recommendations".

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				be briefly communicated within the recommendation, otherwise this term could easily be overlooked when putting the guideline into practice.	
University of Exeter	Draft Guideline	011	023	Question 3. Overcoming challeges - Dealing with uncertainty. It is great to see 'dealing with uncertainty' mentioned explicitly in the recommendation as this is a real barrier to effective shared decision-making for practitioners. It may be useful to indicate that support regarding 'what to do if your patient does not want to hear information that you think is useful' and 'what to do if your patient may lack capacity' is contained within the GMC guidance linked in this paragraph. It would also be helpful to highlight these areas of uncertainty earlier in the guideline, particularly in section 1.2 'Putting shared decision-making into practice'.	Thank you for your comment. Patients who lack capacity are excluded from this guideline (please see section 3.1 of the scope document - https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/documents) Regarding 'what to do if your patient does not want to hear information that you think is useful' please refer to recommendation 1.2.13 that states: Accept and acknowledge that people may vary in their views about the balance of risks, benefits and consequences of treatments, and that they may differ from those of their healthcare professionals." The committee noted that some people may not want to be involved in shared decision making. They also noted that not all decisions can be shared. People have a right to refuse any treatment, and similarly, healthcare professionals are not obliged to provide any treatment that in their clinical opinion is medically futile (this may require a second opinion or discussion with a senior colleague).
University of Exeter	Draft Guideline	014	024	Research: 'Differing intervention effects in different groups'. It would be important to understand how decision-aids can be developed and provided in different formats, whilst ensuring equality of access in their delivery in different	Thank you for your comment. More detail for this research recommendation can be seen in evidence review A.

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				settings and to different groups. The title encompasses this, however this specific example links to the earlier section and it could therefore be stated. Consistency and/or transparency in intervention development and evaluation is required to inform future systematic reviews of shared decision-making interventions in vulnerable groups (Butterworth 2019). *Butterworth, J.E., et al. (2019) Interventions for involving older patients with multi-morbidity in decision-making during primary care consultations. Cochrane Database of Systematic Reviews, 10, CD013124.*	
University of Exeter	Draft Guideline	015	006	Question 1. 'What influences the acceptability of shared decision-making in populations that predominantly believe in the authority of the healthcare professional?' Challenges relating to the management of populations that 'believe in the authority of the healthcare professional', and therefore expect the practitioner to make decisions for them, should be acknowledged in the recommendations. This is relevant to 'supporting practitioner skills and competencies', to 'promoting shared decision-making to people who use services', and to 'putting shared decision-making into practice'. However, it is not	Thank you for your comment. The lack of evidence regarding these groups is what led to the committee to prioritise this research recommendation. The context section discusses how people can choose to what degree they wish to involve themselves in shared decision-making, and recommendation 1.2.6 offers extra support for those who may find it difficult to share in shared decision making.

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				discussed explicitly until the 'recommendations for research section'. Whilst evidence is currently lacking for some of these key population groups (Butterworth 2019), the uncertainty surrounding their management and shared decision-making is a common occurrence in practice, and as such should be highlighted. Support for practitioners, for example from the 'GMC guidance on decision-making and consent' should be referenced earlier in the document in relation to this uncertainty. *Butterworth, J.E., et al. (2019) Interventions for involving older patients with multi-morbidity in decision-making during primary care consultations. Cochrane Database of Systematic Reviews, 10, CD013124.*	
University of Exeter	Draft Guideline	020	013	Question 2. Cost implications - How the recommendation might affect services. 'There is a potential that … appointments may need to be longer'. Whilst this may be true, establishing continuity of care across multiple appointments would be an alternative means of utilising the additional time required for effective shared decision-making, potentially with reduced costs if managed appropriately, and with the added benefit of allowing the person time to mull over their options or to process any information that	Thank you for your comment.

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				has been provided. Continuity could be provided by a consistent practitioner, or (perhaps less preferably) through sufficient documentation in the person's care record – particularly if there is a focus placed on documenting the individual's fundamental priorities and life goals/values as a part of the initial conversation.	
University of Exeter	Draft Guideline	023	007	Question 3. Overcoming challenges - 'Some people prefer not to take an active role in making decisions … but they should always be given the opportunity'. The evidence suggests that practitioners do not facilitate shared decision-making if they believe that the person does not want to participate. Therefore, we feel that this information should be stated in the recommendations under the headings 'supporting practitioner skills and competencies', 'promoting shared decision-making…' and 'putting shared decision-making into practice – before appointments.	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.
University of Exeter	Draft Guideline	023	012	'Involving people in decisions about their care may result in…' There is a focus on benefits to the patient/client here but there are also benefits to practitioners and to the wider healthcare system as a result of successful patient involvement. For example, improved practitioner satisfaction and reduced costs of healthcare from improved patient adherence with treatment	Thank you for your comment. The context section is intended to provide a very brief overview of the current state of policy and practice. It is not intended to be exhaustive.

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				advice. More research is required to understand the wider-reaching benefits of shared decision-making across ecological model of health.	
University of Exeter	Draft Guideline	06	011	Question 3, overcoming challenges: 'Some people prefer not to take an active role in making decisions … but they should always be given the opportunity' is stated in the Rationale section of the guideline but is not referred to in relation to training. Practitioners should be trained to share and discuss information in a way that matches the individual's preferences and ability for involvement, as well as their individual information requirements/preferences. We believe that the recommendations should state this so that training aims to shift practitioner perceptions away from a belief that certain groups of patients do not want to participate in shared decision-making at all, in order to avoid the well-documented phenomenon of 'preference mis-diagnosis' (Mulley 2012). *Mulley, A., Trimble, C., Elwyn, G. (2012) Patients' preferences matter: Stop the silent misdiagnosis, The Kings Fund, online https://www.kingsfund.org.uk/publications/patients-preferences-matter Accessed [03/02/21]*	Thank you. The committee chose to focus on people engaging in SDM as a way to reflect this issue. It was important to acknowledge that some people may not wish to engage in the Rationale section, but throughout the guidelines the committee built in the assumption that people will want to engage in SDM.

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University of Exeter	Draft Guideline	General	General	Question 1: Challenges for implementation. Delivery of this guideline may be particularly challenging in the context of shared decision-making for people with complex multimorbidity. With an ageing population, and with the prevalence of multimorbidity increasing with age, with social deprivation and in certain ethnic groups, this is an important consideration. Recognising that decisions exist in the context of people's wider, 'fundamental' life values is key to addressing patient priorities when making decisions in the context of medical complexity (Elwyn 2020; Tinetti 2019). It is also a means of managing practitioner uncertainty in scenarios where condition-specific clinical guidelines and the evidence base do not readily apply to an individual. We feel that whilst the concept of fundamental priorities does exist within the guideline, it could be described earlier and more clearly, and that it should be a core theme throughout the recommendations. Currently, it is not until page 11, under the heading 'Communicating risks, benefits and consequences', that the 'context of each person's life and what matters to them' is mentioned explicitly. We feel that this concept is central to every section of this guideline and, as such, should be referred to explicitly throughout.	Thank you for this information.

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				Elwyn, G., Vermunt, A. (2020) 'Goal-based shared decision-making: Developing an integrated model', Journal of Patient Experience, 7(5) 688-96. *Tinetti, M. et al. (2019) 'Challenges and strategies in patients' health priorities-aligned decision-making for older adults with multiple chronic conditions', PLoS One, 14(6) e0218249.*	
University of Leeds	Draft Guideline	003	1.1.1 .- 1.1.9	The recommendations sound reasonable. However, some of the recommendations are not obviously linked to the findings from the evidence reviews. The review (Chapter E) acknowledged the empirical evidence was weak, and selected 5 testimonials to provide their experience of implementing SDM development and training.From the testimonials, the Newcastle-UK and Vejle-UK testimonials talk about the MAGIC methods. The AQuA, Wales & Patient-Leadership triangle describe a multi-organisational, partnership structure that is made of components addressing clinical decision making, patient involvement and addressing problems identified by the health organisations. The training involves feedback and monitoring, and an ongoing process of service improvement, using a tool-box of quality improvement training for health professional,	Thank you. As you say these recommendations were mostly based on expert testimony and the expertise of the guideline committee. The committee agreed that there was not a single approach to implementing SDM, and this is why many of the recommendations are constructed to identify the best ways to implement SDM with each organisation, team, individual practitioner or service user.

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				including reference to the MAGIC methods and other frameworks. It was clear from the evidence reviews in A,B,E – there is not a single approach to developing SDM interventions, identifying the active ingredients of these complex interventions, and implementing them in practice.	
University of Leeds	Draft Guideline	003	1.1.7	The recommendation should not refer explicitly to the three choice model in the implementation and/or training of SDM. It would be better to say refers to a framework to help health professionals think critically about their practices and that of their services that boost or bias patient and families involvement in making shared decisions. Other models are used extensively, applied in practice, and evaluated, to train health professionals and implement in practice that address the limitations of the three talk model, such as the decision coaching/ Ottawa decision support framework/ inter-professional shared decision making framework (https://decisionaid.ohri.ca/coaching.html). Bekker's 2015 MIND-IT (making informed decisions individually and together) framework published in https://cjasn.asnjournals.org/content/11/10/1902;	Thank you. The committee saw evidence for the three-talk model, but they have discussed further and agreed to make clear that it is not the only model for SDM and that any evidence based model may be useful.

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				https://academic.oup.com/ndt/article/30/10/1605/2337110 is a representation of Stacey and Legare's review of SDM theories, and of the framework referred to by by the Gilbert and Preece patient-leader testimony. There is no one approach used by people to deliver SDM training. It is more likely to be adopted if people find a framework that works for their organisation and needs, rather than prescribing a method used. [Diouf et al (2016) Training health professionals in shared decision making: Update of an international environmental scan https://www.sciencedirect.com/science/article/pii/S0738399116302725]	
University of Leeds	Draft Guideline	003	1.1.8 & 1.1.9	It is unclear these are the key active components in the training (evidence review B&E). The recommendation should make it clear there are a number of interventions that can change the nature of the conversation to a more shared decision making process. For example, the use of patient reported outcome measures. This is certainly what was identified in the searches for evidence chapter B, and summarised in the Person-centred care evidence review from the health foundation in 2014.	Thank you for your comment. The recommendations are generated from across all evidence reviews. Interventions that embed and encourage shared decision making can be found throughout the guideline. This section only covers "supporting practitioner skills and competences". Please see recommendation 1.1.9 which covers monitoring: "Plan internal or external monitoring and evaluation (including service user and staff feedback activities) and how to feed back the results to staff at individual, team and management level."

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					The committee felt the measuring of shared decision making was still non-uniform and difficult to evaluate, and thus wrote a research recommendation (2): "What are the best ways to measure the effectiveness of shared decision making in different contexts (in different settings and involving different people)?"
University of Leeds	Draft Guideline	007	1.2	It might help the implementation of SDM if health professionals and patients can understand the difference between good communication and delivery of care, and the active ingredients in consultations to support active thinking (see singh et al, 2010 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5060538/). It might help the implementation of SDM if the recommendations signpost health professionals to the evidence explaining how to help health professionals and patients think differently about engaging in health care comes from decision sciences (e.g. Blumenthal-Barby et al, 2020 https://journals.sagepub.com/doi/10.1177/0272989X14547740). It might help the guidelines be implemented if there was an explicit recognition the expertise in helping colleagues, organisations, patients and consultations to 'have a better shared decision making process' comes from the (medical) decision sciences. The testimonials from review	Thank you. We recognise the importance of decision sciences in SDM, but it is not the role of this guideline to add explanatory frameworks or refer to academic courses. The guideline is focussed on implementing shared decision making.

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				chapter E do not make it explicit but at least four of them have drawn on expert advice from decision scientists when developing resources and approaches over the last 25 years as has NICE, and NHS England (e.g. NHS Rightcare Shared Decision Making programme; NHS Patient Involvement). Signposting to the 'non-medical' 'non-communication skills' evidence base is likely to help health professionals identify 'the decision making problem' themselves, and integrate new approaches into usual care practices. (Bekker 2010, DOI: 10.1016/j.pec.2010.01.002). The steps provided by the (updated) three talk model do not help professionals, or patients, 'see' the decision making problem, or what it is about their practice that is not supporting proactive shared decision making. Signposting to this evidence base may help teams draw on expertise to input into assessing the organisation structures impacting on the delivery of SDM. For example, payments/ costs of treatments, tests referrals, information management systems, MDTs, etc.	
University of Leeds	Draft Guideline	010	1.3	Delighted Patient Decision Aids are explicitly mentioned. We know patient decision aid intervention development and acceptability	Thank you. The guideline defines what it means by patient decision aids in the 'terms used in this guideline' section. The

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				research is established, but the evidence-base about their implementation, and their association with SDM, is less systematically investigated across health contexts. It would help the implementation of the guidelines going forward, if PtDA were described 'positively' as research-informed resources designed to support patients to make informed, value-based decisions between health options (original IPDAS definition). Say "Likely their use will enable patients to engage in a shared decision making consultation (Bekker et al, 2003; Stacey et al, 2017) Say "can be accessed independently by patients and/or integrated within consultations and care pathways"; Say "other resources can enhance SDM in the consultation, such as PRO, prompts (e.g. BRAN – choosing wisely; ask 3 questions - trevana), visual aids, etc.(informed by evidence chapters)." Do not say "a 'sub-part' of SDM, part of toolkit, 'cannot stand alone', or qualify their use as this undermines their value as health literacy / patient empowerment / knowledge translation resource in their own right, and will make it less likely health professionals will endorse them.	committee were clear that PDAs alone are not shared decision making and they were just one part of a process.

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				Note - PtDA implementation and use does not 'depend' on a health professional and patient consultation. Although, it might enhance practice if they are utilised appropriately during the patient-practitioner consultations.	
University of Leeds	Draft Guideline	010	1.3	It may help professionals to know where to look for guidance to developing patient decision aids, so signposting to the IPDAS resources in the recommendations / explanation of PtDAs would be useful: • Developing PtDAs (IPDAS 2013- update 2021 https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/1472-6947-13-S2-S2 • Implementing PtDA (IPDAS 2021) https://journals.sagepub.com/doi/pdf/10.1177/0272989X20978208 • Evaluating PtDA (IPDAS 2016) https://pubmed.ncbi.nlm.nih.gov/29269567/ • Consensus on IPDAS checklist for content PtDA (2005) http://ipdas.ohri.ca/IPDAS_results_SMDM_Oct2005.pdf In addition, signposting to the IPDAS evidence reviews will help practitioners in both developing	Thank you. The IPDAS standards are specifically mentioned in the recommendations (recommendation 1.3.4) NICE does not signpost to evidence reviews in recommendations.

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				PtDAs but improving skills to present information about the risks and benefits in a way that patients understand. • Risk perception (IPDAS – 2013 update 2021) https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/1472-6947-13-S2-S7 • Value clarification (IPDAS 2013) https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/1472-6947-13-S2-S8 / (update 2021) https://www.medrxiv.org/content/10.1101/2021.01.21.21250270v1.full • Personal stories (IPDAS 2013- update 2021) https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/1472-6947-13-S2-S8 • Health literacy (IPDAS 2013- update 2021) https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/1472-6947-13-S2-S10 • Balancing information (IPDAS 2013- update 2021) https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/1472-6947-13-S2-S6	

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University of Leeds	Draft Guideline	014	General	Remove the explanation of the three talk model – this appears in the evidence statements and is one of several approaches to implementing and training SDM.	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.
University of Leeds	Draft Guideline	014	General	Include a definition of informed decision making.in the terminology. The ‘Montgromery landmark ruling’ is used throughout the document and it will help the guideline if people understand the component parts of IDM, and what helps patients (and professionals) make informed decisions. “*An informed decision is one where a reasoned choice is made by an individual using relevant information about the advantages and disadvantages of all the possible courses of action, in accord with the individual’s beliefs*” (Bekker et al, 1999; https://discovery.ucl.ac.uk/id/eprint/15902/1/15902.pdf). To make an informed decision requires a person (professional or patient) to appraise the consequences of all options without bias, evaluate the information in accordance with their own beliefs, and make a decision based on a	Thank you. This guideline is about shared decision making. A definition of shared decision making is included in the 'terms used in this guideline' section. The guideline does not refer to 'informed decision making'

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				trade-off between these evaluations (Bekker 2010, DOI: 10.1016/j.pec.2010.01.002) "A landmark ruling was made in 2015 by the UK Supreme Court following the Montgomery v Lanarkshire case. A new legal standard set out that adults 'of sound 33 mind' are entitled to make informed decisions when giving or withholding consent to treatment or diagnosis. Consent 'must be obtained before treatment interfering with bodily integrity is undertaken', and it should only be gained when patients have shared a decision informed by what is known about the risks, benefits and consequences of all reasonable NHS treatment options. It is the healthcare professional's duty to 'take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.'	
University of Leeds	Draft Guideline	015	024	Signpost leadership / clinical teams to utilise decision aid expertise and develop resources that include the active ingredients for a Patient Decision Aid, or decide what type of resource is most useful to their patient and team – is likely to improve practice Health professionals collaborate with health economists for input into cost-effectiveness interventions, statisticians for modelling and	Thank you for your comment.

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				calculating diagnostic or prognostic models, psychologists for behaviour change, it seems a reasonable recommendation to suggest drawing on expertise from a decision scientists when implementing interventions to support people to improve decision making processes. Noted from Veijle testimonial the complexity … "*Developing PtDAs without pre-existing knowledge is quite a task and we have learned that very few clinicians are aware of the international quality criteria for PtDAs (IPDAS). Moreover, building and developing a patient decision aid from scratch is cumbersome and very time consuming.*"	
University of Leeds	Draft Guideline	017	033	Consider adding to the recommendations - health professionals use the term chance or likelihood rather than 'risk'. Risk is used in a technical way by health professionals. To support understanding of both 'benefits' and 'harms' using a neutral term like likelihood and changes helps people attend to the figures. People have an emotional response to the word risk, so avoiding it in communications may be helpful.	Thank you for your comment. The committee stated that discussing "risks, benefits and consequences" should be recommended, as risk can have negative connotations when discussed on its own.
University of Leeds	Draft Guideline	017	033	Consider adding to the recommendation – health professionals use the word 'consequences' in communications rather than pros/cons, advantages/ disadvantages, or risks/benefits'. Not all people judge outcomes of	Thank you for your comment. The committee stated that discussing "risks, benefits and consequences" should be recommended, as risk can have negative connotations when discussed on its own.

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				treatments in the same way, and this avoids the professional providing their preference for an outcome.	
University of Leeds	Draft Guideline	019	001-011	There is a confound between using techniques to facilitate discussions between patients-practitioners about the decision problem, options, values, risks, consequences, and this being attributable to the three talk model. The ODSF, inter-professional SDM model, MIND_IT model all talk about these steps. My study was one of the first to find evidence for changes in the consultation around reasoning in an RCT using a decision analysis conversation (Bekker, 2003, 2004), not the three talk model. The committee heard very little testimony about other models of SDM, and given how much we know about the persuasive nature of testimony on decision making, I suggest this explicit endorsement of the three talk model be removed from the recommendations.	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.
University of Leeds	Draft Guideline	general	general	This guideline was always going to be a challenge. Developing evidence-based guidelines that bridge the gap between a strategic policy, beliefs about ethical imperatives, an evidence-base arising from complex intervention development and evaluations supporting people's healthcare decisions, and quality improvement initiatives to enhance the skills of health professionals to	Thank you for your comment.

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				enable patient involvement in health and illness management. Further there was a remit, *"The committee understood that NICE have already agreed, as part of their social value judgements, that Shared Decision Making (SDM) is a vital aspect of healthcare. It focused on finding the most effective way to encourage the use of SDM in healthcare situations. The committee's aim is that this guideline will aid in the implementation of SDM for those who are not sure of the best way to practice it."* The guideline does provide a document to help health professionals engage with SDM and its complexity. However, it needs to move more towards the evidence for team-based approaches, inter-disciplinary collaboration drawing on evidence from the decision and implementation sciences, and away from beliefs about, or personal experience of, a single SDM approach, short-list of component parts, training resources, and implementation.	
University of Leeds	Evidence review	General	General	The committee acknowledge that the evidence review for embedding SDM in practice was weak (chapter A & Chapter E), and sought the testimony from experts in the field when developing their recommendations: two used the MAGIC programme (Newcastle-UK and advisor	Thank you. The experts were selected by committee agreement based on the key gaps that they identified in the evidence.

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				to Veijle-DK); one the patient-leadership triangle model (Sussex- UK); one a quality improvement organisation approach (AQuA, north west-UK); one choosing wisely approach (Wales with MAGIC-Wales materials). It is unclear how these experts were selected; there are many other experts and evidence in the field from the UK were not (e.g. Laitner - clinical director of the NHS Rightcare SDM programme 2011-2017; e.g. Jyoti Baharani working with Kidney Research UK/ Kidneycare UK peer-led, nurse-led, team-led SDM 2014+). It is unclear why the Veijle experience was selected from outside the UK, other than being mentored by members of the MAGIC team. There are other international experts implementing and training HCPs (e.g. Stiggelbout – NL; Legare – Canada;). Indeed, in the Central Region of Denmark there has been an active patient involvement implementation and research group since 2013; Aarhus University Hospital has developed patient decision aids and patient reported outcomes, and training in shared decision making and self-management support for over 10 000 staff across 31 clinical areas in collaboration with other organisation such as VIBES and DEFACTUM.	

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University of Leeds	Evidence review	General	General	Despite the current update to the wording of the three-talk-model, it has limitations. It does not address sharing understanding about a person's (changing) health state; it does not address factors influencing clinician's decision making and their active role in the consultation; it's simple-to-understand model is an idealised model of a one-patient, one-doctor, and one-consultation decision; it is focused on the doctor presenting a choice of (medical) options to deliberate with patients in a consultation, rather than framing a decision problem in the context of patient lives and engagement with healthcare pathways. Other models that support SDM implementation include Stacey - Ottawa Decision Support Framework, Legare - Inter-Professional Shared Decision Making Framework from Canada, Bekker – Making Informed Decisions Individually and Together. It seems as if the recommendations have gone further than their remit and endorse one 'agreed' approach towards SDM and its implementation. The other evidence reviews (chapter A+B+C+D), and 3 of the testimonials, indicate several approaches to implementing SDM in practice, training staff, and components within this complex intervention to support the	Thank you for this information. The three talk model was chosen because it is a simple framework for understanding SDM and because there is evidence supporting its effectiveness, however the committee discussed this further and agreed that any evidence based model of SDM would be suitable.

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				consultation between patient and professionals to share decision making.	
University of Leeds	Evidence review	General	General	It is unclear why the committee did not base their recommendations more closely with key reviews (e.g. the Health Foundation review of evidence on shared decision making and self-management support (2014); Diouf et al (2016) Training health professionals in shared decision making environmental scan https://www.sciencedirect.com/science/article/pii/S0738399116302725) or frameworks to implement complex interventions or organisation change into organisations (e.g. Greenhalgh NASS; Consolidation Framework for Implementation Research).	Thank you for your comment. These listed papers did not meet the inclusion criteria for the guideline review process. For the methodology behind NICE's reviews please refer to the protocols in the evidence reviews and the Guideline Manual.
University of the West of England	Draft Guideline	004	004-018	We strongly support the comment that 'champions' to promote shared decision making are needed at all levels throughout organisations, including board members, senior practitioners and 'service user champions'. Our paper on challenges of implementing and researching a shared decision making intervention within NHS settings involving breast reconstruction services makes this point based on our experience of a 5 centre trial of an intervention to facilitate shared decision making. See: Tollow, P., Paraskeva, N., Clarke, A., White, P., Powell, J., Cox, D. & Harcourt, D. (2020).	Thank you for your support.

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				Challenges and reflections from a multi-centre trial of a psycho-oncology intervention to support shared decision-making in breast reconstruction, *European Journal of Cancer Care,* https://doi.org/10.1111/ecc.13384	
University of the West of England	Draft Guideline	005	007-009	We support the recommendation to identify departments or teams where shared decision making can be put into practice most easily but this should not be a 'top down' approach: engagement with enthusiastic physicians is key to a successful intervention. We have experience of developing an intervention to facilitate shared decision making within breast reconstructive surgery services which could be implemented within our settings in which surgical decisions are made. See: Harcourt D, Griffiths C, Baker E, Hansen E, White P & Clarke A. (2016). The Acceptability of PEGASUS: an Intervention to Facilitate Patient-Centred Consultations and Shared Decision-Making with Women Contemplating Breast Reconstruction, *Psychology, Health & Medicine.* 21:2, 248-253, DOI: 10.1080/13548506.2015.1051059. Harcourt, D., Paraskeva, N, White, P., Powell, J. & Clarke, A. (2017). A study protocol of the effectiveness of PEGASUS: a multi-centred	Thank you. The committee agreed.

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				study comparing an intervention to promote shared decision making about breast reconstruction with treatment as usual, BMC Med Inform Decis Mak. 17, 143	
University of the West of England	Draft Guideline	005	007-009	Reference could be made to resources to help the process of introducing shared decision making by using behaviour change theory. We have published a paper applying the COM-B model to the PEGASUS intervention which is intended to facilitate shared decision making. See: Clarke, A., Paraskeva, N., White, P. et al. (2020). PEGASUS: the Design of an Intervention to Facilitate Shared Decision-making in Breast Reconstruction. *J Canc Educ.* https://doi.org/10.1007/s13187-019-01656-6	Thank you. The committee discussed how different behaviour change models could help roll out SDM, however they did not think the evidence for any specific model was adequate to make a recommendation. Instead they expected users to refer to the NICE behaviour change guidelines. https://www.nice.org.uk/guidance/ph49
University of the West of England	Draft Guideline	006	005-021	We agree that training is needed to support practitioners. We have developed free training materials for the use of the PEGASUS (Patients' Expectations and Goals: Assisting Shared Understanding of Surgery) intervention, accessed via www.pegasusdecisionmaking.com	Thank you for this information.
University of the West of England	Draft Guideline	008	005-006	section 1.2.5 usefully gives examples of groups that might find decision making difficult, but we are concerned that the guideline has missed the opportunity to state that people who are usually	Thank you for your comment. We have added to the rationale and impact section of the guideline.

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				confident in making decisions may find it difficult to do so when faced with complex decisions and information about treatment for sensitive and emotive issues (which is often the case for health decisions such as surgery). See: Tollow, P., Paraskeva, N., Clarke, A., White, P., Powell, J., Cox, D. & Harcourt, D. "They were aware of who I was as a person": Patients' and health professionals' experiences of using the PEGASUS intervention to facilitate decision-making around breast reconstruction. Under review (response to reviewers' comments submitted) *European Journal of Cancer Care*	
University of the West of England	**Draft Guideline**	**008**	**021-023**	**We are pleased to see the emphasis on clinicians encouraging people to think about what is important to them, but they need to be guided in how to do this (its not as easy as it sounds). Our PEGASUS intervention supports clinicians (a decision/PEGASUS coach) to do this. See:** **Clarke, A., Paraskeva, N., White, P. et al. (2020). PEGASUS: the Design of an Intervention to Facilitate Shared Decision-making in Breast Reconstruction. J Canc Educ. https://doi.org/10.1007/s13187-019-01656-6)**	Thank you for this information. This has been flagged to the surveillance team at NICE,

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				We have also published work demonstrating that psychosocial outcomes are often more important to patients than physical ones when decision making and therefore eliciting these goals is essential in making an informed decision. See: **Guest, E.F ., Paraskeva, N ., Griffiths, C ., Hansen, E ., Clarke, A ., Baker, E ., & Harcourt, D. (2021).** **The nature and importance of women's goals for immediate and delayed breast reconstruction, *Journal of Plastic, Reconstructive & Aesthetic Surgery*, https://doi.org/10.1016/j.bjps.2020.12.085.**	
University of the West of England	Draft Guideline	010	006 - 010	Facilitating access to other patients' experiences of making the same decision can be helpful and worthy of mention here (either in person (if managed carefully), or through online resources of patient experiences such as videos)	Thank you for your comment. We have now clarified that resources can be used from various patient organisations in both section 1.2 of the recommendations and the rationale.
University of the West of England	Evidence B	General	General	The BRECONDA trial has shown it to be an effective aid for breast reconstruction decision making: Sherman KA, Shaw L-K, Winch CJ, Harcourt D, Boyages J, Cameron LD, Brown P, Lam T, Elder E, French J, Spillane A & the BRECONDA Collaborative Research Group (2016). Reducing	Thank you for your comment. Neither decisional conflict nor satisfaction with information were classed as outcomes measuring SDM by the committee and thus this paper is not included.

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				decisional conflict and enhancing satisfaction with information amongst women considering breast reconstruction following mastectomy: Results from the BRECONDA randomized controlled trial, *Plastic & Reconstructive Surgery, 138,* 4, 592-602. DOI: 10.1097/PRS.0000000000002538	
University of the West of England	Evidence C	General	General	There is evidence that decision aids can be cost effective, eg.: Parkinson, B., Sherman, K.A., Brown, P., Shaw, L-K.E., Boyages, J., Cameron, L.D., Elder, E. & Lam, T. (2018). Cost-effectiveness of the BRECONDA decision aid for women with breast cancer: Results from a randomized controlled trial, *Psycho Oncology, 27*(6):1589-1596. doi: 10.1002/pon.4698	Thank you for this information. NICE was not tasked with assessing the cost-effectiveness of SDM. The referenced study assesses the cost-effectiveness of a specific aspect of SDM (i.e., use of decision aids) in a single population (breast cancer) and is therefore limited in its ability to inform questions of the cost-effectiveness of SDM more generally. Furthermore, an assessment of the cost-effectiveness of SDM was out-of-scope for this guideline.
University of Warwick	Draft Guideline	001	General	It is unclear if the guideline is relevant for those who lack capacity. If outside of scope, clarify this in the "who is it for box?" If it is within scope, signpost to the relevant mental capacity legislation.	People who lack mental capacity are outside of the scope of this guideline. We have clarified this as you suggest.
University of Warwick	Draft Guideline	004	017-018	Our research on resuscitation decisions and the ReSPECT process has identified challenges with the transferability of shared decisions between healthcare settings. This concern was	Thank you. The committee did not see this evidence as it did not meet exclusion criteria for study type or specifically look at barriers and facilitators to 'shared decision making', however they discussed the importance of a shared and consistent approach in recommendation 1.1.5, 1.2.20 and 1.1.11

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				also highlighted in the Health Select Committee's report of End of Life Care. We suggest an additional step for high-level leadership (between 1.14 and 1.15) is to identify key external stakeholders to ensure a joined up / system wide approach to implementation. https://fundingawards.nihr.ac.uk/award/15/15/09 https://pubmed.ncbi.nlm.nih.gov/27077163/ https://pubmed.ncbi.nlm.nih.gov/25586369/	
University of Warwick	Draft Guideline	005	028-029	As it is rare for a shared decision to be relevant to only a single care setting, we suggest increasing the emphasis from consider to something stronger e.g. Engage with other support networks in the wider system and across the region.	Thank you. The evidence the committee used for this was from expert testimony and is not strong enough for them to make a strong recommendation. For details of the way NICE uses wording to convey strength of recommendations, see the box at the beginning of the recommendations section of the guideline.
University of Warwick	Draft Guideline	005, 007-010, 018-020	General	The term "appointments" is used throughout the guidance, suggesting that shared decision making is limited to the setting of an outpatient or GP clinic. Given the large number of advance care plans / shared decisions which are made following an acute hospital admission (often during a ward round), we suggest an alternative, more generalisable term is used e.g. "consultation" in place of appointments.	Thank you for your comment. The committee agreed that "appointments" was too focused on a primary care setting, and thus have changed the term where it appears to "discussion with a healthcare professional".

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				This would also cover the context for when shared decisions are made in a person's home or a social care setting.	
University of Warwick	Draft Guideline	006	005 - 017	Our research has shown that it is not always possible for a clinician and patient to reach agreement / shared decision. Guiding clinicians to seek a second opinion can often be helpful in resolving disagreements. Include an additional bullet which prompts organisations to ensure that training and development for practitioners includes what to when the clinician and patient cannot reach agreement.	Thank you for your comment. The committee agreed it was important to clarify a pathway in cases where SDM is not occurring They identified three different scenarios where SDM is impeded: 1. SDM cannot be performed (e.g. In an emergency): In these cases this is out of the scope of this guideline 2. The person is asking for a treatment that is unavailable (e.g. due to funding or referral criteria) and therefore the clinician cannot provide. 3. Clinician believes the treatment to be 'medically futile' and is therefore not required to provide it. In these cases a second opinion might be sought. The committee also noted that starting SDM as early as possible should help avoid situations like the ones outlined above from occurring as frequently. Text relating to this has been added to the rationale under the heder "during discussions with a healthcare professional".

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University of Warwick	Draft Guideline	006	022 - 024	Training needs to be relevant to the setting where shared decisions will be taking place. The context is quite different between an outpatient clinical to a post take ward round. Consider adding "relevant to the type of decision(s) being made and the clinical context within in which they are being made"	Thank you. These plans are at organisational level and therefore will be relevant to the organisational setting.
University of Warwick	Draft Guideline	008	001-004	It may not always be possible to provide supporting materials in advance, for example following an acute hospital admission. In these circumstances it may be necessary for clinicians to return for follow-up conversations. Appropriate time and staff resources would need to be made available for this.	Thank you. We agree.
University of Warwick	Draft Guideline	015	001-004	The research recommendation focuses on sustaining decisions between departments within an organisation. Our research on resuscitation decisions and the ReSPECT process has identified challenges with the transferability of shared decisions between healthcare settings. This concern was also highlighted in the Health Select Committee's report of End of Life Care (2014-15)	Thank you for this information. Settings would be covered under the "departments" aspect of this research recommendation.

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				We suggest the research recommendation should be extended to include transferability between care settings.	
University of Warwick	Draft Guideline	015	001-004	The scale of the training needed for the healthcare workforce could be very large. It is uncertain how an organisation can ensure that the clinical staff who need training the most, realise they need it, and engage with training and development especially when if it is not a personal goal or value. Consider a research recommendation relating to how to engage staff in shared decision making, optimise training models and how competency can be established, monitored and maintained	Thank you for your comment. It is outside of NICE's remit to recommend specific training programmes. The guideline does contain a section on supporting practitioner skills and competencies (see recommendations 1.1.12 to 1.1.15)
University of Warwick	Draft Guideline	018	001-004	We agree that shared decision making interventions will need to be adapted to specific settings and populations. The two examples cited (GP appointment, outpatient clinic) are very similar and do not provide sufficient context to the breadth of settings where shared decision making takes place. We suggest that the examples are extended to include the "post take ward round" or "following an acute admission to hospital".	Thank you for your comment. These terms have been changed to "a GP appointment or on a ward round" to cover both primary and secondary care. NICE appreciate there are many other settings and are providing these as examples.

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University of Warwick	Draft Guideline	General	General	We thank the committee for responding to our previous feedback and extending the scope of this guidance to include advance care planning, so that the relevance of this guidance extends to anticipatory decisions relating to emergency care and treatment (including resuscitation). We believe this will increase the impact of this guidance for the benefit of patients. We are conducting research, funded by the National Institute for Health Research, on the use of the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT), which facilitates clinicians and patients to make shared decisions relating to emergency care and treatment plans (including resuscitation). We undertook a prospective observational study across 6 acute NHS Trusts in England (2018-19) which showed that approximately 20% of patients admitted to hospital have an anticipatory decision relating to emergency care and treatment. The majority (>80%) were made following admission to hospital. Extrapolating these data across the NHS, suggests that over 1 million of such decisions may be undertaken each year. Our qualitative analysis indicates that many of the barriers to shared decision making identified in your review (e.g. time pressure, in-adequate	Thank you for this information.

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				training in communication skills / shared decision making) are also relevant The scale of advance care plans, requiring shared decision making, highlights the importance of embedding those decisions within the frameworks advocated by these guidelines. https://fundingawards.nihr.ac.uk/award/15/15/09 https://pubmed.ncbi.nlm.nih.gov/33482270/ https://pubmed.ncbi.nlm.nih.gov/31964663/ https://pubmed.ncbi.nlm.nih.gov/31945422/	
Winton Centre for Risk & Evidence Communication	Draft Guideline	010	022	The guidelines for practitioners do not state that patient decision aids should be of high quality according to IPDAS standards (although for organisations this is stated). Patient decision aids could be manufactured by any individuals or organisations which do not conform to IPDAS standards (for example, in order to be persuasive towards a particular treatment option) and practitioners should be aware of this and look for quality assurance against IPDAS standards.	Thank you for your comment. Recommendation 1.3.4 states that staff have access to quality-assured patient decision aids (assessed against the International Patient Decision Aid Standards).
Year of Care Partnerships	Draft Guideline	007	017	We think this section is excellent. We wonder if it might be worth including some emphasis on patient preparation. You have highlighted the importance of this in the evidence review. In particular:	Thank you for your comment and support. The examples given in recommendation 1.2.5 are examples and not intended to be an exhaustive list.

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				• Where a decision is anticipated, being clear about the purpose of the consultation (that it is one where decisions will be considered / made) and what type of decisions might be made (treatments, investigations, medications, procedures). Our experience is that patients are often unsure about this in advance and value being forwarned. • Generic consultation prompts are valuable to many patients alongside specific decision aids – 'what else is important to you at the moment?' 'who else might you want to involve in this decision?' 'what else might influence your decision?'. Sometimes there are no specific decision aids that provide information, but stimulating patients to consider options and identify questions remains very helpful. • You mention booklets, flyers and apps for supporting decisions, but patient facing websites, videos and internet resources may also be very valuable in at least identifying people's key questions. Thes have become even more widely used in the setting of remote consultations during the pandemic.	
Year of Care Partnerships	Draft Guideline	008	015	This section is also excellent and thank you. We wonder if it might be worth commenting:	Thank you for your support. The recommendations include being explicit about when decisions will be reviewed 1.2.14 and whether they would like a further appointment to discuss options (1.2.10)

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				- That a decision not to make, or to defer, a decision is still a decision, and is legitimate for the patient. - Where there is agreement to defer a decision, a plan should be put in place for the timeframe of the deferral and how an agreement will be arrived at. This latter is implied but not quite explicit.	
Year of Care Partnerships	Draft Guideline	011	015	The section on discussing risk, benefits and consequences is well expressed.	Thank you for your comment.
Year of Care Partnerships	Draft Guideline	General	General	This is a well thought out and helpful guideline where conventional RCT type evidence is scarce and recognising that RCT may not be the appropriate / best way to identify evidence around SDM. The qualitative research summaries are useful. We welcome the focus on organisational change to support SDM and embed it It might be worth considering health literacy dimensions in further iterations including the complexity of process that patients are subjected to and the difficulties they may have navigating these.	Thank you for your support. The committee discussed health literacy at length and have included recommendations to offer additional support to people who may need it.
Year of Care Partnerships	Evidence review B	026	001	This is a helpful summary if domains that have been researched	Thank you for your comment.

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Document processed	Organisation name – Stakeholder or respondent	Disclosure on tobacco funding / links	Number of comments extracted	Comments

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

Suggested responses to SH comments that raise implementation issues

- When general implementation issues are raised and cannot be addressed by the GDC – 'Thank you for your response. Your comments will be considered by NICE where relevant support activity is being planned'. We emphasise that the developers use their own tailored response when the implementation issues raised can be addressed through the guideline development process – e.g. by redrafting a recommendation etc.

- Examples of good practice received – send to SharedLearning@nice.nhs.uk and give the following standard response: 'Thank you for your response. We will pass this information to our local practice collection team. More information on local practice can be found here (enter hyperlink to shared learning or put in URL'.

- Examples of resources – send to endorsement@nice.org.uk and give the following standard response: 'Thank you for your response. We will pass this information to our resource endorsement team. More information on endorsement can be found here (enter hyperlink to endorsement scheme or put in URL'.

- When asked to produce tools/apps to support guideline – 'NICE routinely produce baseline assessment and resource impact tools. To encourage the development of other practical support tools, we run an endorsement scheme aimed at encouraging our partners to develop these in alignment with NICE recommendations. Eligible tools are assessed and if successful, will be endorsed by NICE and featured on the NICE website alongside the relevant guideline.'

Suggested responses to SH comments that raise surveillance issues

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- When surveillance issues are raised and cannot be addressed by the GDC – 'Thank you for your response. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.' When using this response, please ensure any comments are sent to the Surveillance team at surveillance@nice.org.uk.

Reminder to CfG – delete before goes to developer

- When issues are raised by GDCs we suggest that the guideline centre lead contact the Implementation team to agree a response implementationreferral@nice.org.uk. Sometimes these are straightforward issues that we can deal with ourselves. Other times we may need to allocate an Implementation Manager and ask for more information to understand the key issues before we could consider any proposals coming from GDCs for implementation activity. This information could either be submitted via our proposal template or by sending round the following questions to the committee:
    - What is the challenge that you think needs to be addressed and why is this challenging? (Please give a reference to the related NICE recs/quality standards). If you have highlighted more than one challenge please indicate which you think is the most significant and why.
    - What do you think NICE could do to help?
    - Are you aware of any interest or initiatives being taken by other national partners with whom NICE could work to tackle the problem?
    - If NICE were able to carry out some support work to help overcome this challenge, which stakeholders should we ensure we work with?
- Guideline centre leads need to contact Stephen Brookfield (Stephen.Brookfield@nice.org.uk) the Associate Director for Resource Impact Assessment for the paragraph about implementation in the GE report as the support team no longer produce this.

Registered stakeholders