Shared Decision Making and Consent: Phase 1 Final Report

Appendix A

Evidence Review Report

June 2021

Contents

Glossary of Terms

Term / Abbreviation	Description
AQUA	Advancing Quality Alliance
BMJ	British Medical Journal
BRAN	Benefits, Risks, Alternatives, do Nothing
BRAND	Benefits, Risks, Alternatives, do Nothing, Decision
BRAIN	Benefits, Risks, Alternatives, Intuition, Next steps
BSL	British Sign Language
CCG	Clinical Commissioning Group
COVID-19	Coronavirus Disease 2019
CPOC	Centre for Perioperative Care
CPR	Cardiopulmonary Resuscitation
GMC	General Medical Council
GP	General Practitioner
ISN	Information Standards Notice
IP-SDM	Interprofessional-SDM
MAGIC	Making Good Decisions in Collaboration
MeSH	Medical Subject Heading
NHS	National Health Service
NHSE/I	NHS England/ Improvement
NICE	National Institute for Health and Care Excellence
OSCE	Objective Structured Clinical Examination
OSDF	Ottawa Decision Support Framework
POA	Power of Attorney
PRSB	Professional Record Standards Body
SDM	Shared Decision Making
SDM-Q-9	9-item Shared Decision Making Questionnaire
SNOMED CT	Systemized Nomenclature of Medicine – Clinical Terms

1 Introduction

This document is an appendix to the final report for the Shared Decision Making (SDM) and Consent standard.

2 Methodology

The aim of the evidence review was to identify the information that was relevant for inclusion in the draft standard.

A systematic and pragmatic approach was used to conduct the literature review. After collation of existing project material five core documents were initially reviewed as key documents to identify themes and citation chaining was done on these to identify further papers using Google Scholar®. The key documents were:

1. The GMC guidance on decision making and consent.[1]
2. The draft NICE guidance on shared decision making.[2]
3. The NHS England shared decision making summary guide.[3]
4. The King's Fund report on making shared decision making a reality.[4]
5. The third edition book 'Shared decision making in health care'.[5]

In addition, limited searches were performed on the Medline bibliographic database using PubMed and Social Care Online. This included controlled vocabulary (MeSH terms where appropriate) and key words linked by Boolean operators. Selected articles identified were then excluded/included for further review by title and abstract. Included articles were those thought to be relevant to shared decision making and consent. Articles were generally excluded if they were thought to be out of scope or if the findings of the paper were available at a higher level of evidence (e.g., systematic review). Development of the draft standard and mapping to existing PRSB information standards was done in parallel and iteratively updated in line with the evidence review findings. Additional documents for review were also identified throughout the project via stakeholder recommendations and specific queries to the google search engine as well as the subsequent citation chaining of those.

A summary of the findings is presented in section 3 below along with a conclusion/ recommendation relating to the draft standard. Appendix A includes a table that is derived from the evidence review findings, and comprises of:

- Proposed elements for inclusion in the draft standard.
- Proposed themes for inclusion in implementation guidance.
- Existing PRSB standards, sections and elements that are relevant to shared decision making or consent.
- Other aspects identified that may represent good practice in SDM but are probably not appropriate for inclusion in a record standard.

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[1] GMC. 'Decision Making and Consent.' General Medical Council: 2020 [Accessed November 2020]

[2] NICE. 'Shared Decision Making: NICE Guideline DRAFT.' National Institute for Health and Care Excellence: 2020 [Accessed December 2020]

[3] NHSE. 'Shared Decision Making: Summary Guide.' NHS England: 2019 [Accessed November 2020]

[4] Coulter A and Collins A. 'Making Shared Decision-Making a Reality: No decision about me without me.' The King's Fund: 2011 [Accessed October 2020]

[5] Shared decision making in health care (3rd Edition). Edited by: Elwyn G, Edwards A, and Thompson R.

3 Evidence review

3.1 Montgomery and the law

- The 2015 UK Supreme Court judgement of Montgomery v Lanarkshire Health Board related to 'a case concerning the negligent failure by a doctor to disclose a [rare] risk associated with childbirth'[6]. The model of delivery (vaginal) was 'complicated by shoulder dystocia that resulted in a child being born with cerebral palsy.'[7]
- The judgement (which was based on GMC guidance) shifts the valid basis of consent and shared decision making from that of guidance to a legal requirement and explicitly recognises patients as the decision makers.[8]

3.2 Person's understanding of their diagnosis or condition

- Communication strategies that are known to be effective in improving the quality of the conversation and understanding in patients with low health included 'teach-back' (where the person is asked to explain what they have just heard/discussed), 'chunking and checking' (where the clinician shares information in manageable chunks and checks understanding at each stage) as well as using pictures and illustrations.[9]
- Patients are not always equipped to understand their condition.[10] Especially in the immediate shock of a new diagnosis such as cancer (emotional overwhelm) where information overload (in which the 'decision-making capacity of a patient is overwhelmed by the sheer complexity or volume of information at hand.') and being overwhelmed may limit the person's capacity to give informed consent.[11]

Conclusion: There are several strategies used in SDM to assess and enable patient understanding of their diagnosis and treatment options, including 'teach-back' and 'chunking and checking'. Patients are not always equipped to understand their condition. Especially in the immediate shock of a new diagnosis such as cancer where information overload and being overwhelmed may limit the person's capacity to give informed consent. These issues were explored iteratively in the evidence review following emphasis by stakeholders in the webinar.

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[6] Campbell M. 'Montgomery v Lanarkshire health board.' Common Law World Review:2015. [Accessed November 2020]

[7] Harrison N and others. 'How Montgomery is reconfiguring consent in the UK.' The Lancet: 2018, volume 392 [Accessed December 2020]

[8] Ward J and others. 'Shared decision making and consent post-Montgomery, UK Supreme Court judgement supporting best practice.' Patient Education and Counseling: 2020, volume 103, pages 2609 – 2612 [Accessed December 2020]

[9] Roodbeen R and others. 'Communication and shared decision-making with patients with limited health literacy; helpful strategies, barriers and suggestions for improvement reported by hospital-based palliative care providers.' PLoS ONE: 2020, volume 15(6): e0234926 [Accessed December 2020]

[10] Levit L. 'Chapter 3: Patient-centred communication and shared decision making.' Delivering high-quality cancer care: charting a new course for a system in crisis: 2013. [Accessed June 2021]

[11] Bester J and others. 'The limits of informed consent for an overwhelmed patient: Clinicians' role in protecting patients and preventing overwhelm.' American Medical Association Journal of Ethics: 2016, volume 18(9), pages 869-886 [Accessed May 2021]

3.3 Recording the encounter details:

3.3.1 Persons accompanying the patient and family or carer involvement in shared decisions:

- The involvement of family or carer involvement in SDM is variable. It is dependent on the person's wishes and consent. Often, caregiver involvement increases as the decision-making ability of the person declines e.g., due to worsening dementia.[12]
- Family members caring for a person with mental illness or dementia may be 'disproportionately at risk of carer burden' compared to those supporting individuals with other long-term conditions and frequently express a desire to be involved in decisions about their loved ones' care.[13]
- The GMC guidance on decision making and consent says that clinicians should 'accommodate a patient's wishes if they would like anyone else – a relative, partner, friend, carer or advocate – to be involved in discussions and/or help them make decisions.'[14]
- The draft NICE guideline on shared decision making recognises that SDM may include 'communicating with and involving family members, carers, advocates or other people if the person chooses to include them.' This is suggested to help the person to 'actively engage in the consultation', 'explain what is important to them' and 'remember information they have been given' to 'make decisions about their care.'[15]
- Family, friends, and carers of a person may be encouraged to participate in SDM as *decision partners* – a supportive role to aid decision making for those with 'a trusting relationship with the patient [and] a clear understanding of both the patient's health condition and the decision that must be made.'[16]
- A model of 'Triadic SDM' has been proposed for health and social care decisions shared between a person who uses services, their informal carer and clinician.[17] It has been argued that informal carer involvement in SDM may improve patient outcomes, with notable studies in areas such as mental health and cancer care.[18]

Conclusion: There is professional guidance and academic literature advocating the inclusion of 'decision partners' (such as family, friends or carers) in the SDM process.

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[12] Miller LM and others. 'Shared decision-making in dementia: A review of patient and family carer involvement.' Dementia, volume 15(5), pages 1141 – 1157 [Accessed December 2020]

[13] Bradley E and Green D. 'Involved, inputting or informing: "Shared" decision making in adult mental health care.' Health Expectations: 2018, volume 21, pages 192 – 200 [Accessed December 2020]

[14] GMC. 'Decision Making and Consent.' General Medical Council: 2020 [Accessed November 2020]

[15] NICE. 'Shared Decision Making: NICE Guideline DRAFT.' National Institute for Health and Care Excellence: 2020 [Accessed December 2020]

[16] Gray TF and others. 'The decision partner in healthcare decision-making: A concept analysis.' International Journal of Nursing Studies: 2019, volume 92, pages 79 – 89 [Accessed December 2020]

[17] Schuster F and others. ''Triadic' shared decision making in mental health: Experiences and expectations of service users, caregivers and clinicians in Germany.' Health Expectations: 2021, volume 24(2), pages 507 – 515 [Accessed April 2021]

[18] Hamann J and Stephan H. 'Why and how family caregivers should participate in shared decision making in mental health.' Journal of Psychiatric Research: 2019, volume 70(5), pages 418 – 421 [Accessed December 2020]

3.3.2 Person-clinician communication, language and use of an interpreter:

- There is a risk that consent may not be valid for conversations about investigations or treatment conducted in a language other than that best understood by the patient.[19]
- The GMC guidance on decision making and consent recommends the provision of an 'interpreter or translation service' to support decision making for patients with difficulty understanding spoken English and emphasises that this may be a legal requirement for Welsh speakers.[20]
- The draft NICE guideline on shared decision making also emphasised the need to use 'good-quality translation services…for people who don't speak English well.'[21]
- Guidance from Public Health England emphasises the importance of recording in the EHR (and sharing with transfers of care) a person's preferred written and spoken language (including dialect) and whether they need an interpreter.[22]
- A 2018 study of 13,800 patients in the United States found that limited English proficiency was associated with poor self-reported outcome measures of shared decision making, patient satisfaction and person-clinician communication.[23]
- Studies in the perioperative setting have shown that surgeons may sometimes rely on 'their own non-English language skills, bilingual staff, and family and friends of patients' for translation and that this can lead to preventable adverse events.[24]
- NHSE[25] and Public Health Scotland[26] guidance specifies that in health and care conversations, where English proficiency is an issue, a professional interpreter must be offered instead of using family or friends to translate.
- In adults, language barriers to communication have been associated with increased risk of preventable adverse events.[27]
- In children, language barriers are one of the most significant risk factors for adverse health events.[28] A multicentre study has found that in hospitalised children, having

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[19] Tilak A and Kasodekar S. 'Enigma of valid consent continues in 2021……' Journal of Obstetric Anaesthesia and Critical Care: 2021, volume 11(1), pages 1 – 4 [Accessed May 2021].

[20] GMC. 'Decision Making and Consent.' General Medical Council: 2020 [Accessed November 2020]

[21] NICE. 'Shared Decision Making: NICE Guideline DRAFT.' National Institute for Health and Care Excellence: 2020 [Accessed December 2020]

[22] PHE. 'Guidance: Language interpreting and translation: migrant health guide.' Public Health England: 2017 [Accessed April 2021]

[23] Paredes AZ and others. 'Influence of English proficiency on patient-provider communication and shared decision-making.' Surgery: 2018, volume 163, pages 1220 – 1225. [Accessed December 2020]

[24] Patel DN and others. 'Preoperative consent for patients with limited English proficiency'. Journal of Surgical Research: 2016, volume 200(2), pages 514 – 522 [Accessed December 2020]

[25] NHSE. 'Guidance for commissioners: Interpreting and translation services in primary care. NHS England: 2018 [Accessed December 2020]

[26] PHS. 'Guidance: Interpreting, communication support and translation national policy.' Public Health Scotland: 2020 [Accessed December 2020]

[27] Bartlett G and others. 'Impact of patient communication problems on the risk of preventable adverse events in acute care settings.' Canadian Medical Association Journal: 2008, volume 178(12), pages 1555-1562 [Accessed December 2020]

[28] Flores G. 'Language barriers and hospitalized children: Are we overlooking the most important risk factor for adverse events?' JAMA Pediatrics: 2020, volume 174(12) [Accessed December 2020]

parents who expressed 'limited comfort with English' was the single biggest risk factor for preventable adverse events. [29]

Conclusion: Lack of proficiency in English may be a barrier to valid consent and is associated with adverse health events. The policy documents, professional guidance and literature reviewed supports the recording of measures taken to overcome language/communication difficulties for people making shared decisions about their health and care. The standard could include whether a professional interpreter (or family member, friend, or other person) was used to translate the conversation.

3.3.3 Audio or visual recording of the shared decision making conversation:

- The GMC guidance on decision making and consent advises clinicians to 'accommodate a patient's wishes if they would like to record the discussion.'[30]
- Informed consent is required to make audio/visual recordings of the SDM conversation for purposes of direct care and these form part of the medical record (unless made and therefore owned by the person themselves).[31]
- Randomised controlled trials have demonstrated that use of audio/visual recordings is positively associated with patient reported outcomes such as knowledge, information recall, and decisional self-efficacy and negatively associated with decision regret and anxiety.[32]
- Revisiting the SDM conversation later via audio recordings may help address issues that have arisen due to the COVID-19 pandemic, such as restrictions placed on caregiver attendance at consultations (limiting their involvement with any decisions made) and communication challenges associated with telemedicine that may arise for people with poor technology literacy.[33]

Conclusion: Professional guidance from the GMC and randomised controlled trial data supports the recording of conversations related to shared decision making and consent, as part of the electronic health record.

3.4 Recording the distributed nature of shared decisions

- The draft NICE guidance on shared decision making recognises that shared decision making may take place 'before, during, and after appointments.'
- IP-SDM (see below) is one of several models that recognised the distributed nature of medical decision making.

Conclusion: The NICE guidance on shared decision making recognises that shared decision making may take place 'before, during, and after appointments.' Several models of SDM, such as the IP-SDM recognise the distributed nature of medical decision making that

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[29] Khan A and others. 'Association between parent comfort with English and adverse events among hospitalised children.' JAMA Pediatrics: 2020, volume 174(12) [Accessed December 2020]

[30] GMC. 'Decision Making and Consent.' General Medical Council: 2020 [Accessed November 2020]

[31] GMC. 'Making and using visual and audio recordings of patients.' General Medical Council: 2011 [Accessed November 2020]

[32] Rieger KL and others. 'Should consultation recording use be a practice standard? A systematic review of the effectiveness and implementation of consultation recordings.' Psycho-Oncology: 2017, volume 27(4), pages 1121 – 1128 [Accessed December 2020]

[33] Kwon DH and others. 'Prime time for consultation audio recordings supporting shared decision making during and after the COVID-19 era.' JCO Oncology Practice: 2020, volume 17(4), pages 161 – 164 [Accessed December 2020]

often involves decisions made across multiple professionals and appointments (see section 3.5.3 below). The standard should account for the fact that decision making is 'initiated, sustained and transformed over a range of encounters [and people].'[34]

3.5 Models and core components of shared decision making:

- There are several highly cited models of SDM in the published medical literature and these specifically include:
    - the 'three-talk model', first developed in 2013 & updated in 2017.
    - the Ottawa Decision Support Framework (ODSF), first developed in 2000 & updated 2020.
    - the Interprofessional-SDM (IP-SDM), first developed in 2010.
- Of these models, only the IP-SDM has been used to inform a (recently published) testable theory of 'how SDM works, for whom, in which circumstances, and why or why not [it works].'[35] However, the use of the 'three-talk model' is supported in the draft NICE guideline on shared decision making.[36]
- There are also some notable patient focused models, including:
    - the MAGIC programme's 'Ask 3 questions' campaign.
    - Choosing Wisely UK's 'BRAN' mnemonic (Benefits, Risks, Alternatives, (doing) Nothing).
- A comprehensive systematic review of the key components of 40 unique shared decision making models was published by the BMJ in 2019.[37] This found that although there is no unified model of SDM many of them consistently share core components (found in > 50% of models). These included:
    - Describe treatment options (88%)
    - Make the decision (75%)
    - Patient preferences (65%)
    - Tailor information (65%)
    - Deliberate (58%)
    - Create choice awareness (55%)
    - Learn about the patient (53%)
- A list of the common elements of the SDM models identified in this PRSB evidence review can be found in the table in appendix A.

Conclusion: There are several highly cited models of SDM in the literature as well as notable patient focused/driven models that are used in some areas within the UK health system. A recent systematic review has identified the key components of shared decision making models in the literature. Of the 40 SDM models evaluated, 35 (88%) included describing treatment options (including benefits/risks, feasibility, listing and presenting evidence for them) and 30 (75%) included making the decision (including documenting, making or deferring, and revisiting the decision). The consultation for the draft standard

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[34] Rapley, T. 'Distributed decision making: the anatomy of decisions-in-action,' Sociology of Health and Illness: 2008, volume 30(3), pages 429-444 [Accessed December 2020]

[35] Waldron T and others. 'Development of a program theory for shared decision-making: a realist synthesis.' BMC Health Services Research: 2020, volume 20 (59), [Accessed January 2021]

[36] NICE. 'Shared Decision Making: NICE Guideline DRAFT.' National Institute for Health and Care Excellence: 2020 [Accessed December 2020]

[37] Bomhof-Roordink H and others. 'Key components of shared decision making models: a systematic review.' BMJ Open: 2019, volume 9: e031763 [Accessed January 2021]

should include and test the common features of the models that should be recorded. An overview of the specific models reviewed is provided below.

3.5.1 The 'three-talk model' of shared decision making:

- The three-talk model[38,39] of shared decision making is a three-step model, highly cited in the literature, which originally consisted of the following components:
    - Choice talk: The step of establishing with the patient the fact that 'reasonable options are available.' This step has recently been updated to 'Team talk' to account for the fact that other individuals (such as family members, friends, carers, and others) may be involved beyond the patient and clinician.[40]
    - Option talk: Describing the options, checking the patient's prior knowledge about them, clarifying the harms and benefits, and using patient decision support tools where available.
    - Decision talk: Supporting the patient to explore their preferences, make decisions and offering later review of any decisions made.
- To our knowledge, one randomised controlled trial (RCT) has explored the effectiveness of SDM conducted using the three-talk model, in complex patients with lumbar degenerative diseases.[41] This study compared the use of decision aids guided by a decision coach trained in the three-talk model with standard educational materials guided by a health educator. The trial found that the three-talk intervention led to a 'significant increase in decision self-efficacy [situation specific self-confidence in making a decision] and a significant decrease in decision conflict' as well as decision satisfaction, when compared to the control [health education] group.
- The draft NICE guideline on shared decision making states that 'organisations should ensure that training and development for practitioners [includes] understanding the principles that support shared decision making based on the three-talk model.'[42] The NICE committee heard expert evidence on using the three-talk model to structure the SDM process and concluded the following:
    - the model is simple to understand and practical to use in healthcare settings.
    - interventions demonstrating an effect '…were all consistent with one or more stages of the three-talk model [and] it was useful to think in terms of these key stages of shared decision making.'

Conclusion: The three-talk model of SDM is highly cited in the literature and recommended to be used in clinical practice by NICE in the draft guideline on shared decision making. One RCT in a specific patient group has shown use of the three-talk model in SDM may positively

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[38] Elwyn G. 'Chapter 13: The three talk model of shared decision making.' Shared decision making in health care (3rd Edition). Edited by: Elwyn G and others.

[39] Elwyn and others. 'Shared decision making: A model for clinical practice.' Journal of General Internal Medicine: 2012, volume 27(10), pages 1361 – 1367 [Accessed November 2020]

[40] Elwyn G and others. 'A three-talk model for shared decision making: multistage consultation process.' British Medical Journal: 2017, volume 359: j4891 [Accessed November 2020]

[41] Chen C and others. 'Effectiveness of shared decision-making intervention in patients with lumbar degenerative diseases: A randomized controlled trial.' Patient Education and Counselling: 2021 (Article in Press) [Accessed April 2021]

[42] NICE. 'Shared Decision Making: NICE Guideline DRAFT.' National Institute for Health and Care Excellence: 2020 [Accessed December 2020]

influence decision related patient outcomes; reducing decision conflict and improving the person's confidence and satisfaction with the decision made.

3.5.2 The Ottawa Decision Support Framework (ODSF) of shared decision making:

- The Ottawa Decision Support Framework[43,44,45] is another recently updated and highly cited model of SDM in the literature. The ODSF hypothesises that to improve decision quality and therefore achieve positive decisional outcomes, decision support interventions must address a person's decisional needs. The framework comprises the following three components – decisional needs, decision support, and decisional outcomes – as outlined below:
    - **Decisional needs:** A 'deficit that can adversely affect the quality of a decision and requires tailored decision support' including:
        - Difficult decisional type and timing: Difficult decisions may include (for type) multiple options or uncertain evidence and (for timing) 'urgent, delayed, or unpredictable' timeframes.
        - Unreceptive decisional stage: The patient may not be ready to decide, may prefer that the decision is made for them, or may be experiencing other barriers to deciding e.g., '[experiencing] powerful emotions affecting information processing', 'lack of acceptance of condition or need for treatment', or 'being unmotivated'.
        - Decisional conflict: The pathognomonic manifestation of decisional conflict is the person saying that they are uncertain, but other more subtle signs may include 'wavering between options', 'feeling physically stressed', 'feeling distressed or upset', and others.
        - Inadequate knowledge: A person may be unaware 'of essential relevant facts to make a decision.'
        - Unrealistic expectations: A person may have perceptions of the 'benefits, harms, other' of options that are 'not aligned with the current evidence for similar patients' or they may have 'difficulty believing that the outcome probabilities [discussed] apply to them.'
        - Unclear values: A person may be unclear about how important the various features of the options discussed (e.g., benefits, harms, known and unknown outcomes) are to them.
        - Inadequate support & resources to make and implement the decision: There are several factors given in the ODSF for how/why this may occur. For example, the person may experience 'information overload', information about others' experiences with the options may not be

[43] Hoefel L and others. '20th anniversary update of the Ottawa decision support framework part 1: A systematic review of the decisional needs of people making health or social decisions.' Medical Decision Making: 2020, volume 40(5), pages 555 – 581 [Accessed December 2020]

[44] Hoefel L and others. '20th anniversary update of the Ottawa decision support framework: Part 2 subanalysis of a systematic review of patient decision aids.' Medical Decision Making: 2020, volume 40(4), pages 522 – 539 [Accessed December 2020]

[45] Stacey D and others. '20th anniversary update of the Ottawa decision support framework: Part 3 Overview of systematic reviews and updated framework.' Medical Decision Making: 2020, volume 40(4), pages 379 – 398 [Accessed December 2020]

available (e.g., medication side effects), or there may be other reasons that information of the appropriate level is not shared with them. The patient may experience social pressure or receive conflicting recommendations from others (e.g., family members, friends, or others). Difficulty with decisional roles may also be a factor – for instance there may be 'difficulty deliberating with [the] practitioner' due to a rapport that is poor/not yet established, and there may be difficulty involving the family if their decision related values differ to the person or the patient does not want to worry them by involving them in the discussion. In addition, the person may lack the experience, skills, motivation, or resources (e.g., financial) to make/implement a decision.
        - Personal & clinical needs: SDM interventions may need to be tailored to a person's demographics (e.g., 'age, gender, education, marital status, ethnicity, socioeconomic status, occupation, locale' or 'religion/spirituality') and other information in their full health and care record (e.g., 'diagnosis & duration of condition' and 'health status'). Another influencer described in the framework are the characteristics of the 'practitioner' (e.g., 'age, gender, ethnicity, clinical education, specialty, clinical practice locale, experience, counselling style').
    - **Decision support:** Structured interventions to assist 'in deliberating about the decision and communicating with others' that are 'tailored to the patient's decisional needs' and what matters most to them.
    - The decision support process involves:
        - Establishing rapport (with the person)/
        - Inviting the person's participation in the SDM discussion.
        - Assessing and addressing patient's decisional needs with tailored support (including facilitating their 'receptivity to information or deliberation, providing information and verifying their understanding, and clarifying options that matter most to the person).
    - Decision support interventions may include the use of:
        - Clinical counselling: The core SDM process conducted by health professionals able to 'identify/diagnose a problem/health condition', 'identify options', 'provide decision support' (which may involve use of or signposting to a PDA or referral to decision coaching), 'facilitate implementation of the final decision.' e.g., by ordering tests, prescribing, performing surgery, or making a referral etc.
        - Patient decision aids: These are discussed elsewhere (this document) but for purposes of the ODSF are defined as 'supplementary, condition-specific, evidence-based tools to prepare a patient to participate in making a specific and deliberated choice [in SDM]'.
        - Decision coaching: This is defined as 'supplementary nondirective guidance by trained health professionals [referred to by the health professional who identified the options] to develop patient's deliberation and implementation skills.'
    - **Decisional outcomes:** These include:
        - Quality of the decision: Measurement here requires determining if a person had an informed understanding, aligned with the essential decision-specific knowledge (including accurate risk assessment) needed, and whether the decision made matched their values.

        - Quality of the decision making process: The framework asserts that this outcome is associated with reduction in one or more of decisional needs, proportion of patients undecided, and a person's perceptions of feeling uninformed, unclear on their values, or unsupported in SDM.
        - Impact: This covers secondary outcomes – for example, long term adherence to a chosen prescribed medication or effects on health service use/costs.
        - Optional evaluation when warranted: Commonly used performance measures in trials evaluating the ODSF include the 16-item Decisional Conflict Scale and Decisional Regret Scale.
- Two recent systematic reviews have validated some aspects of the ODSF 'across a range of decisions, populations, and countries.' These reviews included:
    - A synthesis of 45 decisional needs studies, involving 2857 patient decision makers across seven countries (92 parent decision makers, 81 family members, and 523 practitioners were also involved). This found that between existing ODSF decision needs were reported across 4 – 89% of the studies reviewed (decisional conflict = 44%, inadequate knowledge = 89%, unrealistic expectations = 24%, unclear values = 44%, inadequate support and resources = 4 – 82%, complex decision characteristics = 13 – 18%, personal & clinical needs = 24 – 38%).[46]
    - A sub-analysis of the RCTs in the 2017 Cochrane review of PDAs[47] that included PDAs developed using the ODSF. The meta-analysis included 105 trials involving ODSF-developed PDAs. This found that, compared with the standard of care ODSF based PDAs 'improved knowledge [,] increased accurate risk perceptions [,] increased congruence between informed values and chosen options [,] and reduced perceived decisional needs…and the proportion of undecided patients.'[48]
- Two other systematic reviews also support the content of the ODSF for SDM. These include:
    - A review of 253 studies that used the 16-item Decisional Conflict Scale (DCS) to explore decisional conflict in shared decision making. This found that patient exposure to structured decision support interventions (DESIs) was associated with deceased DCS scores in the short term, whereas standard practices tended to be associated with increased DCS scores immediately after decision making.[49]

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[46] Hoefel L and others. '20th anniversary update of the Ottawa decision support framework part 1: A systematic review of the decisional needs of people making health or social decisions.' Medical Decision Making: 2020, volume 40(5), pages 555 – 581 [Accessed December 2020]

[47] Stacey D and others. 'Decision aids for people facing health treatment or screening decisions (Review).' Cochrane Database of Systematic Reviews: 2017, Issue 4, Art. No.: CD001431 [Accessed December 2020]

[48] Hoefel L and others. '20th anniversary update of the Ottawa decision support framework: Part 2 subanalysis of a systematic review of patient decision aids.' Medical Decision Making: 2020, volume 40(4), pages 522 – 539 [Accessed December 2020]

[49] Garvelink M and others. 'Decisional conflict scale findings among patients and surrogates making health decisions: Part II of an anniversary review.' Medical Decision Making: 2019, volume 39(4), pages 315 – 326 [Accessed December 2020].

- A sub-analysis of two RCTs of decision coaching included in the 2011 Cochrane review of PDAs.[50] This found that 'compared with usual care, decision coaching improved [patient] knowledge' but concluded that further trials were needed to establish the effectiveness of decision coaching.[51]

Conclusion: The ODSF is a highly cited and comprehensive model of shared decision making that has been validated by the outcomes of four systematic reviews. The model hypothesises positive decisional outcomes arise from quality decisions that themselves depend on decision support interventions that 'assess and address a person's decisional needs.' Implementation of the framework in clinical practice would likely be complex and is not currently supported by professional bodies in the UK. Some features of the ODSF are relevant for inclusion in the draft standard, in particular those components shared/similar with other established SDM models.

3.5.3 The Interprofessional-SDM (IP-SDM) model of SDM:

- The Interprofessional-SDM is another highly cited model in the peer-reviewed literature, which aims to move beyond the 'patient-practitioner dyad' and focuses on collaborative decisions 'made by patients together with two or more health professionals [involved].'[52] The authors argue that the 'increasingly interprofessional nature' of healthcare delivery meant that a new integrated model of SDM that involves patients in decisions 'not just with a single healthcare provider but with a team' is needed.[53,54]
- The IP-SDM model has the following three levels (*NB*: the latter two levels are beyond the scope of this evidence review):
  - Individual (micro) level:
  - Healthcare system (meso) level: Includes 'healthcare teams and organisations.'
  - Healthcare system (macro) level: Includes 'heath policies, social context, and professional [bodies].'
- The level most analogous to the scope of the draft standard and the other SDM models included in this review is the micro level. This section of the model covers the patient's experience at various steps of the shared decision making process and the other individuals/professionals involved/informed at each stage. The steps are as follows:

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[50] Stacey D and others. 'Decision aids for people facing health treatment or screening decisions (Review).' Cochrane Database of Systematic Reviews: 2011, Issue 10, pages 1 – 208 [updated 2017]

[51] Stacey D and others. 'Decision coaching to prepare patients for making health decisions: a systematic review of decision coaching in trials of patient decision AIDS.' Medical Decision Making: 2021, volume 32(3): E22 – 33 [Accessed December 2020]

[52] Stacey D and others. 'Shared decision making models to inform an interprofessional perspective on decision making: A theory analysis.' Patient Education and Counselling: 2010, volume 80(2), pages 164 - 72 [Accessed December 2020]

[53] Légaré F and others. 'Interprofessionalism and shared decision-making in primary care: a stepwise approach towards a new model.' Journal of Interprofessional Care: 2011, volume 25(1), pages 18-25 [Accessed December 2021]

[54] Hanum C and Findyartini A. 'Interprofessional shared decision-making: A literature review.' The Indonesian Journal of Medical Education: 2020, volume 9(1), pages 81-94 [Accessed December 2020]

- **Step 1 – Patient with a health condition & decision point situation (equipoise):** This occurs where there is 'more than one option (including the option to maintain the *status quo*)' available.
- **Step 2 – Exchange of information:** This requires the patient and others involved (in the model these include healthcare professional(s), family members, decision coach & 'first contact person' (e.g., 'family physician or nurse practitioner' who conducts the SDM process with the patient and acts a 'team leader')) to share information 'about the potential benefits and harms of the options.' This step may use 'educational material, patient decision aids, and other evidence-based resources.'
- **Step 3 – Clarification of values/preferences:** This step acknowledges the values of the patient as 'ideally the cornerstone of SDM' but also recognises that 'the values of all actors may influence the decision.' According to the authors, the 'values at play' should be understood by involved parties even if they are not shared by all participants.
- **Step 4 – Feasibility of the options:** This observes that 'the availability of some healthcare options varies considerably across healthcare systems and nations' and that where a given option cannot be offered this should be established with participants before individual preferences are determined.
- **Step 5 – Preferred choice & actual choice:** This may include the patient's preferred option, the clinician's preferred option ('in the form of a recommendation') and what was decided (or 'in case of disagreement…deferred.').
- **Step 6 – Implementation & health outcomes:** This step involves the actions and evaluations taken to ensure the decision made leads to 'a favourable impact on the health outcomes that [the person] values most' and recognises that 'many healthcare decisions will need to be revisited…especially when the initial choice does not produce the desired health outcomes.'

- The science of interdisciplinary collaborative decision making is in its infancy with some progress being made in several areas including 'limited methodological guidance [and] suitable instruments [for implementation and assessment]', with some initial 'efforts to implement the IP-SDM approach in real-world settings.'[55]

Conclusion: The IP-SDM is a highly cited model of shared decision making that is respected in the field although its implementation is not currently supported by professional bodies in the UK. The model recognises the distributed nature of medical decision making that often involves multiple professionals and appointments. Some features of the IP-SDM are relevant for inclusion in the draft standard, in particular those components shared/similar with other established SDM models.

[55] Dogba MJ and others. 'The evolution of an interprofessional shared decision-making research program: Reflective case study of an emerging paradigm.' International Journal of Integrated Care: 2016, volume 16(3), pages 1-11 [Accessed December 2020]

3.5.4 The 'Ask 3 Questions' model/tool for shared decision making:

- A 2011 cross-over trial of 36 simulated patient contacts aiming to improve the quality of information shared using the following three questions[56]:
    - What are my options?
    - What are the benefits and harms?
    - How likely are these [to happen to me]?
- The study found that the use of these questions improved information shared and patient involvement in decisions as measures by the Assessing Communication about Evidence and Patient Preferences (ACEPP) and OPTION tools.
- The Ask 3 Questions marketing campaign was initiated later as part of the Health Foundation MAGIC (Making good decisions in collaboration) programme, to 'raise patients' awareness of SDM and encourage them to ask three key questions', derived from the original 2011 study, which were:[57]
    - What are my options?
    - What are the possible benefits and risks?
    - How can we make a decision that is right for me?
- Patients were encouraged to ask these questions during consultations with a healthcare professional.
- The original campaign was popular with healthcare staff and patients, but the programme was unable to demonstrate a positive effect on the target outcome of patient 'activation' ('a [person's] knowledge, skill, and confidence for managing their health and health care'[58]) prior to consultations.
- Two small scale research studies have involved adult patients in their evaluations of the feasibility of using Ask 3 Questions in live settings:
    - One study found that 87% of participants invited to view a short Ask 3 Questions video clip prior to reproductive and sexual health clinic asked one or more questions.[59]
    - Another used focus groups and interviews to test a German translation.[60]
- A Dutch study used questionnaires to evaluate and pilot a Dutch version of '3 Good Questions' for use by children in secondary care.[61] The study used CollaboRATE and SDM-Q-9 SDM performance measures to demonstrate that more SDM occurred when the tool was used. The questions adapted for a paediatric population were:

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[56] Shepherd H and others. 'Three questions that patients can ask to improve the quality of information physicians give about treatment options: a cross-over trial.' Patient Education and Counseling: 2011, volume 84(3), pages 379-85 [Accessed November 2020]

[57] Report: 'The MAGIC programme: evaluation: An independent evaluation of the MAGIC (Making good decisions in collaboration) improvement programme.' The Health Foundation: 2013 [Accessed November 2020]

[58] Report: 'Supporting people to manage their health: An introduction to patient activation.' The King's Fund: 2014 [Accessed December 2020]

[59] Shepherd H and others. 'Can consumers learn to ask three questions to improve shared decision making? A feasibility study of the ASK (AskShareKnow) patient-clinician communication Model(®) intervention in a primary health-care setting.' Health Expectations: 2016, volume 19(5), pages 1160-8 [Accessed November 2020]

[60] Lindig A and others. 'Adaptation and qualitative evaluation of Ask 3 Questions – a simple and generic intervention to foster patient empowerment.' Health Expectations, volume 23(5), pages 1310 - 1325 [Accessed December 2020]

[61] Rexwinkel R and others. 'Evaluation of the "3 Good Questions" program for shared decision-making in pediatric medicine: a feasibility study.' European Journal of Pediatrics: 2021, volume 180, pages 1235-1242 [Accessed May 2021]

    - This is what I feel, what is it?
    - What can we do about it?
    - What does this mean for me now and later?
- It is not clear from the studies to date whether the use of different wording, non-English translations, or use in different patient populations or settings with varying levels of SDM training/maturity influences the effectiveness of the tool.
- In 2020, the Ask 3 Questions campaign was adapted for uses as part of the National Shared Decision Making Programme for the NHS, to include the following questions[62]:
    - What are my *options*?
    - What are the *pros* and *cons* of each option for me?
    - How do I get support to help me make a decision that is *right for me*?
- Guidance produced in 2019 by NHSE recommends that healthcare systems prepare people for SDM by 'putting in place a campaign that encourages people to 'ask 3 questions', to ask 4 questions, such as BRAN, or equivalent.'[63]

Conclusion: The Ask 3 Questions is a patient focused tool that may improve the quality of SDM in some healthcare settings, but more research is required to establish this. The tool has been trialled in adults in the UK as part of the MAGIC programme and National Shared Decision Making Programme and is recommended in some UK professional guidance. The use of an equivalent for children has not yet been widely used in the UK. Provision of a version in the draft standard may allow key aspects of shared decision making to be simply recorded in settings where the tool is used.

3.5.5 The 'BRAN' (Benefits, Risks, Alternatives, (doing) Nothing) model of shared decision making:

- Choosing Wisely UK's BRAN tool invites patients to ask the following questions[64]:
    - What are the **B**enefits?
    - What are the **R**isks?
    - What are the **A**lternatives?
    - What if I do **N**othing?
- The use of BRAN is supported by the Academy of Medical Royal Colleges (AoMRC)[65] and NHS Scotland[66] although there are currently no available research studies in the literature to support its use in clinical practice.
- Guidance by NHSE recommends that healthcare systems prepare people for SDM by 'putting in place a campaign that encourages people to 'ask 3 questions', to ask 4 questions, such as BRAN, or equivalent.'[67]
- The USA/Canada based Centre for Collaboration, Motivation and Innovation (CCMI) has produced resources and an app that adapts the tool to the mnemonic BRAIN, where patients are prompted to ask themselves the following questions[68]:

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[62] Aqua: 'Shared decision making – Ask 3 questions.' Advancing Quality Alliance: 2020 [Accessed November 2020]

[63] NHSE. 'Shared Decision Making: Summary Guide.' NHS England: 2019 [Accessed November 2020]

[64] Website: 'Questions to ask your doctor or nurse.' Choosing Wisely UK [Accessed December 2020]

[65] Website: 'Choosing Wisely.' Academy of Medical Royal Colleges [Accessed November 2020]

[66] Report: 'Chief Medical Officer – annual report 2020 to 2021.' Scottish Government [Accessed April 2021]

[67] NHSE. 'Shared Decision Making: Summary Guide.' NHS England: 2019 [Accessed November 2020]

- What us the decision I need to make?
- How much time do I have to make this decision?
- Who is involved in making this decision?
- What are my values that affect this decision?
- **B**enefits: How might this *benefit* me/my caregivers?
- **R**isks: How might this pose a *risk* to me/my caregivers?
- **A**lternatives: What are my options for the short term and long term?
- **I**ntuition: What do I feel and think about these options?
- **N**ext steps: e.g., I need time to think my decision through/I would like to…???

- This review was unable to identified studies that validated the BRAIN tool for use in clinical practice although variants including BRAN, BRAIN and BRAND (Benefits, Risks, Alternatives, do Nothing, Decision) were being used in American childbirth education classes as early as 2007.[69]

Conclusion: The use of the BRAN tool for shared decision making is endorsed by the AoMRC and Scottish Government. There are no current studies validating BRAN (or the CCMI's BRAIN alternative) for use in clinical practice. Inclusion of these tools in the standard should be tested as part of the PRSB consultation.

3.6 Agenda setting

Conclusion: Agenda setting is a process whereby 'patients and clinicians establish a joint focus for their conversation' that is included in approximately 20% of shared decision making models.[70] Core components of agenda setting have been established by health communication expert consensus and include identifying both the clinician and patient 'talk topics', agreeing 'shared priorities', and 'establishing conversational focus, collaboration and engagement.'[71] Recent analysis has found that clinicians infrequently elicit the patient's agenda (36% of randomly sampled clinical encounters and in 7 out of 10 of these the patient was interrupted).[72] The inclusion of agenda setting within the standard may act as a prompt for clinicians to engage in the process and increase 'the chance that [they] will orient the priorities of a clinical encounter towards specific aspects that matter to each patient.'

3.7 Use of decision support tools such as patient decision aids (PDAs) in shared decision making:

- Decision aids are typically developed for 'preference sensitive' health decisions to enable the selection of an option well aligned to a person's values & preferences.[73]

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[68] Website: 'BRAIN Worksheet.' Centre for Collaboration, Motivation and Innovation [Accessed December 2020]

[69] Morton C and Hsu C. 'Contemporary dilemmas in American childbirth education: Findings from a comparative ethnographic study.' The Journal of Perinatal Education: 2007, volume 16(4), pages 25-37 [Accessed December 2020]

[70] Bomhof-Roordink H and others. 'Key components of shared decision making models: a systematic review.' BMJ Open: 2019, volume 9: e031763 [Accessed January 2021]

[71] Gobat and others. 'What is agenda setting in the clinical encounter? Consensus from literature review and expert consultation.' Patient Education and Counselling:2015, volume 98(7) [Accessed December 2020]

[72] Ospina NS and others. 'Eliciting the patient's agenda- Secondary analysis of recorded clinical encounters.' Journal of General Internal Medicine: 2019, volume 34, pages 36 – 40 [Accessed December 2020]

[73] Thompson R and Trevena L. 'Chapter 9: Demystifying decision aids: A practical guide for clinicians.' Shared decision making in health care (3rd Edition). Edited by: Elwyn G and others.

They aim to support the person's understanding of the available options for healthcare interventions (e.g., tests or treatments) and associated risks/harms.

- Commonly used PDA formats include option grids[74] and Cates plots for communicating risk.[75]
- The GMC guidance on decision making and consent urges clinicians to 'consider using visual or other explanatory aids to support patients to understand their personalised risk, taking account of their individual clinical and personalised circumstances, compared with population level risk.'[76]
- NICE produces PDAs 'for selected and prioritised preference sensitive decision points' that are written in a non-technical language and 'summarise the best available evidence relation to the effectiveness, safety and practical factors relating to the treatment or care options.'[77]
- The draft NICE guideline on shared decision making recommends the use of 'up to date', 'good-quality' and 'relevant' patient decision aids as one component of a wide SDM 'toolkit' to support personalised 'risk communication'.[78] There was consensus by the NICE committee that the most useful PDAs will be drawn from a maintained library.'
- The high-level evidence for the use of PDAs in SDM is generally positive. The Cochrane Database of Systematic Reviews, represents the gold standard for evidence-based medicine, and contains several publications on the use of PDAs, including:
    - A significant review of 105 studies, which looked at PDAs for people facing health treatment or screening decisions and involved 31,043 participants.[79] This found that decision aids:
        - improved persons' knowledge of the options presented.
        - helped persons to gain a clearer understanding of what matters most to them.
        - probably improved the accuracy of persons' expectations relating to the benefits and harms discussed.
        - may help people to reach decisions that are more aligned with their informed values and preferences.
    - A review of three randomised controlled trials, which looked at interventions for supporting pregnant women to make decisions about mode of birth after previous caesarean section and involved 2270 participants.[80] This found that

[74] Elwyn G and others. 'Option grids: Shared decision making made easier.' Patient Education and Counselling: 2013, volume 90, pages 207 – 212 [Accessed December 2020]

[75] Drug and Therapeutics Bulletin. 'An introduction to patient decision aids.' British Medical Journal: 2013, volume 346, f4147 [Accessed December 2020]

[76] GMC. 'Decision Making and Consent.' General Medical Council: 2020 [Accessed November 2020]

[77] NICE. 'NICE decision aids: process guide.' National Institute for Health and Care Excellence: 2018 [Accessed December 2020]

[78] NICE. 'Shared Decision Making: NICE Guideline DRAFT.' National Institute for Health and Care Excellence: 2020 [Accessed December 2020]

[79] Stacey D and others. 'Decision aids for people facing health treatment or screening decisions (Review).' Cochrane Database of Systematic Reviews: 2017, Issue 4, Art. No.: CD001431 [Accessed December 2020]

[80] Horey D and others. 'Interventions for supporting pregnant women's decision-making about mode of birth after a caesarean (Review).' Cochrane Database of Systematic Reviews: 2013, Issue 7, Art. No.: CD010041 [Accessed December 2020]

decision support tools did not make a difference to the type of birth planned, although these tools were not designed to be shared.
    - A review of decision aids for people deciding about taking part in clinical trials was only able to identify a single study involving 290 participants and was therefore unable to determine a benefit.[81]
- Another review of six randomised controlled trials looked at the use of decision aids for shared decision making in serious illness.[82] The PDAs studied were a mix of Web-based tools, an EHR portal and interactive applications, which used assessments of patient preferences to guide the treatment options presented. Overall, findings suggested that most computerised decision aids were associated with at least one of the following outcomes:
    - reduced decisional conflict.
    - increased satisfaction with decisions made.
    - improved health outcomes.

Conclusion: There is high quality evidence from randomised trials and systematic reviews that the use of patient focused decision support tools (patient decision aids) improves the quality of shared healthcare decisions. This is reflected in the recommendations made by major professional bodies.

3.8 Performance measures for evaluating the shared decision making process:

- Despite evidence to the contrary, reports by clinicians that they already perform shared decision making in their clinical practice are made so frequently that it has been referred to as one of the myths of SDM.[83]
- A 2013 systematic review of 33 studies explored the extent to which healthcare providers involve patients in the decision making process during consultations. This found that patient involvement in consultations without SDM interventions (as measured by the OPTION instrument) was generally low (average score < 25).[84] However in some studies the use of an SDM intervention improved scores to ≥ 50.
- According to a National Shared Decision Making Programme report, the core purposes of measuring SDM include[85]:
    - Supporting accountability and commissioning.
    - Measuring clinical performance and improvement.
    - Research (developing the SDM evidence base).
- There are two main types of measures to evaluate whether SDM is occurring in clinical practice. These include:

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[81] Gillies K and others. 'Decision aids for people considering taking part in clinical trials (Review).' Cochrane Database of Systematic Reviews: 2015, Issue 11, Art. No.: CD009736 [Accessed December 2020]

[82] Lee J and others. 'Computerized decision aids for shared decision making in serious illness: Systematic review.' JMIR Medical Informatics: 2017, volume 5(4), pages 1 – 9 [Accessed December 2020]

[83] Légaré F and Thompson-Leduc P. 'Twelve myths about shared decision making.' Patient Education and Counseling: 2014, volume 96(3), pages 281 - 286 [Accessed May 2021]

[84] Couët N and others. 'Assessments of the extent to which health-care providers involve patients in decision making: a systematic review of studies using the OPTION instrument.' Health Expectations, volume 18(4), pages 542 – 561 [Accessed December 2020]

[85] Report: 'Measuring Shared Decision Making: A review of research evidence.' Shared Decision Making Programme: 2012 [Accessed December 2021]

- Patient-reported measures: These tools move away from the traditional measure of patient satisfaction to evaluation of the patient experience. The 3 broad categories of patient facing tools in use generally focus on[86]:
  - things that influence decisions: e.g., Decision Self-Efficacy Scale, Patient Attitudes and Beliefs Scale, Preparation for Decision making Scale etc.
  - the decision making process: e.g., 9-item SDM Questionnaire, patient version (SDM-Q-9), CollaboRATE, Facilitation of Patient Involvement Scale etc.
  - decision outcomes: e.g., Decisional Regret Scale, Decisional Conflict Scale, Decision Quality Instruments (DQI) etc.
- Observer measures: These tools provide additional data and a 'fuller understanding' regarding the extent of SDM that occurred in an encounter (especially as there is 'little correlation between observer and patient reports of SDM'). Examples include, the Observer OPTION[12] / Observer OPTION[5], Multifocal Approach to Sharing in Shared Decision Making, Rochester Participatory Decision-Making Scale etc.[87]

- In addition, there are also practitioner completed measures of SDM such as the SDM-Q-9, Physician version, ADOPT (Attitudes toward Decision aids fOr PatienTs), and incorporate (which measures 'physician's willingness to incorporate SDM into practice).[88]
- It has been proposed that use of validated performance measures may have a role in incentivising the practice of shared decision making, but there is not consensus on how best to do this.[89]
- The draft NICE guideline on shared decision making notes that it is not clearly established from the current evidence base 'what the best measures of shared decision making are and how acceptable different interventions are to people who receive them.' This is in line with findings of the National Decision Making Programme in 2013. The NICE committee therefore made the following recommendation for research: '[Establish] what are the best ways to measure the effectiveness of shared decision making in different contexts (in different settings and involving different people)?'[90]
- This recommendation is supported by a recent systematic review, which looked at 51 studies 'describing the development and/or evaluation of 40 shared decision making process instruments [(performance measures)]', including many of the examples listed above. This found that for the majority, either 'measurement properties have not been evaluated at all' or 'the validation studies are of poor quality.' Therefore, the

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[86] Barr PJ and others. 'Chapter 26: 'Patient-reported measures of shared decision making.' Shared decision making in health care (3rd Edition). Edited by: Elwyn G and others.

[87] Elwyn G and Blaine AI. 'Chapter 27: 'Observer measures of shared decision making.' Shared decision making in health care (3rd Edition). Edited by: Elwyn G and others.

[88] Berkowitz and others. 'The development of incorporate: A measure of physicians' willingness to incorporate shared decision making into practice.' Patient Education and Counseling: 2021 (in press) [Accessed May 2021]

[89] Barr PJ and Durand M. 'Chapter 28: 'Implementing shared decision making: The role of incentives.' Shared decision making in health care (3rd Edition). Edited by: Elwyn G and others.

[90] NICE. 'Shared Decision Making: NICE Guideline DRAFT.' National Institute for Health and Care Excellence: 2020 [Accessed December 2020]

study concluded that the quality of the performance measures available for evaluating SDM is currently unknown.[91]

Conclusion: The patient-reported and observer measures of shared decision-making highlighted in this review are not exhaustive. The evidence base for the validity and use of the various instruments is limited. There is consensus in the field that SDM performance measures are useful and needed but none of which are the best performance measures to implement nationally and guidance from professional bodies does not currently recommend any for UK use. Given the above and the large number of measures available, the PRSB consultation should test support for inclusion of a limited number of these in the standard before including more.

3.9 Recording exceptional circumstances where information may be withheld from the patient (or sharing delayed)

Conclusion: The GMC guidance[92] tells that in circumstances where sharing of certain relevant information with the patient is delayed practitioners must record 'the information [they] still need to share, [their] reasons for not sharing it now, and when it can be shared.' The guidance also clarifies that 'in very exceptional circumstances' where information is withheld because it would cause the patient 'very serious harm' legal advice should be sought. This is aligned with the Montgomery judgement and its interpretation in NICE advice.[93] Recording of these aspects in the standard should be tested as part of the PRSB consultation.

3.10 Assessing health literacy

Conclusion: Health literacy is an integral component of SDM and this has been recognised by the recent development of an integrated model.[94] A separate policy model, the Health Literate Shared Decision-Making Framework has been produced by the Patient Information Forum and the Community Health and Learning Foundation for NHSE and is being piloted in Nottinghamshire.[95] The interaction between health literacy and SDM is complex. The PRSB consultation should how/whether levels of health literacy might be recorded.

3.11 Documenting consent

Conclusion: Key documents evaluated in the evidence review relating to consent included the GMC guidance on decision making and consent and the Royal College of Surgeons guidance on consent and supported decision-making.[96]

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[91] Gärtner FR and others. 'The quality of instruments to assess the process of shared decision making: A systematic review.' PLOS ONE: 2018, volume 13(2): e0191747 [Accessed December 2020]

[92] GMC. 'Decision Making and Consent.' General Medical Council: 2020 [Accessed November 2020]

[93] Guidance. 'Key therapeutic topic: Shared decision making.' NICE:2019 [Accessed June 2021]

[94] Muscat DM and others. 'Health literacy and shared decision-making: Exploring the relationship to enable meaningful patient engagement in healthcare.' Journal of General Internal Medicine: 2021, volume 36, pages 521 – 524 [Accessed June 2021]

[95] Website. 'Shared decision making and health literacy – NHS England Framework.' Patient Information Forum [Accessed June 2021]

[96] Guidance: 'Consent: Supported decision-making: a guide to good practice.' Royal College of Surgeons:2018 [Accessed December 2020]