Professional Record Standards Body

Better records for better care

SHARED DECISION MAKING AND CONSENT:

PHASE 1 REPORT V1.0

JULY 2021

Document Management

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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
MoSCoW	Must have, Should have, Could have, Will not have
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

Planned Review Date and Route for User Feedback

The next maintenance review of this document is planned for [3 year period], subject to agreement with NHS Digital as the commissioning body.

Please direct any comments or enquiries related to the project report and implementation of the standard to support@theprsb.org

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1 Executive summary

All people have the right to be involved in decisions about their treatment and care and to make informed decisions wherever and whenever possible. The sharing of information between health or care professionals and individuals and the promotion of individual choice are at the heart of good decision-making and are enshrined in the NHS Long Term Plan. Where people are listened to, given the information they need and the time and support to make informed decisions about their care and treatment, evidence shows they have better outcomes and experiences of care.

Shared decision making is a collaborative process where clinicians and individuals consider treatment options based on evidence about their potential benefits and harms in order that the person can decide the best course for him- or herself. The conversation and decision made should be informed by the person's priorities and concerns, wishes, preferences and goals.

There is currently no recognised standard for recording the process of shared decision making in a person's care record, and documenting the decision in a way that can be shared between settings. PRSB and its member organisations, representing the health and care professions and people who use services, identified this as a key priority for standardisation so that information can be shared digitally to support good care.

Shared decision making is often mistaken for consent to treatment. SDM is necessary for valid informed consent in circumstances where a preference-sensitive decision is made. However, there will be many situations in clinical practice in which a shared decision is made where consent is not required or can be inferred from the fact a shared decision has been made and documented. It differs from consent to treatment insofar as consent involves a person giving their informed verbal or written permission before they receive treatment, investigations or examinations and is needed for all treatment decisions 'even if there is only one option.' However, both informed consent and shared decision making are considered important principles in medical ethics and following the 2015 UK Supreme Court judgement of Montgomery v Lanarkshire Health Board, both are a legal requirement and explicitly recognise individuals as the decision-makers. Shared decision making is no longer an optional process representing best practice, but an essential component of valid consent in the eyes of the courts and professional bodies. Clinicians should document the shared decision making process in a proportionate way, in line with General Medical Council (GMC) guidance. The NICE guideline on shared decision making and consent makes clear that consent 'should only be gained when a person has shared a decision informed by what is known about the risks, benefits and consequences of all reasonable NHS treatment options.'

Shared decision making is beneficial to both professionals and people who use services. Use of a shared decision making standard would support and promote use of the SDM process, which in turn should help to make sure that people have a better understanding of their care and treatment options, leading to better decisions, more concordance with their treatment and care plans, and a renewed sense of ownership for their own health and wellbeing. Health and care professionals benefit from better communication with people, greater confidence that the right care is being delivered with fewer conflicts and less risk of litigation.

The PRSB information standard on shared decision making and consent aims to provide a framework for clinicians to record the decision-making process in line with professional guidance (i.e., the GMC guidance on decision-making and consent and the draft NICE guideline on shared decision making). The final version of the NICE guideline on SDM has

been published since the work on phase one of this project was completed. The updated guideline has been reviewed by the project team and it was concluded that the draft SDM and consent standard continues to be aligned with the NICE publication. This alignment can be tested further in a future phase of the project.

This project was led by the PRSB in partnership with the Academy of Medical Royal Colleges, NHS England Personalised Care Group, Centre for Perioperative Care, the Patient Information Forum and EIDO.

Its aim is to develop and test in pilot an information record standard for shared decision-making and consent to meet the needs of healthcare professionals and people who use services. The project is divided into three phases, the first of which has been completed and is reported on here.

- Phase 1 (complete): Development of preliminary draft standard with smaller scale consultation and testing with patients, their caregivers, and professionals.
- Phase 2 (funding being sought): Consultation at scale to further develop/refine the standard, agree terminology/technical aspects, & finalise supporting materials.
- Phase 3 (funding being sought): Pilot testing of the standard in live clinical settings.

An evidence review was undertaken to identify any information that was relevant for inclusion in the draft standard. Eight use case scenarios were developed to test the first draft of the standard in an online consultation that included a range of health and care professionals and people with lived experience of care for cancer, gynaecology problems, mental ill health, children's dental problems and elective surgery among others. Due to the limitations of lockdown during the Covid pandemic, we were not able to test the standard in pilot, but instead developed a series of role plays that could be done virtually with 'true to life' vignettes to test the standard's usability in practice. This resulted in a second draft of the standard that will be tested in further phases of the project, namely wider consultation and testing the standard in pilot before it is published.

1.1 Findings

The findings from phase one of the project are as follows:

1. The consultation supported inclusion of patient's understanding of their condition and the options available for treatment. Recording a person's justification for the decision made was felt to be a useful way to illustrate that it was fully informed. These elements require further development and testing in the next phase.

2. Details about people accompanying the patient should be recorded and their involvement in shared decisions was recognised.

3. A record of the use of an interpreter where the patient lacks English proficiency should be made. Further phases should test inclusion for other (including non-spoken) communication difficulties.

4. Data relating to audio or visual recording should be supported in the standard.

5. The consultation recognised and supported the capturing of shared decisions across people, time, and place. The consideration of shared decision making as an ongoing process with several touch points was raised as a positive of the standard.

6. The consultation did not resolve whether certain specific models of shared decision making should be included as an optional section in the standard. This should be tested in the next project phase. This includes models such as Three-talk, the Ottawa Decision Support Framework, the Interprofessional model, Ask 3 Questions and BRAN (Benefits, Risks, Alternatives, Do Nothing).

7. Inclusion of agenda setting in the standard was supported by the consultation.

8. There was strong support for recording ‘what matters to patients’, both in their lives and in relation to the decision, in the form of their ideas, concerns and expectations, goals, values and hopes, and their preferences.

9. However, the consultation did not resolve how/whether information withheld from patients in rare/exceptional circumstances should be recorded. Further consultation in the next phase is needed to test its inclusion in the standard and clarify the ethical and legal issues involved.

10. How and to what extent clinician and patient preferences might be incorporated into the record remains to be resolved. This should be tested in detail during phase two including consideration of possible alternatives to the proposed elements for the standard.

11. The importance of recording the Decision Support Tools (such as patient decision aids) used in the encounter was emphasised in consultation. Ways in which the content of decision aids could be added or integrated into the generic standard should be explored in a future phase.

12. Performance measures were not judged as required by the standard and this section has been removed from the second draft of the standard. Nor were measures of health literacy supported by the consultation and these have been removed from the draft standard.

13. Overall, the major focus of the consultation was on the recording of the shared decision making process. The standard captures details of consent forms used but does not include a digitised consent form. We are aware of other projects digitising consent in both general and specific use cases and are exploring options for collaboration as part of the next project phase.

1.2 Recommendations

PRSB recommends the following as part of further phases of this project and future work:

1. Wider consultation: Further consultation is required in line with published PRSB methodology (implementation guidance, clinical safety case etc), to gain endorsement. This should include consultation at-scale to get views from beyond those who are aware or supportive of shared decision making and to test some of the detail and in particular aspects not explored or arising from role plays. This could include an exploration of how the principles might apply in a social care context. Preliminary proposals for two further phases are outlined in section 3.1 of this document.

2. Pilot testing: Pilot testing should be done in at least one speciality (but ideally several disciplines) to address concerns of useability (e.g., time to fill in) raised in the consultation and to identify any unforeseen issues. Several organisations have been identified as possible pilot candidates.

3. Digitised consent forms: The major focus of this project was the recording of key aspects of shared decision making – the patient’s decision journey – much of which occurs before informed consent is given (if it is required). Our shared decision making and consent standard captures details of consent forms used but does not include a digitised consent form. We are aware of ongoing work by other organisations to develop digital consent forms for both general and specific use cases. We have engaged them with a view to collaboration, to establish synergies and possible integration into the generic standard, as part of our next phase of work. Responses to initial enquiries have been positive.

4. Supporting use of the generic standard in specific areas: Testing the generic standard and supporting specific specialties and use cases may require development of new terminology, coding, or other detail to support useability and meet the needs in that specific specialty. The areas with the most value-add for patients should be identified and considered for further development and inclusion in pilot testing. This might include the development of certain area specific 'views' of the generic standard.

5. Information Standards Notice (ISN): Further technical development of the standard must focus on achieving compliance with the ISN process. Part of this will require resolution of recommendation 6 below.

6. Ensuring interoperability: The consultation identified a tension between the use of free text and recording of more structured and coded data. It was felt that while free text may be easier to fill in and may more sensitively capture the details and phrasing of what was said during the discussion, the use of unstructured data was a hindrance to interoperability. The feasibility of implementing the standard components must now be explored with due respect given to the practicality of technical implementation.

7. Education and training: There are many educational/training resources on shared decision making. As a minimum, the best resources to complement the standard should be identified and signposted to users. However, it was observed by stakeholders that a fully resourced plan with culture and transformation change including education and training is required for wider adoption of shared decision making in NHS. For the standard to be used appropriately and work in practice it should be deployed in that supportive context. This would require ownership from NHS England and contribution from PRSB and our member bodies.

8. Rationalising the standard: Some participants, including clinicians and patients were concerned that the size of the standard may burden clinicians and distract them the focusing on the shared decision conversation, to the detriment of patients. The standard needs to be manageable and not a burden on clinicians or patients, to be implemented. Issues around the time required to fill in the standard should be explored, tested, and resolved as far as is practicable in the next phase.

9. Involving patients in the shared decision making record: Stakeholders were overwhelmingly supportive of greater patient involvement in the recording of the shared decision conversation. We are aware that some areas in general practice are exploring the process of allowing access for both clinicians and patients to read and write to the record. Our consultation suggested that the benefits of this would include the detection of mismatched priorities and understanding and would allow documentation of areas of agreement and disagreement. It was suggested that this could allow both parties time to reflect on the conversation, in line with best practice. The draft standard has been designed for direct use by clinicians. The possibility of adapting the standard to allow patients access and the ability to write to the record should be explored, along with the possible implications for clinical safety and considerations of information governance, in future work.

1.3 Focused recommendations

Further exploration, development, and testing is needed on the following provisional standard components:

- Patient's understanding of their diagnosis and justification for the decision made.
- Details about the people accompanying the patient.
- Support for other (including non-spoken) communication difficulties.

- Specific models of shared decision making.
- Recording what matters to people including goals, values, hopes, ideas, concerns, and expectations. This could include an exploration of how to record indicators of how well patients were supported in preparation for SDM conversations.
- Recording exceptions where information may be withheld (or sharing delayed), as described in the GMC guidance on shared decision making and consent.
- Recording patient preferences (and exploring whether there are circumstances where clinician preferences might be usefully recorded)
- Levels of uncertainty.
- Patient satisfaction over time.
- Methods of risk communication.
- Storage of audio/visual recordings, consent forms, and decision aids in an electronic health record (EHR).

1.4 Sections/ element not supported by consultation (removed)

- Performance measures. The first version of the draft standard was aligned to the NHS summary guide and implementation checklist for SDM. The checklist includes Collaborate, Sure, and SDM-Q9 / SDM-Q-DOC scales. However, the consultation process did not support their inclusion (see section 4.1).
- Assessing health literacy. It is an essential requirement of the SDM and consent standard that it supports health literacy by helping to making sure that patients can understand what is documented. However, reliable measures for documenting a person's level of health literacy could not be identified or supported by the consultation (see section 4.1).

1.5 Conclusion

This report documented the first phase of the shared decision making and consent project. Funding is being sought for two proposed further phases. Disruption to the consultation caused by the situation with the COVID-19 pandemic required an agile response that resulted in high levels of engagement from professionals and people with lived experience as well as the use of realistic role play scenarios to test the draft standard. This phase should be followed up with a wider consultation at-scale to get views from beyond those aware of shared decision making as well as pilot testing in live clinical settings. There is potential for collaboration in areas such a digitised consent that should be enthusiastically progressed.

NB: Following completion of phase 1 the SDM and consent standard will be published on the PRSB website in draft for trial use only. The standard is not yet the final version for endorsement and is not yet supported by the core deliverables required for implementation (i.e., clinical safety case and hazard log, implementation guidance and agreement of new clinical terminology, technical standard and business rules). Its contents may be subject to change pending further development and testing in future project phases. If you are considering implementation of the standard in your organisation, please contact the PRSB by emailing info@theprsb.org.

2 Introduction

2.1 Background and context

A key priority of the NHS Long Term Plan is to deliver universal person-centred care and patient choice, supported by the national rollout of the NHS Comprehensive Model of Personalised Care in 2019, which aims to reach '2.5 million people by 2023/24.'[1] The model was co-produced with patients[2] and includes shared decision making (SDM) as one of its six pillars and a foundational component and key strategic theme that applies to the whole population of the UK.[3]

2.1.1 What is shared decision making?

'*Shared decision making at its heart is a conversation between two people [that] brings together what both know best. [This is] the clinician's experience, such as treatment options, evidence, risks, and benefits and what the patient knows best, their preferences, personal circumstances, their goals, their values, and their beliefs…The shared decision process should always allow the clinician to understand this important information and support the patient in choosing the best option for them.*'

Patient Representative for CPOC[4] and PRSB Citizen Lead

Shared decision making is a collaborative process whereby clinicians and individuals deliberate over treatment options and share tailored/evidence-based information about benefits and harms to empower the person to make a decision that is right for them.[5] The conversation and decision made should be informed by and aligned to the person's values, priorities, concerns, wishes, preferences and goals. SDM is 'most appropriate in situations of uncertainty [equipoise]'[6] where the evidence for the superiority of a particular treatment, investigation, procedure, or other course of action over another is unclear.[7] In such situations, where at least two reasonable options exist, resolution requires a preference-sensitive decision to be made that is 'informed by the available evidence and by patients' wishes, needs, [values] and preferences.'[8]

Examples of the types of shared decisions individuals are supported to make include but are not limited to choices about physical examinations, investigations or tests, elective medical/surgical treatments, or procedures (including those made in the context of mental ill

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[1] Policy Document. 'The NHS Long Term Plan.' NHS:2019 [Accessed May 2021]

[2] De Longh and others. 'New personalised care plan for the NHS.' British Medical Journal: 2019, volume 364:I470 [Accessed May 2021]

[3] Guidance. 'Comprehensive model of personalised care.' NHS England: 2019 [Accessed June 2021]

[4] Website: 'Shared decision making.' Centre for Perioperative Care: 2021 [Accessed June 2021]

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

[6] Whitney SN and others. 'A typology of shared decision making, informed consent, and simple consent.' Annals of Internal Medicine:2004, volume 140(1), pages 54-59 [Accessed May 2021]

[7] Elwyn G and others. 'Dual equipoise shared decision making: definitions for decision and behaviour support interventions.' Implementation Science: 2009, volume 4(75) [Accessed May 2021]

[8] 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]

health). In the context of personalised care, the recording of SDM may also include choices around personalised care and support plans, social prescribing and supported self-management.

The benefits of SDM for patients have been described in detail elsewhere[9], including in a Cochrane systematic review[10] and an overview of systematic reviews conducted by National Voices.[11] Benefits described for patients include:

- Improved knowledge and understanding of treatment options and more accurate perceptions of risk.
- Increased patient satisfaction, engagement, and experience of care.
- Although SDM has not yet been definitively proven to improve health outcomes, poor SDM is associated with worse patient-reported health outcomes.[12]

The benefits of SDM would be enabled and accelerated by a widely recognised SDM standard that could be implemented in digital systems to enable consistency, quality, and interoperability. In the long-term decision making could also link to digitised NICE guidance enabling the whole clinical decision support process to be automated and streamlined.

2.1.2 How does SDM relate to consent?

The process of consent to treatment is a legal requirement that involves a person giving their informed verbal or written permission 'before they receive any type of medical treatment, test or examination.'[13] Unlike shared decision making, consent is appropriate for all treatment decisions 'even if there is only one option.'[14] Informed consent and SDM are only valid where applied to individuals with the mental capacity to understand, weigh-up, retain and communicate their decision. If a person lacks capacity and has not appointed a lasting power of attorney, then clinicians can make a Best Interests decision to treat them without obtaining patient consent or undergoing SDM.

Both informed consent and SDM are considered important principles in medical ethics but, until recently, only the process of obtaining consent was mandated in law. That changed following the 2015 UK Supreme Court judgement of Montgomery v Lanarkshire Health Board that related to 'a case concerning the negligent failure by a doctor to disclose a [rare] risk associated with childbirth'[15]. The mode of delivery (vaginal) was 'complicated by shoulder

[9] 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]

[10] 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]

[11] Report: 'Supporting shared decision-making: A summary of the evidence.' National Voices: 2014 [Accessed June 2021]

[12] Hughes TM and others. 'Association of shared-decision making on patient-reported health outcomes and healthcare utilization.' The American Journal of Surgery: 2018, volume 216(1), pages 7-12 [Accessed June 2021]

[13] Website: 'Overview: Consent to treatment.' NHS: 2019 [Accessed June 2021]

[14] Whitney SN and others. 'A typology of shared decision making, informed consent, and simple consent.' Annals of Internal Medicine:2004, volume 140(1), pages 54-59 [Accessed May 2021]

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

dystocia that resulted in a child being born with cerebral palsy.'[16] 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 individuals (patients) as the decision makers.[17] As a result SDM is no longer an optional process representing best practice, but an essential component of valid consent in the eyes of the courts and professional bodies. To align medical records with the requirements of Montgomery, clinicians should document the shared decision making process in a proportionate way, in line with GMC guidance. This required that discussion of the options for medical interventions covers the benefits and the 'material risks' (those that matter most to the patient, no matter how rare) and the viable alternatives or treatment variants raised, including the option to take no action.

2.1.3 What is the key legal, policy, and guidance context of this work?

The key national legislation, policy, and guidance relevant to shared decision making and consent includes the following:[18]

Policy context:

- The NHS Long Term Plan (2019).
- The NHS Comprehensive Model of Personalised Care (2019).
- The NHS Constitution 2012 (updated 2021) that outlines several rights for individuals including the right to:[19]
    - 'accept or refuse treatment.'
    - 'be given information about your proposed treatment in advance, including any significant risks and any alternative treatments which may be available, and the risks involved in doing nothing.'
    - 'be involved in discussions and decisions about your healthcare.'

Legal and statutory context:

- The Montgomery v Lanarkshire Health Board (2015) judgement.
- The National Health Service Act 2006 (as amended by the health and Social Care Act 2012), which outlines the general duties of clinical commissioning groups (CCGs) in section 14[20], and NHS England and Improvement (NHSEI)[21] in section 13[22], including:
    - Sections 14U/13H that describe a 'duty to promote involvement of each patient...and their carers and representatives (if any), in decisions which relate to the prevention or diagnosis of illness in the patients, or their care or treatment.'

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

[17] 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]

[18] Website. 'Shared decision making to comply with national legislation and policy.' NHS England:2021 [Accessed June 2021]

[19] Guidance: 'The NHS Constitution for England.' Department for Health & Social Care: 2012 (updated 2021) [Accessed June 2021]

[20] Website. 'Health and Social Care Act 2012. Section 14. [Accessed June 2021]

[21] NHS England is an alternative operating name for The National Health Service Commissioning Board. See policy document [Accessed June 2021]

[22] Website. 'Health and Social Care Act 2012. Section 13. [Accessed June 2021]

    - Sections 14V/13I that describe a ‘duty as to patient choice…[whereby CCG and NHSEI must] act with a view to enabling patients to make choices with for aspects of health services provided to them.’
- The Mental Capacity Act 2005 that outlines the following principles:[23]
    - ‘A person must be assumed to have capacity unless established otherwise.’
    - ‘Individuals [who lack capacity] should be helped to make their own decisions as far as practicable.’
    - ‘A person is not to be treated as unable to make a decision merely because he makes an unwise decision.’
    - ‘All decisions and actions must be in the best interests of the person lacking capacity.’
    - All decisions and actions must be the least restrictive of the person’s rights and freedom of action.’
- The Gillick v West Norfolk and Wisbech Area Health Authority and Department of Health and Social Security (1985) judgement, which established:[24]
    - That children under the age of 16 can consent to treatment if assessment by a healthcare professional finds they are able to ‘understand what is involved in a proposed treatment, including its purpose, nature, likely effects and risks, chances of success and the availability of other options.’[25]
- Gillick also led to the ‘Fraser Guidelines’ that apply to decisions of children under 16 made without parental consent that are specifically about contraceptive advice and treatment, sexually transmitted infections, and termination of pregnancy. [26]

Professional Guidance context:

- The GMC guidance on decision making and consent, which provides seven principles covering the following themes:[27]
    - One: Patients’ ‘right to be involved’ and supported in decisions about their healthcare.
    - Two: Decision making as an ongoing ‘meaningful dialogue.’
    - Three: Patients’ ‘right to be listened to…be given the information they need to make a decision and the time and support they need to understand it.’
    - Four: Discovering ‘what matters to patients’ to provide tailored and ‘relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action.’
    - Five: The ‘presumption that all adult patients have capacity’ until proven otherwise.
    - Six: Best Interests decisions for ‘patients who lack capacity…should be made in consultation with those who are close to them or advocating for them.’
    - Seven: Supporting ‘patients whose right to consent is affected by law’ to ‘exercise choice if possible.’

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[23] Website: ‘Mental Capacity Act.’ NHS Health Research Authority: 2020 [Accessed June 2021]

[24] ‘Gillick v West Nortfolk and Wisbech Area Health Authority.’ All England Law Reports:1985, volume 1, pages 533-59 [Accessed June 2021]

[25] Website: ‘GP mythbuster 8: Gillick competency and Fraser guidelines.’ Care Quality Commission: 2021 [Accessed June 2021]

[26] Website: ‘GP mythbuster 8: Gillick competency and Fraser guidelines.’ Care Quality Commission: 2021 [Accessed June 2021]

[27] GMC. ‘Decision Making and Consent.’ General Medical Council: 2020 [Accessed November 2020]

The draft NICE guideline on shared decision making, which was published as a final version in June 2021.[28] As this was published since the work on phase one of this project was completed, alignment can be tested further in a future phase.

'A dedicated process that the clinician can use to explain the options is essential…A generic shared decision making standard or tool must allow the patient to understand the options available to them and help them make a choice that is right for them. This process continues throughout the patient journey, from first contemplation when they have a medical problem to full recovery."

Patient Representative for CPOC[29] and PRSB Citizen Lead

The PRSB information standard on shared decision making and consent aims to provide a framework for clinicians to record the decisional process (aligned with professional guidance i.e., The GMC guidance on decision making and consent and the draft NICE guideline on shared decision making), and evidence compliance with the Montgomery ruling. It is recognised that successful implementation of the standard will require a significant change programme including training and cultural and behavioural change.

' [Another] essential aspect is a way for the clinician to understand their patient's individual circumstances. We can use the title of 'About Me', where the patient can be supported in providing information on what matters to them…about their own health – their wishes and fears, what activities contribute to their quality of life so the impact [of the decision] can be understood by both parties.'

Patient Representative for CPOC[30] and PRSB Citizen Lead

We propose that appropriate use of the SDM and consent standard will be best achieved alongside other PRSB standards that have relevance to SDM. We view the completion of the About Me record in advance to be an important aspect of gathering information about what matters to the patient, before the SDM encounter takes place. If not already completed the About me could be filled out by the patient as part of their preparation activities for SDM. Other relevant standards include but are not limited to the Personalised care and support plan and the Core information standard (e.g., sections on mental capacity, end of life care/advance care planning, reasonable adjustments, CPR decisions etc) and the Accessible information standard.

There was previously no recognised standard for a generic information record to support the SDM and consent process. The premise was that a generic record standard could be used to support the decision-making process across different decision-making scenarios and use cases. PRSB members identified this as a key priority and area that needs standardisation. Several of our members have been involved in developing programmes and promoting SDM and consent at a national level, including but not limited to:

- The Academy of Medical Royal Colleges (the Academy).[31]

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

[29] Website: 'Shared decision making.' Centre for Perioperative Care: 2021 [Accessed June 2021]

[30] Website: 'Shared decision making.' Centre for Perioperative Care: 2021 [Accessed June 2021]

[31] Website: About the Shared Decision Making Programme. E-Learning for Healthcare: 2021 [Accessed November 2021]

- British Geriatrics Society.[32]
- Chartered Society of Physiotherapy.[33]
- National Voices.[34]
- NICE.
- Patient Information Forum.[35]

NHSX are currently developing a devices registry and the solution includes a shared decision making component – alignment with this project to be agreed in a further phase.

This project is being led by the PRSB in partnership with the Academy, NHS England Personalised Care Group, Centre for Perioperative Care (CPOC)[36], Patient Information Forum and EIDO.[37]

More background information on our project partners is included in Appendix F.

3 Methodology and Consultation Approach

This section summarises the methods and consultation approach used to develop the draft standard as well as the project objectives and scope.

3.1 Project objectives and scope

The overall aim of this project is to develop and test in pilot an information record standard for shared decision making and consent to meet the needs of healthcare professionals and patients.

The overall approach to the development of the SDM and consent standard has been split into three phases, the first of which has been completed and is reported on in this document.

- Phase 1 (complete): Development of preliminary draft standard with smaller scale consultation and testing with patients, their caregivers, and professionals.
- Phase 2 (funding being sought): Consultation at scale to further develop/refine the standard, agree terminology/technical aspects, & finalise supporting materials.
- Phase 3 (funding being sought): Pilot testing of the standard in live clinical settings.

The first phase was completed in May 2021 and consisted of the following approach:

- A review and synthesis of the evidence needed to support the SDM and consent standard.
- Mapping of existing standards, professional guidance and key SDM models.
- *Ad hoc* calls with identified stakeholders for information gathering purposes.
- Development of clinical use case scenarios to support the consultation process.

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[32] Guideline: 'End of life care in frailty: Last days of life.' British Geriatrics Society: 2020 [Accessed June 2021]

[33] Website: 'Shared decision making.' Chartered Society of Physiotherapy: 2013 [Accessed June 2021]

[34] Report: 'Supporting shared decision-making: A summary of the evidence.' National Voices: 2014 [Accessed June 2021]

[35] Website: 'Shared decision making and health literacy – NHS England Framework.' Patient Information Forum 2015 [Accessed June 2021]

[36] Website: 'Shared decision making.' Centre for Perioperative Care: 2021 [Accessed June 2021]

[37] Website: 'About EIDO.' EIDO: 2021 [Accessed June 2021]

- A preliminary first draft of the SDM and consent standard.
- A webinar pre-briefing to introduce the concepts of SDM & standards to stakeholders.
- A multidisciplinary consultation webinar to introduce the draft standard & identify issues and views/requirements of professionals and patients for inclusion/exclusion.
- Preliminary changes to draft standard made for further testing.
- Structured role plays with practitioners, patients, and actors to test the standard in 'realistic' virtual consultation scenarios (due to the COVID-19 pandemic pilot testing of the standard in live clinical settings has been delayed until phase 3, following agreement of the PRSB assurance committee).
- Finalisation of the second draft of the SDM and consent standard, along with the phase 1 report (this document) and supporting materials (see appendices).

A second phase is planned to include the following:

- A further detailed and wider consultation, including a survey to engage a variety of patients, their families/care givers, and frontline healthcare professionals at scale.
- Pursuing links with related work on consent underway in other projects to make sure that appropriate links are made to other change/transformations & synergies are realised.
- Technical consultation with systems suppliers and informaticians.
- Development of detailed implementation guidance.
- Agreement of terminology, technical standard, and business rules.
- Development of a clinical safety case and hazard log.
- Publication of approved version of the SDM and consent standard, including phase 2 report and supporting materials.

A third phase is planned to include the following:

- Pilot testing of the information standard in live clinical settings.
- Workshops to test standard updates with patients, their caregivers, and professionals.
- Publication of final version of the SDM and consent standard, including phase 3 report and updated supporting materials.
- Endorsement by professional and patient bodies of final version for publication.
- Submission for Information Standards Notice (ISN) publication.

3.1.1 Objectives

The objectives of this initial phase of work (phase 1) were consistent with the wider project objectives, which are:

- To develop a generic information standard that supports good professional practice as outlined in the GMC guidance 'Decision Making and Consent', the draft NICE guideline on shared decision making, and other professional guidance. Thereby the standard should empower clinicians with a framework for demonstrating how a individual's 'right to be involved' in choices about their direct care was supported during clinical encounter and that an informed decision(s) was made consistent with the person's needs, beliefs, values, priorities, and preferences.
- To support clinicians to record aspects of shared decisions that evidence compliance with the 2015 UK Supreme Court judgement of Montgomery v Lanarkshire Health Board. For example, discussion of the options for medical interventions should be followed by documentation of the benefits and the 'material risks' (those that matter most to the patient, no matter how rare) and the viable alternatives or treatment variants raised, including the option to take no action. This legal aspect recognises that 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.[38]

- To enable the proportionate and accurate recording of the pertinent aspects of the SDM discussion (including those ongoing and distributed across multiple encounters) and any supporting processes including any decision support tools or consent forms used, or other information shared.
- To produce an implementable standard that is practical, useable and respects the time of both clinicians and people who use services. The use of the standard should not disrupt the clinical workflow or place an extra recording burden on clinicians, except in cases where this is a legal requirement.
- To make sure that the development and content of the standard is informed and evidenced by key established models of shared decision making found in the peer-reviewed medical literature (including where possible, evidence from high level studies such a randomised controlled trials and systematic reviews).
- To co-produce the standard with the people who will use and benefit from it. This must include iterative testing and piloting at each stage of development with our lay and clinical advisors and multi-disciplinary stakeholders accessed via the PRSB networks & membership, including organisations & individuals representing patients, frontline healthcare professionals, and systems suppliers.
- To reduce the number of occasions where an individual is asked to discuss information they have already shared or to repeat the SDM process with another professional, who may be unaware that this has taken place. The standard must enable interoperability to achieve this outcome.
- To obtain buy-in and support for the new SDM and consent standard from professional bodies and patient organisations at a national level.
- To communicate and promote the adoption of the SDM and consent standard and raise awareness of the need for education and training in shared decision making.

NB: This project is not the major change programme around adoption of an SDM approach – this work will remain connected to related programmes which are dealing with the cultural and behavioural change involved but the work will be undertaken under those other programmes and initiatives.

3.1.2 Scope

The scope of the project was defined during phase 1 and may be refined during future phases. This is set out below.

What the SDM and consent standard ***is***

- For use in all healthcare settings across the four nations of the UK where a patient would like to make a preference-sensitive decision or other choice with two or more reasonable options about a treatment, investigation, or other course of action for their direct care. Patient and professional discretion, ideally by mutual agreement, should be used to decide when shared decision making is used in practice.
- For use by healthcare professionals in all specialties and disciplines where decisions about a person's direct care are made.
- Examples of such decisions include but are not limited to choices about physical examinations, investigations or tests, elective medical/surgical treatments, or

[38] 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]

procedures (including those made in the context of mental health). In the context of personalised care, the recording of SDM may also include choices around care plans/packages, social prescribing and supported self-management. E.g., smoking cessation, exercise regimes, dietary changes, or other goals for people with (or without) long term conditions affecting their physical or mental health.
- For use in encounters with adults aged 18 and over where the person has capacity to decide, or the person does not have capacity but there is a legal power of attorney in place and/or where the Best Interests principle applies.
- For use in encounters with young people aged 16 or over who have capacity or children under the age of 16 assessed as Gillick competent by a medical professional (or in the context of sexual health, where Fraser guidelines apply)[39] or where a person with parental responsibility has the capacity to give consent.[40]
- Aiming to be used appropriately and synergistically with other PRSB standards that have relevance to SDM including but not limited to About me, Personalised care and support plan, and the Core information standard (e.g., sections on mental capacity, end of life care/advance care planning, reasonable adjustments, CPR decisions etc).
- Aiming to be compatible with the use of other standards and professional guidance including the Accessible information standard, the GMC guidance on decision making and consent and the draft NICE guideline on shared decision making.

What the SDM and consent standard ***is not***

- For use in healthcare settings outside the four nations of the UK.
- For recording preference-sensitive decisions made without the involvement of a qualified healthcare professional in health or social care settings.
- Developed or consulted on for use when recording preference-sensitive decisions made in medically urgent, immediately life-threatening, or emergency situations. However, there may be circumstances where the standard would be appropriate and could be used in urgent care.
- A replacement or duplication of either the information already collected and held about a person in other parts of the full health and care record or for existing PRSB standards. The SDM and consent standard should function in synergy with these where they are relevant to the recording of a person's preference sensitive decision.

The SDM and consent project is not yet completed, with two subsequent phases proposed. As such the scope outlined in this phase 1 report recognises that in its current form the SDM and consent standard ***is not***

- A fully digitised consent form (although this will be explored in future phases).
- The final version for publication.
- Endorsed by patient representative or healthcare professional bodies.
- Consulted on for use in social care settings (phase 2).
- Pilot tested in live clinical settings.
- Supported by technical/terminology standards, implementation guidance, clinical safety case/hazard log or other materials that are to be considered for development in future phases.

[39] Website: 'GP mythbuster 8: Gillick competency and Fraser guidelines.' Care Quality Commission: 2021 [Accessed June 2021]

[40] Website: 'Children and young people: Consent to treatment.' NHS.UK: 2019 [Accessed June 2021]

3.2 Project governance and resources

Members of the project team (including professional and lay advisors) and their roles are listed in Appendix B. Project board members are set out in Appendix G.

3.3 Consultation approach and methods

3.3.1 Evidence review

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.[41]
2. The draft NICE guidance on shared decision making.[42]
3. The NHS England shared decision making summary guide.[43]
4. The King's Fund report on making shared decision making a reality.[44]
5. The third edition book 'Shared decision making in health care'.[45]

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. Extra 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 detailed summary of the findings at this stage can be found in the Evidence Review Report (Appendix A – separate document).

3.3.2 Mapping to existing standards, guidance, and SDM models

To our knowledge this is the first information standard developed specifically to support shared decision making in healthcare settings.

The aim of the mapping process was to generate a straw-man proposal for the contents of the draft standard. This was an iterative process that was done in parallel with the evidence review.

The following artifacts were reviewed for components relevant to shared decision making and consent and mapped to each other as part of the work:

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

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

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

[44] 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]

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

- Existing PRSB information standards.
- The GMC guidance on decision making and consent and the draft NICE guidance on shared decision making.
- The following SDM models:
    - Three-talk model.[46]
    - Ottawa Decision Support Framework (ODSF).[47,48,49]
    - Interprofessional-SDM (IP-SDM).[50]
- The following SDM tools/mnemonics:
    - Ask 3 Questions.
    - BRAN (Benefits, Risks, Alternatives, do Nothing).
    - BRAIN (Benefits, Risks, Alternatives, Intuition, Next steps).
    - BRAND (Benefits, Risks, Alternatives, do Nothing, Decision).
- The output of a comprehensive systematic review of the key components of 40 unique shared decision making models that was published by the BMJ in 2019.[51]

A detailed overview of the SDM models used to inform the mapping process (and a simplified version of the output in table form) can be seen in the Evidence Review Report (Appendix A – separate document).

3.3.3 Use case scenario development

The objective of the use case scenario development was:

- To provide material for discussion (team meetings and webinar) to help clarify and test how the standard may be used in clinical practice (which settings, the individuals involved, the types of problems or issues that may arise and need to be recorded in shared decision making).

Eight use cases were co-produced with our project team clinical and citizen advisors and informed by up-to-date evidence and clinical guidelines. These were:

- Colorectal Cancer – An 83-year-old lady who has completed surgery for colorectal cancer and must decide about post-operative chemotherapy.
- Multimorbidity – a complex 73-year-old patient with atrial fibrillation and multiple long-term conditions who is at risk of bleeding and ischaemic stroke is invited to decide about whether to start a new medication.

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[46] 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]

[47] 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]

[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] 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]

[50] 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]

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

- Mental Health – a 26-year-old new mother with post-natal depression who is invited to choose from her treatment options.
- Children's dental case – a 10-year-old child with cerebral palsy and visual impairment and presenting with tooth decay whose parents must agree to his potential treatment.
- Genetic condition – a couple who wish to conceive their first child (one of whom is a 23-year-old man with primary ciliary dyskinesia and low sperm count and motility) and have a decision to make about infertility treatment.
- Polypharmacy – a 70-year-old lady taking multiple medications who has attended an annual medications review, which may require multiple decisions relating to prescribed drugs.
- Elective surgery – a 70-year-old man who has been found to have an incidental abdominal aortic aneurysm as part of another routine scan and wishes to choose from his options for surgery.
- Gynaecology – a 64-year-old lady with uterine prolapse who is invited to decide on her options for surgery.

The scenarios contained background information, a clinical vignette where options were presented along with the benefits, risks, alternatives (including the option to take no action), and a storyboard to simply communicate the key aspects. The use of clinical vignettes to illustrate shared decision making has been described before[52], although the structure of our use cases differed significantly in that they were derived from PRSB methodology and tailored to the requirements of this specific project.

The original use case scenarios can be found in Appendix C (separate document).

3.3.4 First draft of the standard

The outputs from the evidence review and mapping work were developed into a first draft of the standard using the ART-DECOR® software. The draft was then refined by the internal team following feedback from our clinician and lay advisors.

3.3.5 Consultation webinar

The aim of the clinician and citizen led consultation webinar, which was attended by multidisciplinary stakeholders, was to test the draft SDM and consent standard at a high level; to answer which aspects of shared decision making conversations did they feel should and should not be recorded?

- Date: 4 March 2021.
- Duration: 2 hours.
- Participants: 130
- Platform: Microsoft Teams.
- Session objectives:
    - Introduce the PRSB, the project, and familiarise participants with the basic concepts of shared decision making.
    - Introduce and garner feedback on a high-level view of the draft information standard.
    - Review the standard in the context of the eight use case scenarios presented in separate breakout sessions.

[52] Stacey D and others. 'A systematic process for creating and appraising clinical vignettes to illustrate interprofessional shared decision making.' Journal of Interprofessional Care: 2014, volume 28(5), pages 453-9 [Accessed March 2021]

- ‘Washup’ – discuss the output of the breakout sessions amongst all participants.

The following questions were used to prompt discussion in the breakout sessions:

- What are the most important things from your perspective as a clinician or patient to record when you have a conversation about care and treatment options?
- Are these covered in the draft standard?
- Are all the elements in the draft standard needed and useful?
- Does it work for this area of healthcare based on your own experience or the given scenario?
- Does it suitably support professional guidance (e.g., GMC and draft NICE guidelines)?

The main webinar session and breakouts were recorded and participants’ comments in the chat log were retained for analysis purposes. Further information was collected via email on an *ad hoc* basis. The output from the webinar then underwent thematic analysis to identify new learning and proposals for changes to the draft standard. The key findings were summarised and presented in a short video recording that was then sent out to participants for their information.

The high level version of the standard introduced at the webinar, and the participants in attendance organised by groups can be found in Appendix E.

Webinar Pre-Briefing

- Date: 1 March 2021.
- Duration: 1 hour
- Platform: Microsoft Teams.
- Session objectives:
    - Introduce the work done by PRSB on information standards.
    - Introduce the purpose and aims of the SDM and consent project.
    - Discuss questions or issues raised about shared decision making or the main consultation webinar.
    - Participants were given access to a short video and one-page briefing document about shared decision making to help make sure they were familiar with the basic concepts.

To make sure of maximum engagement with frontline clinicians, patients, and membership organisations both the pre-briefing session and consultation webinar were delayed by one month (from early February) due to the disruption caused by the COVID-19 pandemic. The decision to delay was made and agreed by the PRSB assurance committee.

3.3.6 Structured role plays

One of the other risks to the project that arose due to the COVID-19 pandemic situation was to the pilot testing of the standard in live clinical settings, which was delayed until phase 3 as a result. The intended pilot site was unable to spare the resources needed to fulfil project requirements. It was recognised that a viable alternative might involve the use of simulated role plays as previously ‘true-to-life [clinical] vignettes and written case simulations’ of SDM scenarios, adapted for use with visual media, have been successfully demonstrated in research studies[53] and used by professional health education services (e.g., The Shared Decision Making e-learning programme produced collaboratively by the Academy, the

[53] Stacey D and others. ‘A systematic process for creating and appraising clinical vignettes to illustrate interprofessional shared decision making.’ Journal of Interprofessional Care: 2014, volume 28(5), pages 453-9 [Accessed March 2021]

Winton Centre for Risk and Evidence Communication at the University of Cambridge, Advancing Quality Alliance (AQUA), and Health Education England.[54]).

This led to the decision to develop and conduct the structured role play scenarios 'in-house' at the PRSB utilising the 'Microsoft® Teams' platform to allow for the encounters to be conducted remotely. These realistic 'OSCE style' scenarios were co-produced with our project team clinical and citizen advisors and informed by up-to-date evidence and clinical guidelines. Participants in each scenario included a clinician, an actor, and an observer/facilitator. There was a mix of professional actors and real patients (the latter were also acting to a script co-produced by the project team but were able to bring insights derived from their real-life experience of living with one or more long term conditions to the role).

It was made clear to the participants that the aim of the structured role play was to test the standard, not the ability of the clinician or patient to conduct an SDM style conversation. Clinicians were encouraged to conduct a consultation as they normally would and neither clinicians nor patients underwent any specific training in shared decision making or consent as part of this project. After each 'consultation' was conducted, the clinician was asked to fill in a 'human readable' form of the SDM record standard (either as a Microsoft® Excel spreadsheet or printed form) and provided comments as appropriate. As part of this the 'patient' was asked to participate in a 'washup' discussion to give their feedback. The output from the role plays was used to iteratively update the human readable form of the standard to test in the next session. In some sessions multiple encounters/appointments were simulated but only one was required to be recorded.

Participants were sent the materials in advance and underwent individual briefing sessions before their role to make sure they were familiar with the content, could ask questions and resolve any issues. The role play materials can be found in Appendix D (separate document), which includes:

- Role play instructions.
- Clinician and patient specific briefing materials.
- Human readable form of the standard.

Eight role plays were conducted, which are outlined briefly below:

Vascular Surgery

- Date: 15 April 2021.
- Duration: 2 hours.
- Clinician: Consultant Vascular Surgeon.
- Patient: Actor playing 70-year-old male found to have an abdominal aortic aneurysm on a routine scan.
- Platform: Microsoft Teams.
- Simulated encounters: 2.
- Decision support tools used: 0.

Polypharmacy

- Date: 21 April 2021.
- Duration: 2 hours.
- Clinician: Community Pharmacist.

[54] Website: About the Shared Decision Making Programme. E-Learning for Healthcare: 2021 [Accessed November 2021]

- Patient: Real patient with experience of taking multiple medications playing a 70-year-old male attending an annual medications review.
- Platform: Microsoft Teams.
- Simulated encounters: 1.
- Decision support tools used: 0.

Gynaecology

- Date: 22 April 2021.
- Duration: 1 hour.
- Clinician: Consultant Gynaecologist
- Patient: Actor (with experience of living with a chronic gynaecological condition) playing a 60-year-old female with symptoms of pelvic organ prolapse.
- Platform: Microsoft Teams.
- Simulated encounters: 1 (two planned).
- Decision support tools used: 1 (NICE patient decision aid: Surgery for uterine prolapse).

Children's Dental Case

- Date: 27 April 2021.
- Duration: 2 hours.
- Clinician: Dentist (retired).
- Patient: Actor playing the mother of a 10-year-old child (non-speaking part) with visual impairment and cerebral palsy, with tooth decay upon examination.
- Platform: Microsoft Teams.
- Simulated encounters: 1.
- Decision support tools used: 1 (BRAN)

Colorectal Cancer

- Date: 14 May 2021.
- Duration: 2 hours.
- Clinician: Colorectal Surgeon (registrar).
- Patient: Actor (with experience of living with somebody with cancer) playing an 83-year-old male who has rectal cancer. (NB: The scenario was originally planned for a female patient and therefore adapted on the day for a male role).
- Platform: Microsoft Teams.
- Simulated encounters: 1 (2 planned)
- Decision support tools used: 1 (NICE guideline [NG151] on colorectal cancer)

Mental Health

- Date: 14 May 2021.
- Duration: 2 hours.
- Clinician: GP.
- Patient: Actor playing a 26-year-old mother with symptoms of post-natal depression.
- Other: Actor playing patient's partner.
- Platform: Microsoft Teams.
- Simulated encounters: 1.
- Decision support tools used: 0.

Multimorbidity

- Date: 20 May 2021.
- Duration: 2 hours.
- Clinician: GP.
- Patient: Actor playing a 75-year-old male with living with multiple long-term conditions.
- Platform: Microsoft Teams.
- Simulated encounters: 1.
- Decision support tools used: 0.

Genetic Condition

- Date: 26 May 2021.
- Duration: 2 hours.
- Clinician: GP. (Scenario was adapted on the day as it was originally written for a genetic counsellor).
- Patient: Patient (with experience of living with a genetic condition playing an 18-year-old male with a family history of Huntington's disease).
- Platform: Microsoft Teams.
- Simulated encounters: 1 (3 planned).
- Decision support tools used: 0.

Importantly, the decision a patient came to as part of the simulation was not decided in advance. The decision was 'discovered' organically based on the conversation that was had between the clinician and patient.

3.3.7 Second draft of the standard

The outputs from the webinar analysis and structured role plays were used to inform the second version of the draft standard that was updated using the ART-DECOR® software. This was refined further by the internal team following feedback from our clinician and lay advisors. The finalised draft of the standard following the completion of phase 1 can be found in Appendix G (separate document). The output of the consultation is in section 4 below.

4 Findings and recommendations

4.1 Findings that informed the content of the standard and recommendations for future phases

This section provides a summary of the consultation findings that informed and shaped the contents of the standard. In each table there is a summary of the overall consultation findings for that theme/ topic and then below that the separate conclusions derived from the evidence review, webinar and role plays. A detailed evidence review can be found in Appendix A (separate document). More detailed analysis of the webinar consultation can be found in Appendix I.

4.1.1 Problems being addressed

Problem or issue and person's understanding of their diagnosis or condition	
Findings & next Steps	**Overall, the phase 1 consultation showed preliminary support for the inclusion of person's understanding of their condition and the options available for treatment. Recording a person's justification for the decision made was felt to be a useful way to illustrate that it was fully informed. These elements require further development and testing in the next phase.**
Evidence	**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.
Webinar	**Conclusion:** Stakeholders took the view that for a person to make an informed decision about their health it is critical that they understand their diagnosis and what it means. They also recognised that patients may be less equipped to have the conversation than clinicians. What a person understands by their diagnosis should be recorded. A number of participants also felt that shared decisions involve establishing what a person's prior knowledge about a diagnosis or intervention is, and this could be recorded. These aspects were included in the human readable form of the standard for preliminary testing in the role plays. In an *Ad hoc* interview with a

	clinician with expertise in SDM, the importance of linking/coding a relationship of the SDM conversation to a particular diagnosis, problem, or issue was a strongly held view, to make sure of interoperability. *'The most important thing to record [is] the patient's understanding of their condition. Often patients are undergoing a procedure but do not have enough understanding about what is going on with them. It is therefore very difficult for them to make an informed decision. The most important thing to record is exactly what does the patient understand by their diagnosis…if they do not understand their underlying condition clearly it is difficult for them to make these decisions [which are often complex]**.'*** **-Interventional radiologist** *'On communication and language, it strikes me that clinicians will have multiple consent conversations daily but from a patient's perspective it might only be every 5 – 10 years. So, there's an imbalance between patient and clinician.'* - **Decision aid developer (SDM)**
Role Play	**Conclusion:** The recording of a person's understanding of their diagnosis, prior knowledge of the options and the reasons given for what they decided was supported for inclusion in the standard by clinicians and patients. Discussion with our clinician and lay advisors identified this as an area for further exploration and testing in the next phase.

4.1.2 Recording the encounter details

People accompanying the patient and family or carer involvement in shared decisions	
Findings & next Steps	**Overall, the phase 1 consultation supported the inclusion of recording details about people accompanying the patient and recognised their involvement in shared decisions. Other aspects relating to these people that might be recorded could be explored in the next phase.**
Evidence	**Conclusion:** There is professional guidance and academic literature advocating the inclusion of 'decision partners' (such as family, friends or carers) in the SDM process. Family and carers are likely to be more involved and relied upon in the decisions of people with long term and degenerative conditions like dementia where capacity and understanding may fluctuate.

Webinar	**Conclusion:** This aspect was not specifically tested in the webinar. The importance of the health professional understanding a person's support networks was raised and stakeholders recognised the importance of family or carer involvement. The standard does not currently support recording of the values or preferences of people accompanying the patient.
Role Play	**Conclusion:** Clinicians understood and were able to fill in this aspect during the role plays. Patients and professionals supported its inclusion. It was raised that in certain circumstances where capacity is an issue it is important to know if a person accompanying the patient has power of attorney (POA). Our clinical and lay advisors supported the inclusion of a person's 'name, relationship, and role'. Whether other aspects are required and if 'role' is adequate to capture legal information such as POA should be tested in the next consultation phase.

Person-clinician communication, language and use of an interpreter	
Findings & next Steps	**Overall, the phase 1 consultation supported the recording of the use of an interpreter for shared decisions made where the patient lacks English proficiency. Further phases should test the inclusion recording of support for other (including non-spoken) communication difficulties, which may require development of extra terminology for interoperability.**
Evidence	**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.
Webinar	**Conclusion:** Patient and professional stakeholders supported a suggestion that the interpretation section of the standard should be expanded to allow the recording of non-spoken languages and communication. This would

	be aligned with GMC guidance advising that appropriate reasonable adjustments during SDM may include 'making arrangements for those with communication difficulties, such as impaired hearing.' [55] *'Deaf mental health is a specialism therefore are consultants aware of the BSL [British Sign Language] versions of mental health assessments and the need to use BSL interpreters who specialise in mental health? In general health etc do clinicians ensure advocates are invited to the appointments of Deaf patients along with the BSL interpreter?'* **– Advocate for deaf equality**
Role Play	**Conclusion:** The recording of the use of British Sign Language or other non-spoken language interpreters was not tested in the role plays. No codes relating to this issue could be found in SNOMED CT or the data dictionary. Consideration should be given to developing new terminology as part of a future phase. The human readable form of the standard included the NHS Data Dictionary 'Interpreter present at care contact indication code' as a drop-down list. Clinicians were able to fill this in without difficulty and understood the rationale for its inclusion in the SDM and consent standard. Review by our clinical and lay advisors emphasised the importance of being able to identify and trace who the person translating was. Further work is required to ascertain if this requires an update to the professionals present sub-section.
Audio or visual recording of the shared decision making conversation:	
Findings & next Steps	**Overall, the phase 1 consultation supported the inclusion of data relating to audio or visual recording in the SDM and consent standard. How this information might be collected and stored automatically should be explored during piloting and implementation.**
Evidence	**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.

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

Webinar	**Conclusion:** The recording of data relating to audio/visual recording was introduced but not directly tested in the webinar.
Role Play	**Conclusion:** Clinicians in the role plays were able to fill in this part of the standard without issues. It was raised that this type of information should be automated where possible.

Recording the distributed nature of shared decisions	
Findings	**Overall, the phase 1 consultation recognised and supported the capturing of SDM across people, time, and place. The consideration of SDM as an ongoing process with several touch points was raised as a positive of the standard. Further exploration and testing of the standard is needed across multiple appointments and transfers of care.**
Evidence	**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 often involves decisions made across multiple professionals and appointments. The standard should account for the fact that decision making is 'initiated, sustained and transformed over a range of encounters [and people].'[56]
Webinar	**Conclusion:** Webinar participants recognised that the SDM process can be distributed across more than one encounter with enough time needed for patients to prepare in advance and reflect after appointments on the options; or revisit the decision made. Stakeholders supported the recording of the information/support tools relevant to the decision that were shared in advance (including patient owned resources). It was queried if the

[56] 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]

	standard needed to be organised differently dependent on whether an initial or subsequent SDM conversation (about the same issue) was being recorded. This should be explored in a subsequent phase. *'Shared decisions will change over time (e.g., new evidence, changing personal circumstances) – would it help to build a briefer standard for subsequent conversations (versus first) to capture key changes?'* **– Pharmacist** *'The standard goes beyond consent & also recognises shared decision making as a process and not a one-off decision.'* **– Hospital doctor**
Role Play	**Conclusion:** Certain role play scenarios were written to test the standard over more than one appointment and in cases where there had been transfers of care. These were not fully tested in practice, as the time required for role play and detailed discussion of the initial appointment usually meant that there was not enough time to run a subsequent encounter. In one scenario where this was completed successfully, it was unclear from the clinician's perspective what aspects needed to be captured from the initial appointment. This issue should be explored further in the next phase.

4.1.3 Specific models of shared decision making and core components of the SDM and consent standard

Models and core components of shared decision making	
Findings & next Steps	**Overall, the phase 1 consultation did not definitively resolve whether certain specific models of SDM should be included as an optional section in the standard. This should be tested in the next project phase. However, key components of the generic standard (as identified from the evidence review, suggested/supported in the webinar and tested in the role plays) align with several models as well as the GMC guidance on decision making and consent and the NICE guidance on shared decision making. In the next phase the standard should be tested in further detail and at-scale (utilising surveys and other methods) in line with standard PRSB methodology.**
Evidence	**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 should include and test the common features of the models that should be recorded.
Webinar	**Conclusion:** The inclusion of specific SDM models was not directly tested in webinar. However, stakeholders described various versions of a minimum viable standard with suggested components that are included within many of the over 40 SDM models evaluated in the literature. Suggestions made included the following*****: • What was discussed? 23 (58%) • What was decided? 30 (75%) • What decision support tools were used? 8 (20%) • What was the person's perspective and understanding? 26 (65%) • What matters to the person? 26 (65%) • Was a shared understanding/agreement reached? 14 (35%) • What was the person's capacity/involvement in the process? 14 (35%) Where these components already existed in the draft standard steps were taken to made this more explicit and where not these were added to test in the role plays. *****NB: Number out of 40 (percentage of SDM models studied that include components that map to the stakeholder suggested component) in parentheses above.[57]
Role Play	**Conclusion:** The inclusion of specific SDM models was not tested in role plays. However, clinicians were able to fill in the core components of the standard in all eight role plays.

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

The ‘three-talk model’ of shared decision making	
Findings & next Steps	**Overall, the phase 1 consultation did not definitively resolve whether the three-talk model should be included as an optional section in the standard. This should be tested in the next project phase.**
Evidence	**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 randomised controlled trial in a specific patient group has shown use of the three-talk model in SDM may positively influence decision related patient outcomes; reducing decision conflict and improving the person’s confidence and satisfaction with the decision made.
Webinar	**Conclusion:** The inclusion of specific SDM models was not tested in the webinar although there was significant stakeholder support for aligning the standard to the NICE guideline on shared decision making, which itself recommends the three-talk model for use in clinical practice.
Role Play	**Conclusion:** The inclusion of specific SDM models was not tested in the role plays.

The Ottawa Decision Support Framework (ODSF) of shared decision making	
Findings & next Steps	**The phase 1 consultation did not test whether the ODSF model should be included as an optional section in the standard. This should be tested in the next project phase.**
Evidence	**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.
Webinar	**Conclusion:** The inclusion of specific SDM models in the standard was not tested in the webinar.
Role Play	**Conclusion:** The inclusion of specific SDM models in the standard was not tested in the role plays.

The Interprofessional model of SDM (IP-SDM)	
Findings & next Steps	**The phase 1 consultation did not test whether the IP-SDM model should be included as an optional section in the standard. This should be tested in the next project phase.**
Evidence	**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.
Webinar	**Conclusion:** The inclusion of specific SDM models was not tested in the webinar.
Role Play	**Conclusion:** The inclusion of specific SDM models was not tested in the role plays.

The ‘Ask 3 Questions’ model/tool for shared decision making

Findings & next Steps	**Overall, the phase 1 consultation did not definitively resolve whether the Ask 3 questions model should be included as an optional section in the standard. This should be tested in the next project phase.**
Evidence	**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 (Making good decisions in collaboration) 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.
Webinar	**Conclusion:** The inclusion of specific SDM models was not tested in the webinar.
Role Play	**Conclusion:** The inclusion of specific SDM models was not tested in the role plays.

The ‘BRAN’ (Benefits, Risks, Alternatives, (doing) Nothing) model of shared decision making	
Findings & next Steps	**Overall, the phase 1 consultation did not definitively resolve whether the BRAN model (or similar) should be included as an optional section in the standard but did suggest that where the mnemonic was utilised the generic standard was able to capture four core aspects. This should be tested in the next project phase.**
Evidence	**Conclusion:** The use of the BRAN tool for shared decision making is endorsed by the Academy and Scottish government. There are no current studies validating BRAN (or the Centre for Collaboration, Motivation & Innovation’s BRAIN alternative) for use in clinical practice. Inclusion of these tools in the standard should be tested as part of the PRSB consultation.

Webinar	**Conclusion:** The inclusion of specific SDM models was not tested in the webinar.
Role Play	**Conclusion:** The inclusion of specific SDM models was not tested in the role plays. However, in one scenario a clinician did use BRAN as a mnemonic to help structure the SDM conversation. This session therefore demonstrated that the generic record standard was able to capture the four core aspects of the BRAN model.

4.1.4 Supporting the shared decision

Agenda setting	
Findings & next Steps	**Overall, the phase 1 consultation supported the inclusion of agenda setting in the SDM standard. This should be tested in further detail in the next phase. To clarify the proposed requirements for recording the agenda set, the description has been updated in the second draft of the standard.**
Evidence	**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. 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.' 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). 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.'
Webinar	**Conclusion:** The inclusion of agenda setting was not directly tested in the webinar.
Role Play	**Conclusion:** Several clinicians queried initially the purpose of the agenda setting element in the role plays and were unsure what to record. This is in line with findings in published literature. However, following a verbal

	explanation of proposed requirements they were mostly supportive of capturing this in the record, and in particular ensuring that the patient's agenda was noted. This highlights the importance of a clear description for each element of the standard and anticipates the need for training in SDM concepts for optimal recording. *'It's important that with this aspect there is a focus on the patient's agenda and establishes what is most important to them.'* **– Clinician**
	Establishing what matters to patients: Goals, values, hopes, ideas, concerns, and expectations
Findings & next Steps	**Overall, the phase 1 consultation strongly supported the recording of 'what matters to patients', both in their lives and in relation to the decision, in the form of their ideas, concerns and expectations, goals, values, hopes and preferences. How/whether these should be coded requires further consideration.**
Evidence	**Conclusion:** Establishing what matters most to patients and their ideas, concerns, and expectations about the options for investigations or treatment is central to many SDM models. The standard should capture these important aspects.
Webinar	**Conclusion:** There was strong support from stakeholders for the recording of the relevant influencers of the decision made that were most important to the patient. This was felt to be critical and may include the ideas, key concerns, and expectations of the person and that these aspects needed to be more explicitly captured in the standard. 'What's missing [from the standard] is 'What values and preferences are driving the patient's shared decision?' What's the really important point driving the decision?' **– GP** '"The discussion opens with learning 'what matters to patients' it is framed within how the condition being discussed relates to what matters in patient's [lives]." **– Surgeon & digital health advocate** "It's that concern, what matters to people, that needs to be central [to the standard]." **– Patient advocate**

Role Play	**Conclusion:** Recording of patient ideas, concerns, expectations, values/preferences, goals, and hopes was supported by the role plays. There was a tension identified between recording these together as free text, which may support ease of recording (recognising overlap), versus separate coding of these factors for interoperability. Following discussion with our clinician and lay advisors these factors were combined in the second draft of the SDM standard. This aspect may require further testing.

Recording exceptional circumstances where information may be withheld from the patient (or sharing delayed)	
Findings & next Steps	**Overall, the phase 1 consultation did not definitively resolve how/whether information withheld from patients in rare/exceptional circumstances should be recorded. Further consultation in the next phase is needed to test its inclusion in the standard and clarify the ethical and legal issues involved.**
Evidence	**Conclusion:** The GMC guidance 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. Recording of these aspects in the standard should be tested as part of the PRSB consultation.
Webinar	**Conclusion:** A patient representative argued the importance that, in the rare situations where a decision has been made to withhold information from a patient with capacity, that other professionals responsible for the person's direct care may need to be made aware of this. They cited the analogy of out-of-hours special patient notes that are shared by day-time GPs with out-of-hours clinicians. These are 'brief summaries of key information that include [amongst other information] patient wishes and particular insights that come from knowing someone well.'[58] Testing with our clinician and lay advisors resulted in a recommendation for further

[58] Holt V and others. 'Out-of-hours special patient notes.' London Journal of Primary Care: 2013 , volume 5(2), pages 102-5 [Accessed May 2021]

	consultation to clarify the legal and ethical issues involved around information withheld from patients with capacity, the situations where it may occur in practice and how/whether it should be recorded in the standard.
Role Play	**Conclusion:** The recording of information relating to circumstances where information may be withheld from the patient was not tested in the role plays.

Clinician and patient values and preferences.	
Findings & next Steps	**Overall, the phase 1 consultation did not conclusively resolve how and to what extent clinician and patient preferences might be incorporated into the SDM record. This should be tested in detail during phase 2 including consideration of possible alternatives to the proposed elements for the standard.**
Evidence	**Conclusion:** The evidence review identified the fact that certain SDM models included clinician recommendations (25%), clinician values & preferences (18%), and patient preferences and values (65%).[59] In the first draft of the standard patient preferences were *de facto* assumed to be synonymous with the decision made, although it is now recognised that this may not always be the case. Recording of clinician values, preferences or recommendations was not considered at this stage.
Webinar	**Conclusion:** Both patient and clinician stakeholders raised the issue of capturing the preferences behind the decision made. *'What's missing [from the standard] is 'What values and preferences are driving the patient's shared decision?' What's the really important point driving the decision?'* **– GP** *'[the standard should include] where patient choice cannot be accommodated and why that might be.'* **– Patient**

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

Role Play	**Conclusion:** In one of the role plays a comment was made around capturing patient and clinician preferences and in particular situations where a patient's first preference cannot be accommodated. This led to a rich discussion between participants and the co-production of the following (very preliminary) proposed elements for the standard: • Was the decision made the person's preferred option? (Y/N) • If NO, what was the reason given to the person? • What was the person's preferred option? • Person's reason given for preferred option. • Did the clinician agree with the person's decision? • If NO, what was the reason given to the person? These were added as written into the human readable form of the standard and were supported for inclusion in the draft standard in principle during discussions held in the next role play and with our clinician & lay advisors.

Use of decision support tools such as patient decision aids (PDAs) in shared decision making	
Findings & next Steps	**Overall, the phase 1 consultation emphasised the importance of recording the patient decision aids used in the encounter. Ways in which the content of specialty and/or use case specific PDAs could be added or integrated into the generic standard should be explored in a future phase.**
Evidence	**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.
Webinar	**Conclusion:** The inclusion of PDAs was not tested in the webinar although the Cochrane systematic review supporting their benefits was seen by a key stakeholder as supporting the benefits of SDM overall for patients.

Role Play	**Conclusion:** Three role plays involved the use of PDAs in the simulated encounter. Overall, clinicians supported the inclusion of PDAs in the SDM standard. This view was supported by several patients. It was suggested that there may be a need to optimise the standard for specific use cases by integrating the content of certain PDAs or adding digitised PDAs as extra modules. In one session it was highlighted that the recording of PDAs used should not add extra burden. As our clinician and lay advisors together emphasised the importance of documenting this information, ways in which this could be collected automatically could be explored during pilot testing and implementation of the standard. *'Which patient information leaflet/ patient decision aid [was] given [/used should be recorded] but not the version number etc, as this is too onerous.'* **– Clinician**

4.1.5 Evaluating the decision

Performance measures for evaluating the shared decision making process	
Findings & next Steps	**Overall, the phase 1 consultation did not support the inclusion of SDM performance measures in the standard. This section has been removed from the second draft of the standard.**
Evidence	**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 for 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.
Webinar	**Conclusion:** The inclusion of specific performance measures was not tested in the webinar.
Role play	**Conclusion:** The role plays tested the inclusion of various performance measures including several versions of CollaboRATE and the SDM-Q-9 (but not the Sure scale at this stage). Overall, clinicians queried the purpose

	and value of general and specific performance measures in the SDM and consent standard. This view was supported by several patients. In one session, the potential issue that such measures might be biased by inclusion in the record standard was raised: *'Would you as a patient give a fair evaluation of a clinician's performance in shared decision making if you knew they would have access to your answers before they were going to operate on you?'* **– Clinician**

Assessing health literacy	
Findings & next Steps	**Overall, the phase 1 consultation did not support the inclusion of measures of health literacy in the standard. This section has been removed from the second draft of the standard.**
Evidence	**Conclusion:** Health literacy is an integral component of SDM and this has been recognised by the recent development of an integrated model.[60] 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. The interaction between health literacy and SDM is complex. The PRSB consultation should how/whether levels of health literacy might be recorded.
Webinar	**Conclusion:** Stakeholders felt that the use of adaptive communication techniques from the clinician, such as 'teach back', 'chunk and check' and the use of plain English should be encouraged in SDM but felt that measures of health literacy should not be included in the standard as these are not well established. *'There is no standard / recommended way [to measure health literacy] and some are controversial or with flaws. It may be better to take a cautious approach by assuming that everybody has some issues with health literacy and use adaptive communication techniques like 'teach back' and 'chunk and check.' That way it will be a lot*

[60] 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]

	less daunting to clinicians on the front line. That would also help us to ensure that we are putting the patient at the centre of our practice.' **– Health literacy advocate**
Role play	**Conclusion:** Assessment of health literacy was not tested in the role plays.

4.1.6 Documenting consent

Documenting consent	
Findings	**Overall, the major focus of the phase 1 consultation was on the recording of the SDM process. The standard captures details of consent forms used but does not include a digitised consent form. We are aware of other projects digitising consent in both general and specific use cases and are exploring options for collaboration as part of the next project phase.**
Evidence	**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.[61]
Webinar	**Conclusion:** Stakeholders recognised that there is a relationship between SDM and informed consent that includes capturing the patient's decision journey as well as the final decision and permission to proceed (if applicable). *'…you need a two-way communication when providing a consent process. You do need some form of way that the patients can come back and ask further questions after they have left the consultation or even when they are at home you need that two-way communication to be available. And again, with modern message senders*

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

	that can be integrated as well. …you don't have to have everything written down, but you do have to have documentation from start to finish on how that patient got from A to B.' **– Surgeon**
Role Play	**Conclusion:** Scenarios where informed consent was taken, including completion of a consent form, were not tested in the role plays. However, concerns were raised that a generic standard may not capture or be tailored appropriately to the requirements of specific use cases in healthcare. It was our intention from early on in the project that a generic standard should have the ability to be easily adapted for specific use cases as required (which may for instance require authoring of extra terminology e.g., SNOMED CT. This should be explored and tested in a future phase.

4.2 Other consultation findings and themes

More detailed findings and analysis of the consultation webinar can be found in Appendix I (separate document)

Summary of other general consultation themes	
Strengths	**Conclusion:** Stakeholders felt the standard was well evidenced, recognised SDM as ongoing across multiple encounters or touch points, and would help to formalise the SDM process: *'I think one of the important things of having a standard in place is that it formalises the importance of SDM and aids the clinician in standardising the way that it's recorded. In my experience, SDM isn't embedded right now (not every patient is brought into the decision making process) and recording of it is haphazard...'* **– Patient engagement champion**
Transfers of care	**Conclusion:** Stakeholders felt that interoperability of the standard was important to share the SDM record with other healthcare professionals to avoid duplication of patient and clinician effort and to support future SDM: *'[Following] transfers of care SDM could have taken place really well in a clinic or inpatient setting but if it's not been documented when they come back to general practice… then I don't know what standard of decision has been made so I often…rediscuss with the patient and duplicate the effort. To put that discussion in that transfer*

	of care…either a discharge letter or a clinic letter is really important. even though that's quite onerous it will save time for the system [&] it will help the patients and clinicians to work together.' **– *GP***
Doing nothing	**Conclusion:** Stakeholders emphasised the importance of presenting to the patient and distinguishing between the option to do nothing, delaying a decision, or taking no further action: *'Doing nothing is such an important thing to discuss but is so often overlooked. Many patients don't even know that this can be an option because it's never presented to them.'* **– Patient engagement champion**
Evidence for SDM	**Conclusion:** Stakeholders were equivocal about the evidence base for the benefits of SDM and what measures were appropriate: ***'***It's actually quite difficult to show SDM leads to better outcomes. Depends on what you consider 'better' and how you measure SDM. It's thought to be not though to be worse than alternative though, and morally, legally and professionally it is encouraged!'* **– Academic GP** *'[SDM] may not improve outcomes at all. We have to be very cautious about that criticism because if an outcome is bad everybody can demonstrate that an appropriate process has been gone through to make a decision. What's the purpose of SDM? Is it to get better outcomes for patients or is it elaborate defensive medicine? Do all patients want it?....Have we got to the bottom of what we're writing the standard for?'* **– Hospital doctor**
Education and training	**Conclusion:** Stakeholders strongly supported the use of education and training in SDM to support the implementation of the standard. There are many educational/training resources on SDM, including those produced by the project partner organisations and PRSB members. The best resources to complement the standard should be identified and signposted to users. *'The tools [and record standard] will only be used appropriately if supported by facilitation, education and wider incentives to shift to SDM processes at all levels of care.'* **– Academic in medicine**

Capacity & mental health	**Conclusion:** Stakeholders promoted the importance of establishing and recording a person's mental capacity and emphasised that accurate recording of the SDM dialogue is important in mental health: *'We then need to ensure that the records accurately reflect the conversations that have occurred. Particularly around mental health which can affect cognition and decision making, having an accurate reflection of the conversation and options is important.'* **– Patient advocate**
Uncertain decisions	**Conclusion:** Some stakeholders argued that it was important to be frank with the patient about areas of uncertainty and to document this. It was also suggested that risk and uncertainty should be clearly distinguished. An element for documenting uncertainty was included in the human readable form of the standard and tested in the role plays but the purpose was not well understood by clinician or patient participants and inclusion of the concept requires further consultation. *'The standard is missing a way to document uncertainty…we have to be honest about the known unknowns.*' **– GP** *'Risk and uncertainty are not the same. We are often talking about the latter in complex decisions.'* **– Hospital consultant & clinical safety officer**
Size of the standard	**Conclusion:** Some participants, including clinicians and patients were concerned that the size of the standard may burden clinicians and distract them the focusing on the SDM conversation, to the detriment of patients. The standard needs to be manageable and not a burden on clinicians or patients, to be implemented. The role plays were not time limited as the primary aim was to test the content of the standard. Issues around the time required to fill in the standard should be explored, tested, and resolved as far as is practicable in the next phase. *'Regarding the standard, are we aiming for something that's completely comprehensive or a standard that is feasible, easy to record and likely to be implemented?'* **– Subject matter expert (SDM)** *'We have to find a balance between pragmatism and aspiration…The recording has to be doable in the time or it won't be done.'* **– GP** *'Is all of this information going to be documented by the clinician? This is a lot of information.'* **– Surgeon & digital health advocate**

Time	**Conclusion:** The theme of time was widely discussed during the consultation. Some clinicians expressed worry about having enough time to perform SDM in their daily practice but recognised that time was needed to allow patients the time they need to decide. *'A key theme here is 'Time' 'It takes time, we've got to give the patient time and the timing of the conversation [when it happens].'* **– Clinician lead advisor, PRSB** *'We have to find a balance between pragmatism and aspiration…The recording has to be doable in the time or it won't be done.'* **– GP** *'Time for reflection i.e., "time to ponder" is very important….'* **– Patient** *'Time is a factor. Time is required to undertake a comprehensive SDM process. Investing in this time can make a huge difference to how a patient accesses health resources in the future. The standard should recognise the time.'* **– Consultant physiotherapist** *'SDM is very time consuming. When people are referred to us it is often almost at the point they are going for surgery and people often day to us 'I wish I'd had this conversation with someone earlier in my diagnosis.' The earlier in a diagnosis this can be started the better.'* **– Healthcare commissioner of services**
Capturing materials shared by patients	**Conclusion:** Stakeholders felt that materials and tools brought by the patient to inform the conversation should be captured. This was already a capability of the first draft standard but has now been made explicit in the description and should be captured in the implementation guidance (phase 2). ***'****The standard focuses on what the clinician gives to the patient. It needs to be factored in that sometimes it can be more of a reciprocal process and there needs to be mechanisms in place to enable patients to share information and resources beforehand as well. Because that can very much guide the content of the discussion and feeds into the record.'* **– Patient advocate** 'It would be interesting to record information that the patient has brought to the clinician rather than the other way around.' **– Patient**

Involved patients	**Conclusion:** Stakeholders were overwhelmingly supportive of the standard facilitating greater patient involvement in the recording of the SDM conversation, including exploring the possibility during implementation that both clinicians and patients could read and write to the record to detect mismatch of priorities and understanding and to document areas of agreement/disagreement. It was suggested that this could occur 'asynchronously' to allow both parties time to reflect on the SDM conversation. The draft SDM standard has been designed for use by clinicians. The possibility of adapting the standard to allow patients to write to the record should be explored in future. *'Patient agreement is something that is not really explored within the culture of sharing patient letters…We need a way to document mismatch of understanding of medical letters [and the conversation].'* **– Retired surgeon** '*GPs have been totally electronic for a long time. Increasingly our patients have access to their record. We are moving towards them being able to write into their records. These standards reflect several encounters and it's a journey towards a decision*.' **– GP** *'For a lot of patients, it would be useful to have access to a summary of what has happened. People have different perceptions of conversations…there is real potential to record all this and know that it has made sense to both parties. It's a 'shared decision' but really it is a 'supported decision' - it is the patient that makes the decision about what they are going to have in the end with the support of the information. Fundamentally all of this is [the patient's] information and it needs to be there for them to check and reflect on. We know that people often can't recall [what was said] in consultations. It's important for both parties to have that clear view of what was said in case they wish to reconsider.'* **– Patient advocate** *'There could be a field where the patient and clinician could share input asynchronously. So, you have a shared decision on the record, but if something is forgotten or needs to be added this would be a brilliant way of having a more drawn-out decision time for patients and clinicians to step back and have more time.'* **– Patient**

5 Conclusion and recommendations

5.1 Recommendations

To consider the following as part of the proposed further phases of this project and future work:

1. **Wider consultation:** This project has been funded for an initial phase to produce a draft standard that requires further consultation in line with published PRSB methodology (implementation guidance, clinical safety case etc), to gain endorsement. This should include consultation at-scale to get views from beyond the aware or supportive of shared decision making and to test some of the detail and in particular aspects not explored or arising from role plays. This could include an exploration of how the principles might apply in a social care context. Preliminary proposals for two further phases are outlined in section 3.1 of this document.

2. **Pilot testing:** Pilot testing of the standard in live healthcare settings was originally planned for phase 1 but was delayed by the situation with the COVID-19 pandemic. It is critical that this is done in at least one speciality (but ideally several disciplines) to address concerns of useability (e.g., time to fill in) raised in the consultation and find unforeseen issues. Several organisations have been identified as possible pilot candidates. Pilots should test the standard across 'person, place and time' by incorporated shared decisions made involving multiple encounters, with more than one professional, across different settings and including transfers of care. How the standard works alongside existing standards should also be explored.

3. **Digitised consent forms:** The major focus of this project was the recording of key aspects shared decision making – the patient's decision journey – much of which occurs before informed consent is given (if it is required). Our SDM and consent standard captures details of consent forms used but does not include a digitised consent form. We are aware of ongoing work by other organisations to develop digital consent forms for both general and specific use cases. We have engaged them with a view to collaboration, to establish synergies and possible integration into the generic standard, as part of our next phase of work. Responses to initial enquiries have been positive.

4. **Supporting use of the generic standard in specific areas:** A need has been identified for testing of the generic standard and support for specific specialties and use cases. This may require development of new terminology, coding, or other detail to support useability and meet the needs in that specialty. The areas with the most value-add for patients should be identified and considered for further development and inclusion in pilot testing. This might include the development of certain area specific 'views' of the generic standard. This was done previously for the 'care homes view' of the core information standard.

5. **Information Standards Notice (ISN):** Further technical development of the standard must focus on achieving compliance with the ISN process. Part of this will require resolution of recommendation 6 below.

6. **Ensuring interoperability:** This project has produced an information standard (in draft) that incorporates the aspects of the SDM process that patients and

professionals have told us should be recorded. This was supported by an evidence review and validated in structured role play scenarios. However, the consultation identified a tension between the use of free text and recording of more structured and coded data. It was felt that while free text may be easier to fill in and may more sensitively capture the details and phrasing of what was said during the SDM discussion, the use of unstructured data was a hindrance to interoperability. The feasibility of implementing the standard components, as drafted, must now be explored in detail with due respect given to the practicality of technical implementation.

7. **Education and training:** There are many educational/training resources on SDM, including those produced by the project partner organisations and PRSB members. For example, NHSEI has commissioned (via the Personalised Care Institute) a 30-minute e-learning SDM introductory module and NICE has produced an accompanying learning package. As a minimum, the best resources to complement the standard should be identified and signposted to users. However, it was observed by stakeholders that a fully resourced plan with culture and transformation change including education and training is required for wider adoption of SDM in NHS. For the standard to be used appropriately and work in practice it should be deployed in that supportive context. This would require ownership from NHSE and contribution from PRSB and our member bodies.

8. **Rationalising the standard:** Some participants, including clinicians and patients were concerned that the size of the standard may burden clinicians and distract them the focusing on the SDM conversation, to the detriment of patients. The standard needs to be manageable and not a burden on clinicians or patients, to be implemented. The role plays were not time limited as the primary aim was to test the content of the standard. Issues around the time required to fill in the standard should be explored, tested, and resolved as far as is practicable in the next phase.

9. **Involving patients in the SDM record:** Stakeholders were overwhelmingly supportive of the standard supporting greater patient involvement in the recording of the SDM conversation. We are aware that some areas in general practice are exploring the process of allowing access for both clinicians *and* patients to read and write to the record. Our consultation suggested that the benefits of this would include the detection of mismatched priorities and understanding and would allow documentation of areas of agreement and disagreement. It was suggested that this could occur 'asynchronously' to allow both parties time to reflect on the SDM conversation, in line with best practice. The draft SDM standard has been designed for direct use by clinicians. The possibility of adapting the standard to allow patients access and the ability to write to the record should be explored, along with the possible implications for clinical safety and considerations of information governance, in future work.

5.2 Focused recommendations

To consider further exploration, development, and testing of the following provisional standard components:

- Patient's understanding of their diagnosis or condition and person's justification for the decision made.
- Details about the person's accompanying the patient.
- Support for other (including non-spoken) communication difficulties.
- Specific models of SDM including the three-talk model and others.

- Recording of matters to patients including goals, values, hopes, ideas, concerns, and expectations. This could include an exploration of how to record indicators of how well patients were primed to prepare for SDM conversations.
- Recording exceptional circumstances where information may be withheld from the patient (or sharing delayed), as described in the GMC guidance on shared decision making and consent.
- Recording patient preferences (and exploring whether there are circumstances where clinician preferences might be usefully recorded)
- Levels of uncertainty.
- Patient satisfaction over time.
- Methods of risk communication.
- Storage of audio or visual recordings, consent forms, and PDAs into the EHR.

5.3 Sections/ elements not supported by consultation (removed)

- Performance measures. The first version of the draft standard was aligned to the NHS summary guide and implementation checklist for SDM. The checklist includes Collaborate, Sure, and SDM-Q9 / SDM-Q-DOC scales. However, the consultation process did not support their inclusion (see section 4.1).
- Assessing health literacy. It is an essential requirement of the SDM and consent standard that it supports health literacy by helping to making sure that patients can understand what is documented. However, reliable measures for documenting a person's level of health literacy could not be identified or supported by the consultation (see section 4.1).

A table showing the proposed components of the draft SDM and consent standard and current status after phase 1 (with MoSCoW prioritisation) can be found in Appendix J of this document.

5.4 Conclusion

This report documented the first phase of the shared decision making and consent project. Funding is being sought for two proposed further phases. Disruption to the consultation caused by the situation with the COVID-19 pandemic required an agile response that resulted in high levels of engagement from professionals and patients and successful deployment of realistic role play scenarios to test the draft standard. This phase should be followed up with a wider consultation at-scale to get views from beyond the SDM aware as well as pilot testing in live clinical settings. There is potential for collaboration in areas such a digitised consent that should be enthusiastically progressed.

6 Appendices

6.1 Appendix A - Evidence review report

This a separate document published alongside this report on the PRSB website.

6.2 Appendix B - Project team

Team member	Title / Responsibility
Martin Orton	PRSB, Project Manager
James Critchlow	PRSB, Analyst
Helene Feger	PRSB, Director of Strategy, Communications and Engagement
Alannah McGovern	PRSB, Membership Manager
Ramai Santhirapala	Clinical Lead – Consultant Anaesthetist
James Brown	Clinical Lead - Consultant Surgeon & CCIO
Nilesh Bharakhada	PRSB, Clinical director for health and care & Clinical Lead – GP
Lawrence Mudford	Citizen Lead

6.3 Appendix C - Use cases

This a separate document published alongside this report on the PRSB website.

6.4 Appendix D – Role play materials

This a separate document published alongside this report on the PRSB website.

6.5 Appendix E – Webinar materials & participants

This a separate document published alongside this report on the PRSB website.

6.6 Appendix F – Project partner organisations

Organisation	Description
Academy of Medical Royal Colleges	The coordinating body for the UK and Ireland's 23 medical Royal Colleges and Faculties. The organisation has one representative on the project board.
NHS England and Improvement Personalised Care Group	The NHSE/I personalised care group is responsible for making sure that personalised care becomes standard practice across the health and care system. The team has two representatives on the project board.
Centre for Perioperative Care	A cross-organisational, multidisciplinary collaborative between patients and the public, Royal Colleges and similar organisations established in 2019 to facilitate and promote the delivery of high-quality perioperative care. The organisation has two representatives on the project board.
Patient Information Forum	A UK membership organisation and network for people working in health information and support. The organisation has one representative on the project board.
EIDO	EIDO are a software vendor specialising in consent and SDM with a dominant market position and extensive experience of digitising these processes. EIDO have contributed to funding of this work (without preference) as they see the need for a standard to improve quality across health and care. The organisation has two representatives on the project board.

6.7 Appendix G - Project board members

Name	Organisation	Role
Lorraine Foley	PRSB	Chair/CEO
Martin Orton	PRSB	Project Manager
Helene Feger	PRSB	Director of Strategy, Communications and Engagement

Nilesh Bharakhada	PRSB	Clinical director for health and care & Clinical Lead – GP
Ramai Santhirapala	Royal College of Anaesthetists/ Guy's and St Thomas' NHS Foundation Trust	Clinical Lead – Consultant Anaesthetist
James Brown	Mid and South Essex NHS Foundation Trust	Clinical Lead - Consultant Vascular Surgeon & CCIO
Lawrence Mudford	Centre for Perioperative Care (CPOC)	Citizen Lead
Sharon Drake	Representing Academy of Medical Royal Colleges, Royal College of Anaesthetists and Centre for Perioperative Care	Deputy CEO of AoMRC and managerial lead for CPOC
Jeremy Wilkinson	NHS England/Improvement	Senior Manager, Digital Architecture - Personalised Care Group
Jonathon Berry	NHS England/Improvement	Personalisation and Control Specialist - Personalised Care Group
Joanna Dundon	NHS Wales Informatics Service/ Digital Health and Care Wales	National Clinical Informatics Lead – Public (Wales)
Sophie Randall	Patient Information Forum	Projects and Partnerships Manager
Alistair Firth	EIDO	CEO, EIDO
Adrian Lead	EIDO	Director EIDO, Informed Consent for surgical and medical treatment
Irina Bolychevsky	NHSX	Director of Standards and Interoperability

6.8 Appendix H – Draft standard following phase 1 completion

This a separate document published alongside this report on the PRSB website.

6.1 Appendix I – Webinar analysis

This a separate document published alongside this report on the PRSB website.

6.1 Appendix J – Proposed components of SDM record (based on phase 1 consultation)

Proposed elements supported for inclusion in draft SMD and consent record						
Element/theme	**Evidence Review**	**Webinar**	**Role plays**	**Overall**	**MoSCoW prioritisation**	**For inclusion in which deliverable?**
Problem or issue						
Diagnosis problem or issue	Y	Y	Y	Y	Must have	SDM Standard
Person understanding of their diagnosis or condition	Y	Y	Y	Y	Could have	SDM Standard
Encounter details						
Location type	N	N	Y	Y	Must have	SDM Standard
People accompanying patient	Y	Y	Y	Y	Must have	SDM Standard
Family, friend, or carer values and preferences	N	N	N	N	Could have	SDM Standard
Professionals present	Y	N	Y	Y	Must have	SDM Standard
Use of an interpreter	Y	Y	Y	Y	Must have	SDM Standard
Patient preferred written or spoken language/dialect	N	N	N	N	Will not have	Separate PRSB standard
Audio or visual recording of the conversation	Y	N	Y	Y	Should have	SDM Standard
Relevant background information (not exhaustive)						
Individual requirements						

Support SDM process (assess patient needs)	N	N	N	N	Will not have	SDM best practice
Accessible information	Y	N	N	N	Will not have	Separate PRSB standard
Reasonable adjustments	Y	N	N	N	Will not have	Separate PRSB standard
Legal information						
Mental capacity assessment	Y	N	N	N	Will not have	Separate PRSB standard
Lasting power of attorney	Y	N	Y	N	Could have	Separate PRSB standard
Advance decision to refuse treatment	Y	N	N	N	Will not have	Separate PRSB standard
Consent for treatment	Y	N	N	N	Could have	Separate PRSB standard
Consent for information sharing	Y	N	N	N	Could have	Separate PRSB standard
Consent relating to a child	Y	N	Y	N	Could have	Separate PRSB standard
Safeguarding						
Safeguarding concerns	Y	N	N	N	Will not have	Separate PRSB standard
End of life care (Advanced care planning)						
End of life care	Y	N	N	N	Will not have	Separate PRSB standard
CPR decision	Y	N	N	N	Will not have	Separate PRSB standard
Personalised care and support planning						
Personalised care and support plan	Y	N	N	N	Will not have	Separate PRSB standard
Other EHR components (not exhaustive)						
Learn about the patient	N	N	N	N	Will not have	SDM best practice

Person demographics	Y	N	N	N	Will not have	Separate PRSB standard
Participation in research	Y	N	N	N	Will not have	Separate PRSB standard
Medications & medical devices	Y	N	N	N	Will not have	Separate PRSB standard
Allergies and adverse reactions	Y	N	N	N	Will not have	Separate PRSB standard
Risks (to self and others etc)	Y	N	N	N	Will not have	Separate PRSB standard
Family history	Y	N	N	N	Will not have	Separate PRSB standard
Examination findings	Y	N	N	N	Will not have	Separate PRSB standard
Investigation requests/results	Y	N	N	N	Will not have	Separate PRSB standard
Services and care	Y	N	N	N	Will not have	Separate PRSB standard
Social context	Y	N	N	N	Will not have	Separate PRSB standard
Supporting the shared decision						
Pre-appointment Actions						
Pre-meeting information shared	Y	N	N	Y	Should have	SDM Standard
Patient understanding of pre-meeting information	N	N	N	N	Could have	SDM Standard
Establishing what matters to the person						
Foster partnership/rapport	Y	N	N	N	Will not have	SDM best practice
Advocate patient views	Y	N	N	N	Will not have	SDM best practice
Agenda Setting	Y	N	Y	Y	Should have	SDM Standard
About Me	Y	N	N	N	Will not have	Separate PRSB standard
Goals, values, and hopes	Y	Y	Y	Y	Must have	SDM Standard

Ideas, concerns, expectations	Y	Y	Y	Y	Must have	SDM Standard
Information shared (deliberation)						
Options	Y	Y	Y	Y	Must have	SDM Standard
Risks communication	Y	Y	Y	Y	Must have	SDM Standard
Documenting uncertainty	N	Y	N	Y	Could have	SDM Standard
Benefits	Y	Y	Y	Y	Must have	SDM Standard
Decision support tools	Y	Y	Y	Y	Must have	SDM Standard
Deliberation	Y	Y	Y	Y	Must have	SDM Standard
Shared expertise	N	N	N	N	Will not have	SDM best practice
Provide neutral information	N	N	N	N	Will not have	SDM best practice
Tailoring information including checking understanding.	N	N	N	N	Will not have	SDM best practice
Doctor recommendation	N	N	N	N	Will not have	SDM best practice
Answer patient questions	N	N	N	N	Will not have	SDM best practice
Patient access to information	N	Y	N	N	Could have	Implementation
Information withheld or sharing delayed						
Information withheld	Y	N	N	N	Could have	SDM Standard
Reason information withheld	Y	N	N	N	Could have	SDM Standard
Legal advice sought (Y/N)	Y	N	N	N	Could have	SDM Standard

Information still to share	Y	N	N	N	Could have	SDM Standard
Reasons for not sharing now	Y	N	N	N	Could have	SDM Standard
When it can be shared	Y	N	N	N	Could have	SDM Standard
Recording the decision						
Decision	Y	Y	Y	Y	Must have	SDM Standard
Reach mutual agreement	Y	Y	Y	Y	Could have	SDM Standard
Confirm person understanding	Y	Y	Y	Y	Should have	Implementation guidance
Actions for person or their carer	Y	Y	Y	Y	Should have	SDM Standard
Actions for professionals	Y	Y	Y	Y	Should have	SDM Standard
Planned review date/interval	Y	Y	Y	Y	Should have	SDM Standard
Offer time	N	N	N	N	Will not have	SDM best practice
Evaluating the decision						
Health literacy evaluation	Y	N	N	N	Will not have	SDM Standard
Patient decision satisfaction	Y	N	N	N	Could have	SDM Standard
Clinician decision agreement	Y	N	N	N	Could have	SDM Standard
Performance measures	Y	N	N	N	Will not have	SDM Standard
Clinician disagreement with patient choice of option	N	N	N	N	Could have	SDM Standard

Patient perceived self-efficacy	Y	N	N	N	Could have	SDM Standard
Person's option preferences	Y	Y	Y	Y	Should have	Implementation guidance
Clinician preferences & values	Y	N	N	N	Could have	SDM Standard
Person preferences & values	Y	Y	Y	Y	Could have	SDM Standard
Post-appointment Actions						
Post-appointment actions	Y	N	N	N	Could have	SDM Standard
Specific models of SDM						
Ask 3 questions	Y	N	N	N	Could have	SDM Standard
BRAN/BRAIN	Y	N	N	N	Could have	SDM Standard
Three-talk model	Y	N	N	N	Could have	SDM Standard
Ottawa Decision Support Framework (ODSF)	N	N	N	N	Could have	SDM Standard
Interprofessional-SDM (IP-SDM)	N	N	N	N	Could have	SDM Standard
Documenting consent						
Consent forms used	Y	Y	N	Y	Should have	SDM Standard
Digitised consent form	Y	N	N	N	Could have	SDM Standard

Key: Y = Yes (supported), N = No (not supported or not tested)