Professional Record Standards Body

Better records for better care

Shared Decision Making

FINAL REPORT

May 2022

Document Management

Revision History

Version	Date	Summary of Changes
0.1	23.03.2022.	Initial early draft
0.2	04.05.2022	Next draft after agreeing final changes to the information model
0.3	05.05.2022	Updated after NHSE review
0.4	06.05.2022	Update after further review comments
0.5	23.05.2022	Updates from review and approval
1.0	26.05.2022	V1 for publication
1.1	11.07.2022	Update to add EIDO acknowledgement
1.2	10.08.2022	Update to full standard references

Reviewers

Reviewer name	Title / Responsibility	Date	Version
Martin Orton	Project Manager	04.05.2022	0.2
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Approved by

Name	Title/Responsibility	Date	Version
Project Board		20.05.2022	0.4
PRSB Assurance Committee		20.05.2022	0.4

Glossary of Terms

Term / Abbreviation	What it stands for
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
DAPB	Data Alliance Partnership Board
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 a 3 year period, subject to agreement with NHS England & Improvement as the commissioning body.

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

Acknowledgements

PRSB acknowledges the role EIDO Healthcare played in the development of this Shared Decision Making standard through sponsoring the first phase of work. This was key in getting the work started, bringing together the key stakeholders, and showing the standard was feasible with an early draft.

PRSB acknowledges the role of NHSE/I as sponsor for phase 2 for completion of the development of the standard.

PRSB acknowledges the role of the Centre for Perioperative Care who supported the project including providing the patient lead and one of the clinical leads for the first phase of work.

Contents

1 Executive Summary

1.1 Background and Purpose

Shared decision making (SDM) is the process by which a patient and a health or care professional consider treatment options and agree the one best suited to meet the aims and goals of the patient.

The NHS has a duty in law to 'promote involvement' of the person using services, their carer or representative in any decisions about their care and treatment.[1] The Montgomery v Lanarkshire Health Board (2015) judgement also sets the context for the SDM.

In England SDM is one of the six components of personalised care which is a key part of the NHS Long Term Plan. Scotland, Wales and Northern Ireland health strategies also include person centred care focused on supporting people to make shared decisions to support their needs and values.

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.

The PRSB information standard on shared decision making provides a framework for clinicians to record the decision-making process, based on professional guidance, General Medical Council guidance on decision making and consent and the NICE guideline, evidence review, and extensive consultation with healthcare professionals, people and carers.

The standard will also allow the shared decision information to be shared between professionals and their different record systems.

1.2 Methodology

The standard was developed over 2 phases of work. The project team included 2 clinical leads covering primary and secondary care and a person lead to guide the project. The work was done in partnership with NHSE/I Personalised Care Group, Academy of Medical Royal Colleges, Centre for Perioperative Care and Patient Information Forum.

Phase 1 through 2020/21 developed a draft standard through research and evidence gathering, a multidisciplinary webinar with 110 clinicians and people, and tested through role plays using 8 scenarios across a range of healthcare areas.

Phase 2 used wide consultation with a diverse range of clinicians, patients, and system suppliers to further test and socialise the standard and complete the development.

- An online survey on the proposed SDM information standard.
    - 498 responses: 32% doctors, 25% people and carers, with a good spread across health disciplines including allied health professionals and nurses, plus academics, charity workers, administrators and IT professionals comprising the rest of those who responded.

[1] National Health Service Act 2006 (as amended by the health and Social Care Act 2012) sections 14U/13H 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.'

- 89% of responses from people who lived or worked in England, 8% from Wales, 6% from Scotland and 3% from Northern Ireland.

- An online consultation for system suppliers and informaticians including a webinar attended by 30 people covering 25 organisations with a mix of system suppliers and informaticians.

1.3 Findings

The consultation broadly confirmed the content of the standard, but also raised a number of important issues.

On the whole 70% to 75% of clinicians replying to six specific questions agreed the standard supported the shared decision making process with the question on the possible balance between the burden and requirement of data collection proving the topic of highest disagreement with 25% disagreeing and 45% agreeing that the standard got the balance correct.

People using services and their carers also responded to six specific questions and on the whole were positive about SDM and the information standard with on average 7% of those responding negatively to the question on how well they felt the standard supported SDM.

Many people left comments to accompany question responses, this varied between 26% and 55% of the people answering each question. These comments fell into three main categories: comments on shared decision making as a policy and process, comments on the enablers and barriers to implementation of SDM information standard and comments on the information standard content.

Findings relating to the overall process of SDM

- The need to support cultural change in the NHS that enables 'balanced' shared decision making between the clinician and the patient. This may include trust building between clinicians and patients and ensuring transparency in all decision making.
- The need to empower and support the patient to gain confidence to actively engage in SDM. Suggestions included where necessary the use of advocacy, peer support and appropriate support tools.
- The importance of clinician training in communication skills especially listening and patience skills, thus enabling the patient to feel heard and an 'equal partner' in the SDM process.
- The importance of patient health literacy in shared decision making and the need to inform and support patients at different levels of literacy. This may mean targeted information and support to differing patient groups.
- Comments on the scope and if further consideration was needed for paediatrics, anaesthetics, end of life, emergency care, and for complex cases where patients had multiple co morbidities and a shared decision may be required across specialties and with more than one clinician.

Findings relating to the implementation of the SDM information standard

- The requirement to ensure enough consultation time is available both for the clinician and person to ensuring an optimum shared decision is reached.
- the need for digital and IT systems to support SDM process and reduce the burden of data collection.
- Informing the patient both before and during the consultation was considered key to shared decision making.

Findings related to the content of the SDM information standard

- Concerns about the need to ensure a balance between data collection and the burden on the clinician.
- The need to look at rationalising certain data items. This included ensuring mandatory data was rationalised and clear and other data were made optional where appropriate.
- Concerns about how shared decision making and thus the information standard would work for people with reduced capacity or special needs.
- Many felt data should be included on family, carers or advocates involved in the shared decision.
- The importance of certain data were highlighted and the inclusion of other data were questioned though many felt the information standard adequately supported the shared decision making process.

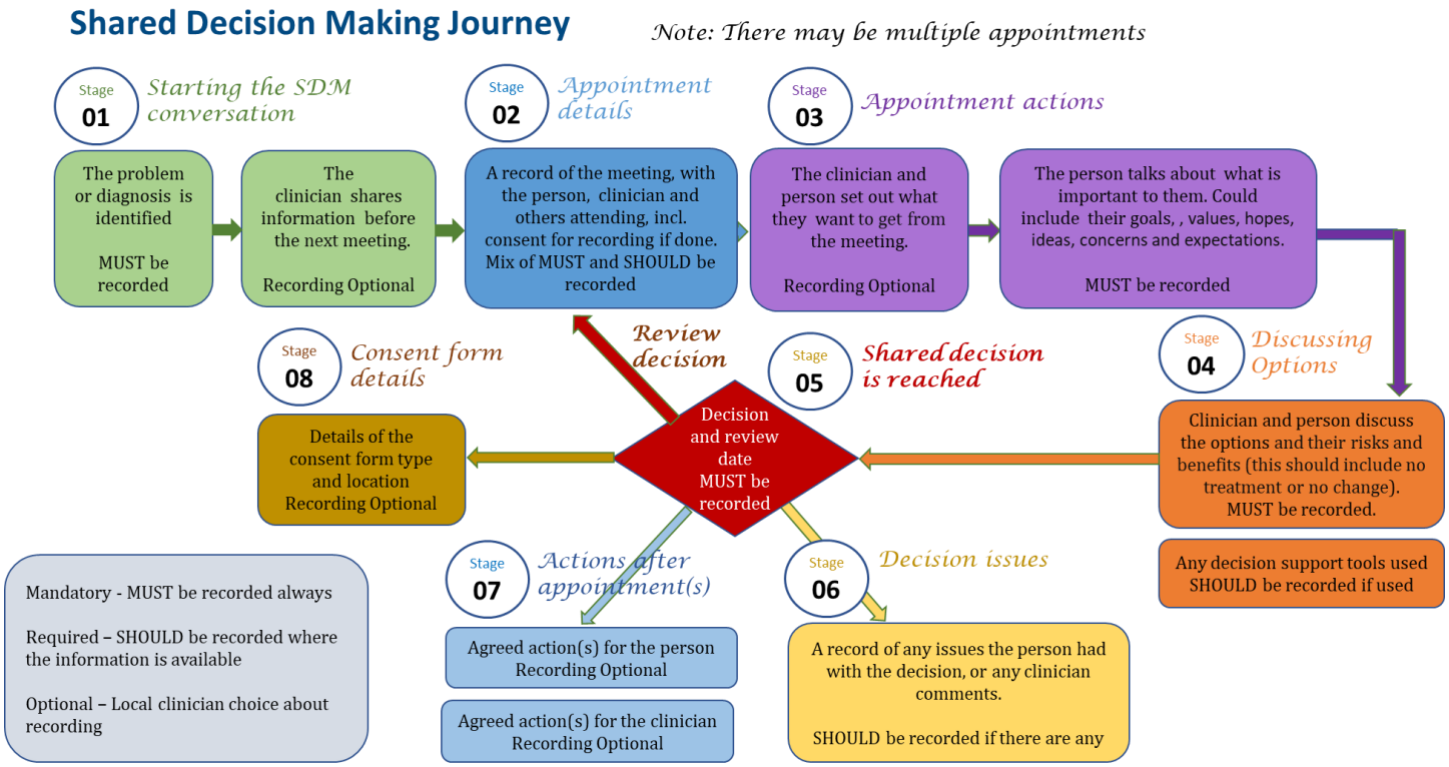
1.4 Conclusions

The survey broadly confirmed the content of the standard, but also raised a number of important issues which were considered further and addressed through:

- Changes to the standard. These are detailed in section 5 and summarised below:
    - New parts were added for “People involved in making the decision” and “Shared decision status”.
    - Some parts were removed in response to questions about their use
    - Some parts were simplified in response to comments.
    - Some additional elements were made mandatory, but keeping these to a minimum to avoid any unnecessary burden.
    - A number of elements were made optional. In many cases these relate to needed stages in the process, but where the recording of information isn’t essential.
- Inclusion in the implementation guidance. For example, to provide guidance for situations where the person lacks capacity, to share a copy of the record with the person after SDM discussions, how the standard caters for multiple appointments and different clinicians.
- Planned follow-up discussions during the endorsement period to check the suitability of the standard or if further additional work is needed for the areas of paediatrics, anaesthesia, emergency care and end of life.
- Recommendations to support implementation of the SDM information standard
- Recommendations to support implementation of SDM overall

1.5 The Standard

The diagram below shows a generic SDM journey with the key stages of the SDM process and a high level view of the information recorded as specified in the standard. This journey will often be over multiple appointments and could be with different clinicians. More detail is given in Section 6.



In order to minimise the burden of recording while specifying an effective SDM record, only the very essential elements have been made mandatory (must always be recorded) (10 elements) and required (should be recorded where available) (29 elements). The other 8 elements would be recorded for best practice, but were not considered to be essential for an effective record and so have been made optional to minimise the burden of recording.

A one-page table with a high-level view of the standard is shown below. The detailed standard is available via the PRSB standards webpage.

Section & Element Name	Conformance	Description
Contacts with professionals		The details of the person's contact with a professional. Repeated for each contact (appointment/meeting)
Date, location, who seen by, responsible professional	M	
Method (e.g. face to face), Use of interpretor	R	
Recording indicator and consent for recording	R	
Other professionals present and people accompanying the person	R	
Problem list	M	A summary of the problems that require investigation or treatment.
Problem	M	The problem that the shared decision is addressing
Shared decision point	M	This is a shared decision point record entry. There may be 0 to many record entries under a section. Each record entry is made up of a number of elements or data items.
Shared decision status	M	The current status of the decision (In progress, Valid, Cancelled).
Pre-discussion information shared	O	A record of the actions taken to prepare the patient to make a shared decision before the encounter where a shared decision was made. This should include a summary of any resources the person was offered to prepare them for the decision making process.
Discussion actions	R	A record of the actions taken to support shared decision making during the encounter.
People involved in making the decision	R	This section records all those who were involved in the shared decision, either with the person or on behalf of the person.This may be where the person does not have mental capacity or the decision is made in the person's best interest as a shared decision. People involved in the decision may include family members, carers, Legal Power of Attorney, Independent Mental Capacity Advocate.
Agenda setting	O	A record of the agenda setting process undertaken to support the shared decision covering both the patient and clinician agendas.
What matters to the person	M	A record to establish what matters to the person in the context of the decision to be made, which may include as appropriate: Person goals, values, hopes, ideas, concerns, expectations.
Options, risks & benefits discussed	M	Record of the options discussed with risks and benefits. Where relevant the option to 'take no further action' at this time or to 'do nothing' should be included in the options discussed.
Decision support tools	R	Record of any decision support tools used.
Recording the decision	M	Details of the decision made with person. This includes details of the decisions made and agreed timescales for review.
Decision Issues	R	A flag to indicate whether the patient held issues, reservations or comments with the decision agreed, or if the clinician had any comments about the decision. If Yes, then issues or comments should be recorded
Information withheld or sharing delayed	R	A record of any information that is withheld or the sharing is delayed, with reasons. This may occur in very exceptional circumstances
Post-discussion actions	O	A record of the actions agreed to support the shared decision after the appointment for both the professional and the person or their carer.
Consent form details	O	Record of type of consent form used and where it is located

1.6 Recommendations

11 recommendations are made in Section 7. The recommendations were grouped in 3 categories:

Recommendations for further development of the standard

2 recommendations to address maternity in a further phase of work and give consideration as to if further work is needed for paediatrics, anaesthesia, emergency care, and end of life.

Recommendations to support implementation of the SDM information standard

7 recommendations around supporting implementation including working with suppliers and providers on pilots across some disciplines to ensure effective implementation to minimise the burden and improve the likelihood of wider adoption.

Recommendations to support implementation of SDM overall

2 recommendations for education and training to support the changes anticipated for both clinicians and people to enable effective shared decision making to occur, and to gather feedback on the effectiveness of the process outside of the SDM discussions.

2 Introduction

2.1 Background and Context

Shared decision making (SDM) is the process by which a patient and a health or care professional consider treatment options and agree the one best suited to meet the aims and goals of the patient.

SDM is recognised as an important strategic theme with widespread interest, support, and activity across a broad and diverse set of stakeholders from policy setters to front line practitioners to those people's interests. It is a central plank of the drive for more personalised care common across the UK and internationally.

The National Health Service Act 2006 (as amended by the health and Social Care Act 2012) sections 14U/13H 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.'

The Montgomery v Lanarkshire Health Board (2015) judgement also sets the context for the SDM.

In England SDM is one of the six pillars of personalised care, a key part of the NHS Long Term Plan.

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.

The PRSB information standard on shared decision making 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 NICE guideline on shared decision making).

3 Methodology and Consultation Approach

The SDM information standard has been developed in 2 phases.

Phase 1 through 2020/21 developed a draft standard through research and evidence gathering, a multidisciplinary webinar and tested through role plays using 8 scenarios across a range of healthcare areas.

Phase 2 used wide consultation with clinicians, patients, and system suppliers to further test and socialise the standard and complete the development.

3.1 Objectives

The overall aim is to support the widespread adoption and use of Shared Decision Making with an information standard which:

- defines what should be recorded in a person's record about a shared decision
- supports on-going discussions and provides an audit trail
- supports good professional practice as outlined in the GMC & NICE guidance on SDM
- supports evidence of compliance with the Montgomery Judgement
- supports sharing of the SDM information with other professionals

The aim of this phase 2 project is to complete development of the standard through:

- wide consultation with professionals and people, engaging beyond those who are supporters of SDM
- consultation with suppliers and informaticians
- endorsement by relevant professional bodies
- approval as a formal information standard by the Data Alliance Partnership Board (DAPB)

3.2 Scope

3.2.1 In Scope

The scope of the standard includes:

- Applicable to all UK nations
- All ages including children
- Alignment with NICE & GMC guidance
- The standard should be developed as far as is reasonably possible to be generic for wide use across all areas of care, and supported by high level use cases for these 8 areas:
    - Elective surgery including orthopaedics
    - Multiple long-term conditions
    - Mental Health
    - Cancer
    - Children
    - Genetic conditions
    - Polypharmacy
    - Gynaecology
- Endorsement by relevant professional bodies
- Approval of an Information Standards Notice (ISN) by the DAPB

3.2.2 Excluded from scope

The following areas are excluded from the scope of the standard:

- Maternity. The standard may work for maternity, but it is believed that this complex area justifies specific additional work and potentially an extended standard.
- Social Care. SDM is defined for clinical uses and the consultation was targeted at healthcare professionals **not** social care professionals. However the SDM principles may work in social care and in the future the standard could potentially be adapted for use in social care.
- Pilot testing – potentially part of a further phase of work
- Implementation support – potentially part of a further phase of work
- The major change programme around adoption of an SDM approach – this work will remain closely connected to related programmes which are dealing with the cultural and behavioural change involved but the work will be undertaken under those programmes and initiatives

3.3 Project Team and Project Board

Phase 1 of the work was sponsored by EIDO Healthcare and the Phase 1 report is published on the PRSB standards SDM page.

Phase 2 of the work was sponsored by the NHSE/I Personalised Care Team. The project team comprised the following core members including clinical and patient leads, supported by the wider PRSB team and with collaboration and participation from the NHSE/I commissioning team and the Centre for Perioperative Care (CPOC).

- Project Manager
- Analyst
- Clinical lead secondary care
- Clinical lead primary care
- Patient lead
- PRSB Membership manager
- PRSB consultation lead

The project board involved NHSE/I as the commissioners, PRSB as the supplier, the clinical and patient leads along with representatives from:

- Centre for Perioperative Care
- Health and Care Wales
- The Patient Information Forum

3.4 Benefits

Benefits of SDM for patients are expected to be:

- improved knowledge and understanding
- more accurate risk perceptions
- greater comfort with decisions
- more participation in decisions and creates a patient-professional partnership

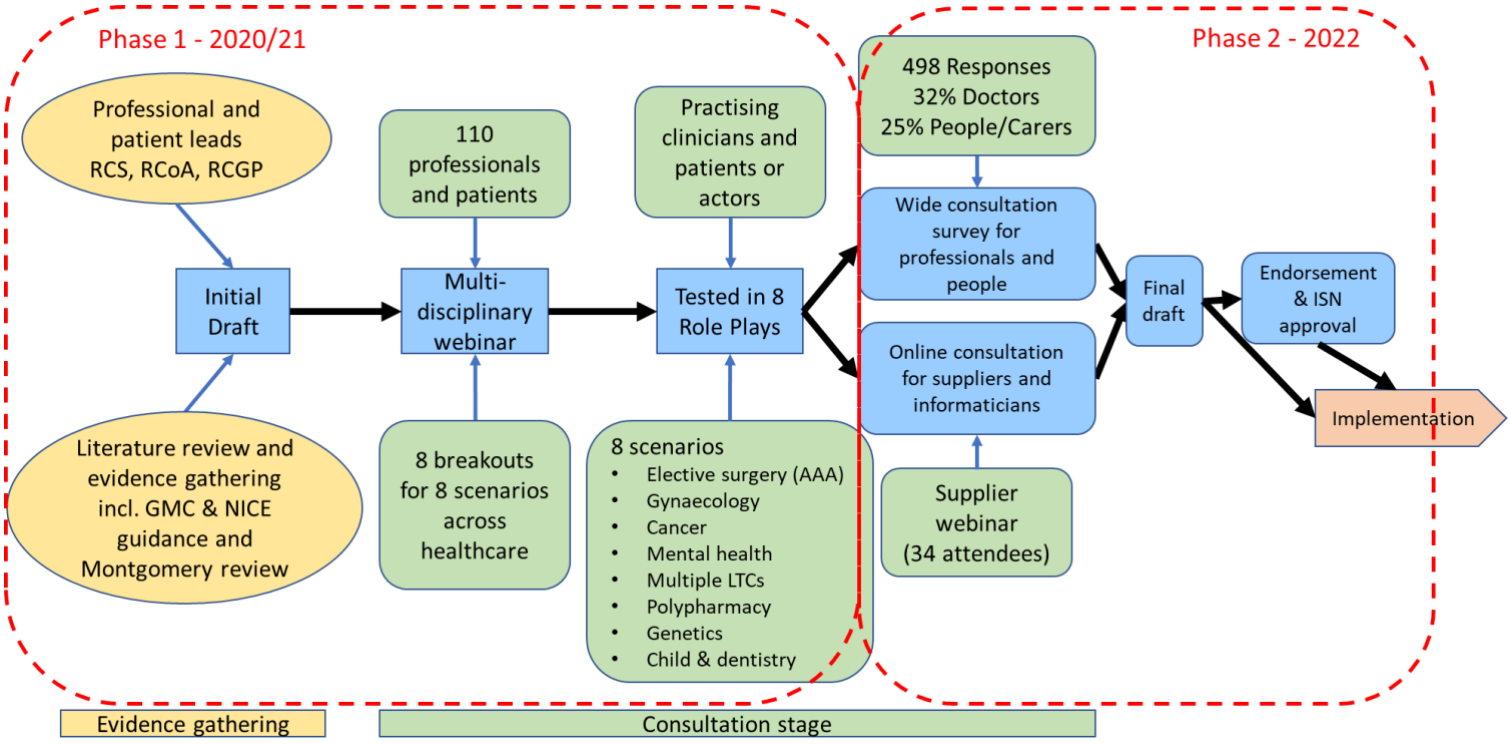
- fewer patients choosing inappropriate surgery
- better treatment adherence
- improved confidence and coping skills
- improved health behaviours
- more appropriate service use
- Improved patient experience

Benefits of SDM for health and care professionals are expected to be:

- improved patient-clinician communication and creates a patient-professional partnership
- reduced decision conflict
- supports tailoring treatment for people with multimorbidity, which might justify deviation from single condition guidance
- achieving both reduced pressures for operational efficiency and the elevated satisfaction that comes with being confident that they are delivering the right care, every time, to every patient (Note; shared decision making has been shown to lead to a reduction in elective surgeries, implying that without it sub-optimal decisions are made)
- potential to reduce medical malpractice litigation
- improved professional wellbeing
- ethical improvement
- sharing of SDM discussions to save repetition by other professionals

3.5 Consultation Approach and Process

The SDM information standard was developed in 2 phases.



Phase 1 (2020/21)

In this phase PRSB developed a draft standard through research and evidence gathering, a multidisciplinary webinar with over 110 clinicians and patients, and tested with role plays with clinicians and either patients or actors using 8 scenarios across a range of healthcare areas (Elective surgery (AAA), gynaecology, cancer, multi long term conditions, poly pharmacy, mental health, children and dentistry & genetics).

Phase 2 (January 2022 – April 2022)

This phase used wide consultation with a diverse range of clinicians, patients, and system suppliers to further test and socialise the standard and complete the development.

- In February 2022 and March 2022 PRSB conducted an online survey on the proposed SDM information standard. This survey asked stakeholders for their views on the SDM standard including questions specifying further requirements if necessary and providing feedback on what stakeholders thought was most important information to record as part of the standard to support shared decision making both for the person and the clinician.
- An online consultation in February 2022 and March 2022 in parallel to the survey where the full detail of the draft standard was made available to IT suppliers, informatic and digital specialists. It included a webinar in March 2022 with the purpose of informing suppliers of the consultation and allowing them the opportunity to pose questions or comment on the technical detail of the standard.
- Reviews with the project working group and other one to one email or discussions with key stakeholders ongoing throughout this phase, ensuring a broad church of opinions were sought and included in the development of the standard.
- In parallel PRSB worked with NHS Digital to verify the terminology used and to review SNOMED reference sets to identify where existing codes could be used or new codes could be requested.
- A Clinical Safety Case was developed in parallel with the national consultation.

4 Consultation Findings

4.1 Consultation Survey

A survey was conducted for 4 weeks through February and March 2022. It was aimed at all clinicians/professionals who could be having SDM discussions, people (patients or potential patients or service users) and other key stakeholders. It was widely publicised, based on a detailed comms plan, through PRSB's members and networks, a wide range of newsletters, forums and networks and social media. The following sections provides an overview of the survey and findings. A full survey report is available in Appendix 1.

4.1.1 Overview of Who Completed the survey

In total there were 498 responses to the online survey on the SDM information standard, with 89% of responses from people who lived or worked in England, 8% from Wales, 6% from Scotland and 3% from Northern Ireland. Some people lived in one country and worked in another.

A further breakdown of the role of responders showed the majority at 32% were doctors, 25% people using services and their carers, allied professionals, nurses other clinicians , academics, charity workers, administrators and IT professionals comprising the rest of those who responded.

41% of those responding worked in secondary care, 17% in primary care, 13% in community services and 12% in tertiary care.

4.1.2 Summary of Responses by Category

People completing the survey were asked to respond to a series of 22 questions some of which were directed at clinicians and some directed at people using health services. Everyone completing the survey were asked how important they felt it was to record each data sections of the standard along the SDM pathway.

On the whole 70% to 75% of clinicians replying to six specific questions agreed the standard supported the shared decision making process with the question on the possible balance between the burden and requirement of data collection proving the topic of highest disagreement with 25% disagreeing and 45% agreeing that the standard got the balance correct.

People using services and their carers also responded to six specific questions and on the whole were positive about SDM and the information standard with on average 7% of those responding negatively to the question on how well they felt the standard supported SDM.

Many people left comments to accompany question responses, this varied between 26% and 55% of the people answering each question. These comments fell into three main categories: comments on shared decision making as a policy and process, comments on the enablers and barriers to implementation of SDM and comments on the information standard content.

4.1.3 Summary of Findings

The main findings from the consultation are shown below under 3 headings

Findings relating to the overall process of SDM

Many responders to the online survey pointed toward the necessity to support cultural change in the NHS that enables 'balanced' shared decision making between the clinician and the patient. This may include trust building between clinicians and patients and ensuring transparency in all decision making.

> "The structure diagram looks a good descriptive ideal, not sure we are there yet"

There was considerable feedback on the need to empower and support the patient in gaining confidence to actively engage in SDM. Suggestions included where necessary, the use of advocacy, peer support and appropriate support tools

> "In discussions currently there is a power imbalance and people like me as a patient or my son with a learning disability with no voice at all are quite disempowered. It's stressful going to appointments and we can forget things or because we are unwell not be able to get our point of view across. There is also bias in discussions that I experience all the time e.g. about women's health, health inequalities, diagnostic overshadowing and discrimination for people with a learning disability and who are autistic like my son, or about where I come from and incorrect assumptions relating to that (e.g. very recently told surprised i don't drink alcohol as many Irish people do). The experience overall is not always positive and these are asking for a new approach that's not currently happening at all"

Many survey responses from persons using health services pointed to the importance of clinician training in communication skills especially listening and patience skills, thus ensuring the patient feels heard and is an 'equal partner' in the SDM process

> "It depends on how clinician gives & is responsive to receiving information -requires time and good communication skills"

There was recognition of the importance of patient health literacy in shared decision making and the need to inform and support patients at different levels of literacy. This may include targeted information and targeted support to differing patient groups.

> "Some of the words & language used may not be clear to every member of society so prepare to be adaptable within every setting, to be truly 'person' centered."

Feedback from the survey included questions and comments on the scope of SDM. This included where SDM may need further consideration including in paediatrics, anaesthetics, end of life and emergency care. There were also comments and questions on how shared decision making would work for complex cases where patients had multiple co morbidities and a shared decision may be required across specialties and with more than one clinician.

> "One size doesn't fit all but in the majority of treatment following an outpatient consultation then yes but as an emergency admission there are additional challenges."

Findings relating to the implementation of the SDM information standard

One of the main themes from the survey feedback included the requirement to ensure enough consultation time is available both for the clinician and person to ensuring an optimum shared decision is reached. Acknowledging that consultation time was somewhat dependent on the complexity of the problem under discussion many pointed to the need to pause the process for reflection (if required) or in some instances the need for more than one consultation.

> "The patient may need to take more time to consider their options and talk to wider family members. This could be for reassurance / to check their understanding of the options or for cultural reasons."

There was wide spread acknowledgement of the need for digital and IT systems to support SDM process and reduce the burden of data collection. Suggestions included automation of data collection processes, use of templates, standard coding and need for interoperability between IT systems thus enabling data sharing across services.

> "Agree, provided data capture was simple as possible and entries pre-populated based on previous/existing data where available. This standard should avoid double-keying to minimise time burden on clinicians. This could be enhanced by utilising pre-configured drop-down options where relevant"

Informing the patient both before and during the consultation was considered key to shared decision making. Many felt this should include two-way information sharing where the patient may complete an 'About Me' form, or have the opportunity to pose queries to the clinician. Other felt this was dependent on the information shared by the clinician and should include information on how shared decision making works, decision support tools, and information on reducing risk.

> "There needs to be more focus on ways of allowing the patient to record/submit what they want to get out of a meeting before it starts".

> "Yes - but information must be tailored at the right level for the patient. Different patients will want different levels of detail"

Findings related to the content of the SDM information standard

Many clinicians completing the survey raised concerns about the need to ensure a balance between data collection and the burden on the clinician. There was concern about too much process detracting from the purpose of the shared decision consultation.

> "This is the aspect which concerns me as a clinician - there seem to be many steps in the process and recording required for each. I don't disagree with the step content but the time involved is a concern"

Responders to the survey raised the need to look at rationalising certain data items. This included ensuring mandatory data was rationalised and clear and other data were made optional where appropriate

> "Any goals, values, hopes, ideas, concerns and ALSO risk perceptions that are relevant to the decision being made must be recorded so that other professionals involved in the person's care are aware of the person's rationale and perspective with regard to the decision made and also so that the person can verify that his rationale and perspective has been understood by the clinician".

Many raised concerns about how shared decision making and thus the information standard would work for people with reduced capacity or special needs.

> "what about those making decisions on behalf on someone else - or assessments of capacity?"

Many also felt data should be included on family, carers or advocates involved in the shared decision.

> "The patient may need to take more time to consider their options and talk to wider family members. This could be for reassurance / to check their understanding of the options or for cultural reasons."

The importance of certain data were highlighted and the inclusion of other data were questioned though many felt the information standard adequately supported the shared decision making process"

> "No. I think the standard looks good but it will be -as always - about how it is applied. Hopefully there will be training around how to use it, and sufficient time given for conversations, but we know that in reality that is not always the case"

4.2 System suppliers and informaticians webinar and online consultation

An online consultation with a webinar for system suppliers and informaticians was run for 3 weeks through February and March 2022 with a webinar on 8 March. The webinar was attended by 30 people (excluding the PRSB and NHSE/I team) covering 25 organisations with a mix of system suppliers and informaticians from the NHS and private organisations, and was primarily to raise awareness with this community of the survey and online consultation.

There was good discussion at the webinar, but no specific feedback on the draft standard. There were no significant responses to the online consultation.

Appendix 2 shows the attendees.

5 Conclusions

The survey broadly confirmed the content of the standard, but also raised a number of important issues which were considered further and addressed through;

- changes to the standard
- implementation guidance
- planned follow-up discussions during the endorsement period to check the suitability of the standard or if further additional work is needed for the following areas:
    - Psychological services (low response from psychological professionals)
    - Paediatric services (concerns raised about complexities for children)
    - Anaesthesia (concerns raised about link between anaesthesia SDM and the main options SDM)
    - Emergency care
    - End of life
- recommendations to support implementation of the SDM information standard
- recommendations to support implementation of SDM overall

5.1 Changes to the standard

After consideration by the project team to the survey responses and comments the following changes were made to the standard.

Added a cluster for “People involved in making the decision” to specifically record other people involved in the decision and their relationship to the person. This is different to others present which is recorded in the “Contacts with professionals” section.

Added “Shared decision status” to make the status of the SDM decision really clear in situations where the process is still in progress, including if the person is taking time for consideration or reflection, or there has been a change in the decision. The options for status are; active (in progress), valid (complete) or cancelled.

Removed “Person understanding of their condition or diagnosis”. If a person is assessed to lack capacity, then that will be recorded elsewhere in the record and in the SDM record “People involved in the decision” are recorded and a note can be made that this was a “best interests” decision. If the person has capacity but doesn’t want to understand or engage, then it can’t be a shared decision.

Removed both clinician and patient decision satisfaction from the standard. These will be recommended to be done elsewhere outside of the actual SDM process.

Simplified the “Evaluating the decision” section to become “Decision Issues” and record if the person had any issues or reservations about the decision and any clinician comments.

Removed Agenda setting and Persons goals, values, ideas, concerns and expectations from being in a cluster together, and renamed “Persons goals, values, ideas, concerns and expectations” to “What matters to the person” (Note the description remains the same covering all of goals, values, ideas, concerns and expectations).

6 further elements of the standard were made mandatory in addition to 4 elements which were already mandatory. This is to ensure that the elements which are essential for an effective SDM record are recorded, and that only essential elements are made mandatory. The full list of mandatory elements is:

- Problem (the problem which is the subject of the SDM discussion)
- Date & time of contacts with clinicians, seen by and responsible professional

- Shared decision status (active, valid (complete), cancelled)
- What matters to the person (their goals, values, hopes, ideas, concerns, expectations)
- Options, Risks and Benefits
- Decision entry

7 elements of the standard were made optional in response to concerns about the burden and time needed for recording SDM conversations. While the process will mostly require these items to be performed, their recording wasn't considered essential for an effective record. This means that local judgement can be applied about the use these elements. In total there are 8 optional elements which are:

- Pre-appointment information shared (1 element)
- Agenda setting (2 elements)
- Post appointment actions (2 elements)
- Consent form details (3 elements) – Consent, when required, will be recorded separately from SDM, this just notes what form was used and its location

5.2 Clarifications or issues addressed through implementation guidance

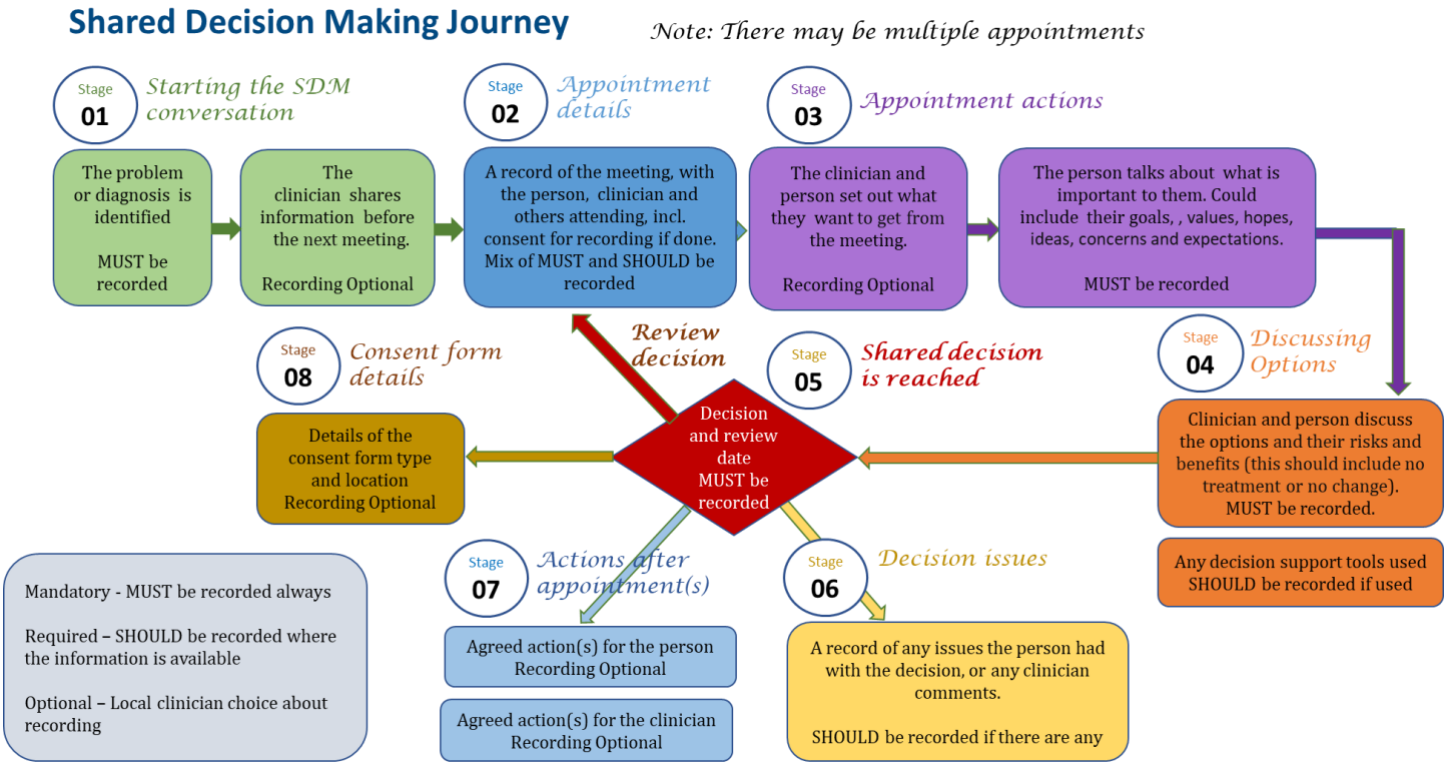
A number of comments and suggestions for changes or additions to the standard from the survey have been addressed through the implementation guidance. A summary of these follows:

- Recording in situations where the person is assessed to lack capacity.
- Recording in situations where the person has capacity but doesn't want to understand or engage in their condition or the shared decision making process.
- Clarification on the purpose and use of the cluster for evaluating the decision which was also simplified.
- The "What matters to the person" (previously named "Person goals, values, hopes, ideas, concerns, expectations") should be recorded in their own words as far as possible.
- The implementation of the standard should work in a way which includes prompts to support the clinician through the process using be used. This is included in the business rules for implementors.
- Intended outcomes can be recorded as part of the risks and benefits of the options.
- The standard was developed to allow for multiple appointments with multiple different clinicians and to allow for pauses for consideration and reflection. This is clarified in the implementation guidance and the general notes about the standard, and in examples to be published alongside the standard.
- The person should be given a copy of the record after an SDM discussion so they can review the record and can address any concerns with the clinician(s). This is also specified in the business rules for implementors as something which must be possible for the system to produce in human readable format. The suggestion of signatures to verify the record and conclusions was considered but not included at this stage to avoid extra burden in the recording process but is something system suppliers could include.
- Clarification on how the added "Shared decision status" element is used when a patient changes the decision.
- Post appointment actions for the professional and the person should include timescales when this is appropriate and within the control of the professional and person.

6 The SDM Information Standard

The standard is evidence based and in particular draws on the NICE guideline and GMC guidance.

The generic SDM journey below shows key stages of the SDM process and a high level view of the information recorded as specified in the standard. This journey will often be over multiple appointments and could be with different clinicians. The standard is designed for this and also to allow for pauses in the process for consideration and reflection and for changes of the decision.



The standard has a total of 47 elements;

- 10 elements are mandatory – i.e. must be recorded in the record
- 29 elements are required – i.e. should be recorded where the information is available
- 8 elements are optional – i.e. local choice about recording the information

The number of mandatory elements has been kept to a minimum and are the elements which are essential and always part of an SDM record. Some of the required items will only be needed in very rare circumstances, for example if information is withheld from the person, but then it is very important that this information is recorded. Most of the optional items would be recorded for best practice but were not considered to be essential for an effective record and so have been made optional to try and minimise the burden of recording SDM in the current period when health services are under intense pressure.

The table below shows a high-level view of the standard. The detailed standard is referenced in Appendix 4.

Section & Element Name	Conformance	Description
Contacts with professionals		The details of the person's contact with a professional. Repeated for each contact (appointment/meeting)
Date, location, who seen by, responsible professional	M	
Method (e.g. face to face), Use of interpretor	R	
Recording indicator and consent for recording	R	
Other professionals present and people accompanying the person	R	
Problem list	M	A summary of the problems that require investigation or treatment.
Problem	M	The problem that the shared decision is addressing
Shared decision point	M	This is a shared decision point record entry. There may be 0 to many record entries under a section. Each record entry is made up of a number of elements or data items.
Shared decision status	M	The current status of the decision (In progress, Valid, Cancelled).
Pre-discussion information shared	O	A record of the actions taken to prepare the patient to make a shared decision before the encounter where a shared decision was made. This should include a summary of any resources the person was offered to prepare them for the decision making process.
Discussion actions	R	A record of the actions taken to support shared decision making during the encounter.
People involved in making the decision	R	This section records all those who were involved in the shared decision, either with the person or on behalf of the person.This may be where the person does not have mental capacity or the decision is made in the person's best interest as a shared decision. People involved in the decision may include family members, carers, Legal Power of Attorney, Independent Mental Capacity Advocate.
Agenda setting	O	A record of the agenda setting process undertaken to support the shared decision covering both the patient and clinician agendas.
What matters to the person	M	A record to establish what matters to the person in the context of the decision to be made, which may include as appropriate: Person goals, values, hopes, ideas, concerns, expectations.
Options, risks & benefits discussed	M	Record of the options discussed with risks and benefits. Where relevant the option to 'take no further action' at this time or to 'do nothing' should be included in the options discussed.
Decision support tools	R	Record of any decision support tools used.
Recording the decision	M	Details of the decision made with person. This includes details of the decisions made and agreed timescales for review.
Decision Issues	R	A flag to indicate whether the patient held issues, reservations or comments with the decision agreed, or if the clinician had any comments about the decision. If Yes, then issues or comments should be recorded
Information withheld or sharing delayed	R	A record of any information that is withheld or the sharing is delayed, with reasons. This may occur in very exceptional circumstances
Post-discussion actions	O	A record of the actions agreed to support the shared decision after the appointment for both the professional and the person or their carer.
Consent form details	O	Record of type of consent form used and where it is located

7 Recommendations

7.1 Recommendations for further development of the standard

1. Maternity should be addressed in a future phase of work to consider what additions or changes are required to make the standard suitable for use in maternity.
2. Discussions, which are planned to be held in parallel to the endorsement process, should be held with relevant professional bodies and stakeholders to consider if the standard is suitable for the following areas after concerns were raised in the consultation, or whether further work is required:
    a. Paediatrics
    b. Anaesthesia
    c. Emergency care
    d. End of life

7.2 Recommendations to support implementation of the SDM information standard

3. Simulation work is carried out to ensure the detail of the standard is ready for implementation and to work with a group of clinicians to consider ideas for how SDM information should be presented and captured.
4. Technical FHIR specifications are developed to support interoperable transfer of SDM information between systems and professionals.
5. The PRSB Core Information Standard (CIS) should be updated to include SDM so that shared care records can be used to share SDM decisions to all those providing care to the person and to the person themselves.
6. Pilot testing of the standard should be done in several different settings or disciplines to ensure the standard is usable in practice, with attention given to paediatrics (parents/capacity), anaesthetics, end of life and urgent care.
7. Work with suppliers and providers during the pilots to support effective implementation and to minimise the burden, including automating processes and developing templates for data capture. The consultation feedback noted that good systems could help reduce the burden of recording. Ensuring this is addressed and developed with the pilot suppliers and providers and is then published and shared for wider implementation will be vital to achieving effective roll out at a time when health services are under intense pressure.
8. Feedback from pilots and early implementors should be used to update the standard and supporting materials.
9. Evaluation of the benefits of the SDM information standard should be assessed from the pilots and used to inform implementation support and tools and develop case studies to share the benefits and learning to those adopting SDM.

7.3 Recommendations to support implementation of SDM overall

10. Comprehensive implementation support should be put in place to cover all aspects of the changes anticipated for implementing SDM and the information standard.

    This should include education and training on SDM for clinicians and work with people so they can take an active role in SDM and their healthcare.
11. Satisfaction with the SDM process and record of the discussion should be assessed separately from the SDM process to understand how well it is working for both people and clinicians and enable feedback to those implementing SDM.

8 Appendices

8.1 Appendix 1 – Survey Report

The survey report is available on the PRSB webpage.

8.2 Appendix 2 – Supplier and Informatician webinar attendance

Job Title	Company Name
Strategic Support Consultant	Bramble Hub
Clinical Decision Systems eproduct manager	Elsevier
Head of New Initiatives	Consultant Connect
Product Sales Manager - Clinical Decision Support	Elsevier
Managing Director	Doctrin
Intern	Concentric Health
Student	Concentric Health
Chief Nursing Information officer	ESNEFT
Business Development Manager	Healum
Transformation Programme Director	Q5
Bid Manager	Holt Doctors
Commercial Executive	EMIS Health
Consultant Surgeon	Worcestershire Acute Hospitals NHS Trust
CEO	Vital Hub UK
Business Development Manager	Bridgehead Software
Product Director of Patient Management	System C Healthcare
Business Development Manager	RioMed
My Medical Record Programme Manager	University Hospital Southampton NHS Foundation Trust
OpusVL Founder	OpusVL
Chair	Virtually Healthcare
Business Development Lead	Cinapsis
Business Development Manager	Cinapsis
Account Director	Definition Health
Solution Owner - Mental Health & Social Care	Graphnet
Business Coordinator, Choice, PCSP and SDM	NHS England and Improvement

Product Director	Graphnethealth
CEO & Co-Founder	DigiBete
Systems Director	Porism Limited
Head of Partnerships	PRSB
Analyst	PRSB
Head Of Policy (Personalised Care - SDM and PCSP)	NHS England and Improvement
Informatics Director	X-Lab
Senior Programme manager	PRSB
Head of Marketing & Communications	PRSB
Shared Decision Making delivery lead	NHS England and Improvement
Business Analyst	Graphnet Health
Head of Projects and Product	Healthcare Gateway
Membership and Stakeholder Manager	PRSB
CCIO & consultant vascular surgeon	MSE FT (PRSB Clinical Lead)

8.3 Appendix 3 - Clinical Safety Case and Hazard Log

The clinical safety case and hazard log are available on the PRSB standards webpage.

8.4 Appendix 4 – The SDM information standard

The SDM information standard is available via the PRSB standards webpages.