Professional Record Standards Body

Better records for better care

Diabetes implementation support consultation

FINAL REPORT V1.0

NOVEMBER 2022

Document Management

Revision History

Version	Date	Summary of Changes
0.1	07/11/22	First draft created.
0.2	16/11/22	Updated following feedback from project team
0.3	17/11/22	Updated following further feedback from project team
0.4	05/12/22	Updated following feedback from NHSE
0.5	14/08/23	Updated recommendations removing proposed owner of recommendations
1.0	13/11/24	Uplifted for publication

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Glossary of Terms

Term / Abbreviation	What it stands for
API	Application Programming Interface
CCG	Clinical Commissioning Group (Superseded by ICBs in England, July 2022)
CDA	Clinical Data Architecture
CGM	Continuous Glucose Monitoring
CSV	Comma-Separated Values
DAPB	Data Alliance Partnership Board
DHSC	Department of Health and Social Care
DPIA	Data Protection Impact Assessment
EHCH	Enhanced Health in Care Homes
EHR/ EPR	Electronic Health Record/ Electronic Patient Record
EMIS	Egton Medical Information Systems
FHIR	Fast Healthcare Interoperability Resources
FXY	F = Finding, X = Theme number, Y = Finding letter
GIRFT	Getting It Right First Time
GP Connect	General Practice Connect
HL7v2	Health Level Seven International Version 2
ICB	Integrated Care Board
ICS	Integrated Care System
IGT	Impaired Glucose Tolerance
IPS	International Patient Summary
ISN	Information Standards Notice
ISO	International Organization for Standardization
LTC	Long-term Condition
MDT	Multidisciplinary team
MHRA	Medicines and Healthcare products Regulatory Agency
NICE	National Institute for Health and Care Excellence
NRL	National Record Locator
PCSP	Personalised Care and Support Plan
PDF	Portable Document Format
RXY	R = Recommendation, X = Theme number, Y = Recommendation letter

SNOMED CT	Systematised Nomenclature of Medicine Clinical Terms
TPP	The Phoenix Partnership
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
UI	User Interface

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 England as the commissioning body.

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

Contents

1 Executive Summary

An estimated 5.3 million people in the UK will be living with diabetes by 2025, which when uncontrolled leads to serious metabolic, vascular and neuropathic health complications. Most people with diabetes self-manage their condition, which involves self-monitoring of blood glucose (fingerstick testing) or increasingly using flash or continuous glucose monitoring devices. People on insulin (mostly type 1 diabetes) use multiple daily injections along with meals but an increasing number use connected insulin pens, insulin pumps, and hybrid closed loop systems.

The Professional Record Standards Body (PRSB) was commissioned by NHS England (NHSE) to develop the diabetes record and self-management information standards to address respectively:

- The difficulty in sharing digitally a person's diabetes information across different health and social care settings and teams, risking harm.
- Difficulties of digitally sharing self-managed diabetes data from devices and apps with clinicians who, if they have access, often must view data from different devices across multiple platforms.

Following draft publication for endorsement, this follow-on phase of work was to start to address the requirement to support the implementation of these standards through:

- mapping the PRSB diabetes standard to Fast Healthcare Interoperability Resources (FHIR) (in collaboration with NHS Digital)
- identifying what messaging standards and associated guidance are required to support standardised sharing of data
- supporting the requests for new Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT) codes
- defining an approach for testing and piloting the standards
- supporting the application for Information Standards Notice (ISN) status for the standards

This work will ultimately benefit people with diabetes and professionals as it will help with the implementation and piloting of the diabetes standards.

This report covers the findings of a short consultation into:

- How suppliers and Integrated Care Systems (ICSs) will use the standards in the short, medium and long term.
- When and what technical artefacts and guidance are needed to support the standardised sharing of diabetes information.

The implementation support consultation explored the following themes:

- Theme 1: Scenarios where information sharing breaks down (for piloting the diabetes standards)
- Theme 2: Approaches to sharing data now and in the future
- Theme 3: Current and future use of Application Programming Interfaces (APIs), standards and interfaces
- Theme 4: Technical guidance or artefacts to support implementation
- Theme 5: Helping to drive uptake and adoption of the diabetes standards

These were explored at three 1-hour semi-structured interviews held with system suppliers during August 2022 and a follow-up online workshop in September with suppliers, interoperability experts and Integrated Care Board (ICB) staff.

The key consultation **findings** are summarised in the table below:

No.	Finding	Corresponding recommendation

Theme 1: Scenarios where information sharing breaks down (for piloting the diabetes standards)		

F1A	• Stakeholders supported testing of the following scenarios for sharing of data between primary, community and secondary care (including General Practice (GP) to GP) during piloting of the diabetes standards:
	  ○ Sharing of a care plan
	  ○ Sharing self-management data (e.g. blood pressure, weight, glucose levels (from continuous glucose monitors (CGM)), insulin administration (insulin pumps, connected pens))
	  ○ Sharing of test results (identified as a major issue)
		R1A

F1B	• Self-management data including food and nutrient intake (e.g., carbohydrates and calories) needs to be shared with health care professionals to support diabetes treatment/ management.	R1B
F1C	• It is important to ensure consistency of care plans used in care homes and the multidisciplinary team (MDT) in line with NHSE's enhanced health in care homes requirements.	R1C
Theme 2: Approaches to sharing data now and in the future		
F2A	• **Now**: Shared Care Record at ICS or local collaborative is a priority for all suppliers but some of these might not be granular enough. • Inability to retrieve eye screening data (grading result) was also identified as a significant gap for record systems.	R2A/ R2C
F2B	• **Moving forwards**: People with diabetes should have access to their interoperable diabetes record including via person held apps allowing their record to travel with them (this would help with information sharing where the person receives unplanned treatment across borders/ boundaries e.g. person with diabetes from England uses their app to share extracts from their diabetes record with healthcare professionals in Scotland).	R2B/ R2C
Theme 3: Current and future use of APIs, standards and interfaces		
F3A	• A standard using FHIR (facilitating a strategic move towards a common set of FHIR profiles) would be useful in the medium term but there is a pragmatic need to support other interfaces now. • Being clear about the data items (and codes) required is the priority as suppliers can work out how to share.	R3A
F3B	• It is important in the medium-term to explore use of existing interoperability standards to develop information sharing aligned to the PRSB standards. • Linking with the International Patient Summary (IPS) (which allows sharing of an electronic health record extract containing essential healthcare information about the subject of record for unplanned care across international borders) could be considered.	R2B/ R3B
F3C	• Stakeholders held a range of views with some wanting to move as soon as possible to nationally mandated FHIR sharing and some wanting pragmatic use of existing interoperability approaches, allowing the market to make the decisions on how the information is shared. • Some held that short term implementations based on Health Level Seven International Version 2 (HL7v2) might be "wasted work" as the direction of travel is use of FHIR.	R3C
Theme 4: Technical guidance or artefacts to support implementation		

F4A	• Stakeholders thought NHSE should provide each supplier with a set of clear and unambiguous requirements and expectations to ensure consistent interpretation by suppliers. • There is a need for suppliers implementing the diabetes standards to know what is a **must have** and what is a **should have** (and when a **should have** will become a **must have**).	R4A
F4B	• Suppliers need to be aware of changes to SNOMED CT codes and **coding requirements** (what codes to use to transfer data) so that they can update their systems to support new codes and coding requirements.	R4B
F4C	• Standardised high level summary views should be available for professionals to enable efficient care but also standardised granular data views for use by specialists should also be developed. It would be useful to test views of the data in piloting (e.g., for GP versus diabetes specialist) as GPs and diabetologists have different information requirements e.g., glucose/ insulin data from self-management devices (in terms of the resolution/ granularity of data needed). It would be helpful to have Royal College approved content for summary screens with flexibility for customers to modify the user interface (UI) as they would like to.	R4C
F4D	• The pulling of data from care home records should be explored so that care homes can manage, record and share key information about residents with diabetes with MDTs, which would support monitoring. • Standard codes for unplanned admissions should be built into software used by care homes to facilitate analysis by ICSs to inform provision of services.	R4D
Theme 5: Helping to drive uptake and adoption of the diabetes standards		
F5A	• Frameworks and contracts should mandate that all data collected and displayed must be accessible for use in software for NHS systems (or third-party systems in use in the NHS) e.g. where calculated summary glucose and insulin dosing metrics are exposed for sharing, the system **MUST** make the underlying data used for the calculation available for consumption by these other systems.	R5A
F5B	• Frameworks and contracts should recommend that the data is shared in conformance with the diabetes standards (as defined in the Information Standards Notice (ISN).	R5B
F5C	• Frameworks and contracts should mandate that there are data sharing agreements in place between suppliers – this would help avoid the situation where a system stops sharing data because they have partnered with a different supplier or exited the UK market etc.	R5C
F5D	• Example use cases with benefits should be developed/ provided to support implementation.	R5D
F5E	• It should be explored whether NHS Digital or Medicines and Healthcare products Regulatory Agency (MHRA) could store validated responses to data protection questionnaire providing access to Trusts and suppliers when needed (see Data sharing from point of care systems report).	R5E

The consultation **recommendations** are summarised in the table below:

No.	Recommendation

R1A	Consideration **should** be given to piloting the following candidate scenarios: • Sharing a care plan • Sharing self-management data • Sharing investigation (pathology test) results
R1B	PRSB **should** demonstrate how the diabetes record information standard supports recording of food and nutrient intake.
R1C	The care plan used by the care home and MDT **should** be the same. The sections (Care and support plan, Contingency plan and Additional support plan) of the diabetes record information standard **should** be used to structure care plans in both care homes and the MDT to ensure consistency and interoperability.
R2A	**Now:** Data sharing via shared care record systems including national eye screening grading result data **should** be encouraged and explored. The data shared **must** be of a sufficient granularity to allow for effective professional decision making.
R2B	**Moving forwards**: People with diabetes **should** have access to their interoperable diabetes record, which may include via person held apps This would allow them to bring their record with them when traveling across borders for unplanned treatment.
R2C	A national architecture for sharing diabetes data with a roadmap for achieving this **should** be developed and maintained to enable sharing of a person's diabetes record within the UK including across local and national borders/ boundaries.
R3A	**Short-term:** Where information is already being shared, continue to do so.
R3B	**Medium-term:** Use existing interoperability specifications and infrastructure, modified where necessary to align with PRSB standards.
R3C	**Long-term:** Converge on SNOMED CT and FHIR (with connectors for legacy systems) in line with the strategic direction of travel for sharing health information in England.
R4A	Guidance to support implementation **should** be produced that clearly articulates the data items to be supported (must/should haves)
R4B	There **should** be central development and maintenance of a SNOMED CT guide for suppliers defining concept use (in PRSB diabetes standards implementation guidance).
R4C	There **should** be approved content for a diabetes summary screen (not UI design). This could be explored as candidate examples (e.g. person facing, general practitioner and diabetes specialist summary screens) in the piloting phase of the diabetes standards work. If validated these **could** be standardised and endorsement/ ownership sought from professional bodies in a subsequent phase.
R4D	Exploration of information sharing from care home records **should** be done including profiles of the diabetes record information standard for care home recorded data. .
$R5A_1$	Frameworks and contracts **should** mandate that all data collected and displayed must be accessible for use in software for NHS systems (or third-party systems in use in the NHS) as appropriate. This means that where calculated summary glucose and insulin dosing metrics are exposed for sharing, the system **MUST** also make the underlying data used for the calculation available for consumption by these other systems.
$R5A_2$	It **should** be investigated how to incorporate the diabetes standards as a requirement for access to purchasing frameworks for systems (including software and devices).
R5B	Frameworks and contracts **should** mandate or recommend as appropriate that information sharing is aligned to the diabetes standards (as defined in the Information Standards Notice (ISN).

R5C	Investigate whether it is possible to mandate in frameworks and contracts that there are data sharing agreements in place between suppliers to facilitate the person with diabetes having access to and the ability to share their data in human and machine-readable forms.
R5D	Example use cases with benefits **should** be developed/ provided to support implementation.
$R5E_1$	It **should** be explored whether a standardised data protection questionnaire (Data Protection Impact Assessment (DPIA)), see Data sharing from point of care systems report) could be developed for England.
$R5E_2$	It **should** be investigated how DPIA responses could be stored to reduce duplication across organisations and providing access to Trusts and suppliers when needed (see Data sharing from point of care systems report).

In conclusion, there was good agreement from stakeholders, including diabetes systems suppliers, interoperability experts and others around scenarios for testing the diabetes standards and the technical artefacts and guidance needed to support their delivery; including products on implementation, conformance and coding/ terminology requirements and clinically endorsed summary screens of the diabetes record.

This work recognised shared care records as a priority now for enabling information sharing, with pragmatic use of a variety of standards, APIs and interfaces in the near term, and a strategic direction of travel towards FHIR messaging in the medium to long term.

The promise of utilising interoperable patient held information for cross-border information exchange in future was considered. It is suggested that it is investigated that whether it is possible to include in procurement frameworks that:

- all data collected and displayed must be accessible for use in NHS and other software/ systems as appropriate (in use within the NHS estate)
- there should be data sharing agreements between device and systems suppliers
- recommendation that data is shared in conformance with the ISN.

We now need to build on this work in the next phase of focused implementation.

2 Introduction

2.1 Background and Context

The number of people living with diabetes in the UK is estimated at 4.8 million and is expected to rise to 5.3 million by 2025. Ninety percent of those are living with type 2.[1] Uncontrolled diabetes can lead to serious health complications like heart disease, stroke and kidney failure as well as diabetic eye disease, peripheral nerve damage and diabetic emergencies like ketoacidosis.

As the number of people with diabetes is so large and expected to rise rapidly, the NHS Long term plan (January 2019) sets out that it will accelerate support for people to manage their own health and will roll out the NHS Personalised Care model to reach 2.5 million people by 2023/24. For people newly diagnosed this means structured education and digital self-management support tools. There is also an important role for informal carers such as

[1] Diabetes UK. [Accessed June 2021]

parents of children with diabetes and family members of older people living with diabetes and other long-term conditions.

In the UK, there are approximately 400,000 people currently living with type 1 diabetes, including around 29,000 children, with the number of new diagnoses in children under 5 rising by 5% each year.[2]

In March 2019, NHS England published national arrangements outlining that all patients with type 1 diabetes in England would be offered flash glucose monitors and at least 34% of the type 1 population now have one.[3] In March 2021, NHS England released funding to support the aim that all pregnant women with type 1 diabetes in England will be offered continuous glucose monitoring, helping to improve neonatal outcomes.[4] In March 2022 NICE (National Institute for Health and Care Excellence) recommended wider access to Flash and Continuous Glucose Monitors including some people with type 2 diabetes.[5]

There is a commitment to ensure that 'all hospitals provide access to multidisciplinary footcare teams and diabetes inpatient specialist nursing teams to improve recovery and to reduce lengths of stay and future readmission rates'.

The NICE impact report for diabetes[6] (September 2018) recommends that adults with diabetes should take part in annual care plans to collaboratively agree goals and actions aligned to the nine care processes. It highlights that there is wide variation in whether the care processes are received. The RightCare Pathway sets out that structured care planning should occur collaboratively and immediately after diagnosis and address comorbidities.

The Getting It Right First Time report (GIRFT) into diabetes (November 2020) identified that young people with type 1 diabetes are more likely to be admitted to hospital that other people with type 1, data is collected in different ways and not always reported to the national audit, there is inconsistency in coding in relation to diabetes and almost 40% of patients treated with insulin experience an error during their stay in hospital. In relation to insulin dosing in hospitals the report recommends use of electronic insulin passports, electronic patient records which include information on insulin needs, and electronic prescribing.

The use of electronic insulin passports and digital sharing of other information about a person's diabetes both from the patient to a professional and between professionals as part of a multidisciplinary team requires systems to be able to talk to one another. Information standards provide the structure and content to enable this to happen.

Two key challenges were identified related to digital sharing of information about a person's diabetes:

1. With increased self-management of diabetes (and other long-term conditions) and increasing use of devices and apps (such as Flash Glucose Monitors and Continuous Glucose Monitors (CGMs) to monitor glucose levels) to support self-management, the data generated can be shared with clinicians and used in clinic or during remote consultations. However, there is currently no information standard for self-reported

[2] JDRF. Type 1 diabetes facts and figures [Accessed November 2022]

[3] NHS. 'Glucose monitoring for patients living with diabetes.' [Accessed November 2022]

[4] NHS Supply Chain. 'Continuous glucose monitors available for all pregnant women with type 1 diabetes.' [Accessed November 2022]

[5] Overview | Type 1 diabetes in adults: diagnosis and management | Guidance | NICE, Overview | Diabetes (type 1 and type 2) in children and young people: diagnosis and management | Guidance | NICE, Overview | Type 2 diabetes in adults: management | Guidance | NICE

[6] NICE. NICEimpact diabetes [Accessed November 2022]

data related to diabetes, which means that different devices and apps cannot always share data with clinical systems. This means that healthcare professionals may have to view data from different devices across different platforms.

2. It is also difficult to digitally share diabetes information about a person (e.g., care plans) between professionals across different settings and within multidisciplinary teams, leading to a risk of harm. This may also lead to patients having to tell their story more than once and duplication of clinical effort or investigations. In addition, the National Diabetes Audit and National Paediatric Diabetes Audits are important for quality improvement of diabetes services, however a lack of information sharing between systems contributes to labour intensive manual data collection and variable response rates across settings.

Professional Record Standards Body (PRSB) was commissioned by NHS England and Improvement to address these two challenges through the development of information standards to be tested) and provide recommendations and guidance on how these can be integrated with hospital laboratory and Electronic Patient Record (EPR) systems.

Two standards were developed following wide consultation:

- **The Diabetes Record Information Standard**
  This defines the information needed to support a person's diabetes management. It includes information that could be recorded by health and care professionals or the person themselves that is relevant to the diabetes care of the person and should be shared between different care providers.

- **The Diabetes Self-management Information Standard**
  This defines information that could be recorded by the person (or their carer) at home (either using digital apps or medical technology) and shared with health and care professionals. (This is a subset of the diabetes record information standard.)

This follow on phase of work was to start to address the requirement to support the implementation of these standards through:

- mapping the PRSB diabetes standard to FHIR resources (in collaboration with NHS Digital)
- identifying what messaging standards and associated guidance are required to support standardised sharing of data
- supporting the requests for new SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms) codes
- defining an approach for testing and piloting the standards
- supporting the application for Information Standards Notice (ISN) status for the standards

This report covers the findings of a short consultation into:

- How suppliers and Integrated Care Systems (ICSs) will use the standards.
- When and what technical artefacts and guidance are needed to support the standardised sharing of diabetes information.

3 Methodology and Consultation Approach

3.1 Project Objectives and Scope

3.2 Aims

This implementation support phase supports the overarching aims of the diabetes standards project, which are:

1. to enable key information about a person with diabetes to be shared between themselves, their carer and professionals to support self-management and to enable the best care to be delivered by professionals.
2. to enable information collected as part of routine care to be used once anonymised, for audit and population health management purposes.

3.3 Objective of this phase (implementation support)

- To move forward key areas of work needed to advance us towards technical readiness for implementation of the diabetes standards.

3.4 Scope (implementation support)

3.4.1 In scope

1. Working with NHS Digital providing input supporting issue resolution to the mapping of the two diabetes standards to Fast Healthcare Interoperability Resources (FHIR) UK Core
2. Working with NHS Digital terminologists to request new SNOMED CT codes for diabetes.
3. **Consultation identifying how suppliers and ICS digital staff plan to implement the standards over the short, medium and long term and any technical support materials they require to support implementation (focus of this report).**
4. Defining approach to piloting the standards (including the development of the scope for piloting, test scenarios, approach for selecting sites, planning for piloting and evaluation criteria).
5. Supporting progression of the Information Standards Notice for the diabetes standards through the Data Alliance Partnership Board (DAPB).

3.4.2 Exclusions from scope

- Carrying out the testing and pilots – this phase is for planning the pilots.
- Development of the technical artefacts and guidance (including technical standards and documentation) – this phase of work is to identify what is needed and plan for it.

3.5 Project team

The project team is detailed in appendix A.

3.6 Benefits

The benefits to implementers of the standards, including clinical systems and medtech suppliers and local transformation and IT staff, is an articulation for how it is expected that these standards are used in practice in the support short, medium and longer term with a plan for developing technical artefacts and guidance to support this. This work will ultimately benefit people with diabetes and professionals as it will help with the implementation and piloting of the diabetes standards.

3.7 Themes explored in consultation

The implementation support consultation explored the following themes:

- Theme 1: Scenarios where information sharing breaks down (for piloting the diabetes standards)
- Theme 2: Approaches to sharing data now and in the future
- Theme 3: Current and future use of APIs, standards and interfaces
- Theme 4: Technical guidance or artefacts to support implementation
- Theme 5: Helping to drive uptake and adoption of the diabetes standards

3.8 Participant framework

Stakeholder organisations involved in the implementation support consultation are detailed in Appendix B.

3.9 Methods and rationale

3.9.1 Semi-structured interviews with systems suppliers

Three 1-hour semi-structured interviews were held with system suppliers during August 2022 to understand their current use of standards and plans to support the information sharing scenarios identified for diabetes in the short, medium and long term. See findings and recommendations section for further information. Stakeholder organisations represented at the interviews are detailed in Appendix B.

3.9.2 Implementation support workshop

The interview output including candidate recommendations were tested with a wider group of suppliers at an online implementation support workshop in September 2022. Other attendees included interoperability experts and ICB staff. See findings and recommendations section for further information. Stakeholder organisations represented at the workshop are detailed in Appendix B.

4 Findings and Recommendations

4.1 Findings

Findings from the consultation are detailed in the analysis table below organised by theme.

4.2 Recommendations

A summary of the final recommendations organised by theme is below. The rationale for these is detailed in the analysis table (section 4.3).

4.2.1 Theme 1: Scenarios where information sharing breaks down (for piloting)

- Consideration **should** be given to piloting the following candidate scenarios [R1A]:
    - Sharing a care plan
    - Sharing self-management data
    - Sharing investigation (pathology test) results
- PRSB **should** demonstrate how the diabetes record information standard supports recording of food and nutrient intake [R1B].
- The care plan used by the care home and MDT **should** be the same. The sections (Care and support plan, Contingency plan and Additional support plan) of the diabetes record information standard **should** be used to structure care plans in both care homes and the MDT to ensure consistency and interoperability [R1C].

4.2.2 Theme 2: Approached to sharing data now and in the future

- **Now:** Data sharing via shared care record systems including national eye screening grading result data **should** be encouraged and explored. The data shared **must** be of a sufficient granularity to allow for effective professional decision making [R2A].
- **Moving forwards:** People with diabetes **should** have access to their interoperable diabetes record which may include via person held apps. This would allow them to bring their record with them when travelling across borders for unplanned treatment [R2B].
- A national architecture for sharing diabetes data with a roadmap for achieving this **should** be developed and maintained to enable sharing of a person's diabetes record within the UK including across local and national borders/ boundaries [R2C].

4.2.3 Theme 3: Current and future use of APIs, standards and interfaces

- **Short-term:** Where information is already being shared, continue to do so [R3A].
- **Medium-term:** Use existing interoperability specifications and infrastructure, modified where necessary to align with PRSB standards [R3B].
- **Long-term:** Converge on standardised sharing using SNOMED CT and FHIR (with connectors for legacy systems) in line with the strategic direction of travel for sharing health information in England [R3C].

4.2.4 Theme 4: Technical guidance or artefacts to support implementation

- Guidance to support implementation **should** include:
  - Clear articulation of data items to be supported (must/should haves) [R4A].
  - Development and maintenance of SNOMED CT guide for concept use (in PRSB diabetes standards implementation guidance) [R4B].
- Summary views for key stakeholders (e.g., diabetes specialists and non-specialists) **could** be developed and tested as part of the pilots. There **should** be approved content for a diabetes summary screen (not UI design) to be explored as candidate examples (e.g. person facing, general practitioner and diabetes specialist summary screens) in the piloting phase of the diabetes standards. If validated these **could** be standardised and endorsement/ ownership sought from professional bodies in a subsequent phase [R4C].
- Exploration of information sharing from care home records **should** be done including profiles of the diabetes record information standard for care home recorded data [R4D].

4.2.5 Theme 5: Helping to drive adoption and uptake of the diabetes standards

- Mandate that all data collected and displayed must be accessible for use in software for NHS systems (or third-party systems in use in the NHS) as appropriate. This means that where calculated summary glucose and insulin dosing metrics are exposed for sharing, the system **MUST** also make the underlying data used for the calculation available for consumption by these other systems [R5A$_1$].
- Investigate how to incorporate the diabetes standards as a requirement for access to purchasing frameworks for systems (including software and devices) [R5A$_2$].
- Mandate or recommend as appropriate that information sharing is aligned to the diabetes standards (as defined in the Information Standards Notice (ISN)) [R5B].
- Investigate whether it is possible to mandate that there are data sharing agreements in place between suppliers to facilitate the person with diabetes having access to and the ability to share their data in human and machine-readable forms. [R5C].
- Explore whether a standardised data protection questionnaire (Data Protection Impact Assessment (DPIA)) for England could be developed, see Data sharing from point of care systems report) [R5E$_1$].
- Investigate how DPIA responses could be stored to reduce duplication across organisations and providing access to Trusts and suppliers when needed (see Data sharing from point of care systems report) [R5E$_2$].
- Provide example use cases with benefits to support implementation [R5D].

4.3 Analysis table

Theme 1: Scenarios where information sharing breaks down (for piloting)

Interview findings

We sought views at interview from diabetes systems suppliers on the following proposed scenarios for testing diabetes information sharing:

1. Eye screening results with hospitals
2. **Test results between primary, community and secondary care**
3. Observation data (e.g., weight, body mass index (BMI), blood pressure (BP), smoking) between primary, community and secondary care
4. Foot check results between primary, community and secondary care
5. Diabetes “status” on admission
6. **Self-management data (e.g. blood pressure, weight, glucose levels (from CGM), insulin administration (insulin pumps, connected pens)) with a) primary and community and b) secondary care**
7. Simple insulin dosing information (collected manually or automatically from devices) between primary, community and secondary care
8. **Care plan between primary, community and secondary care**
9. Structured education attendance with primary, community and secondary care

Interviewees identified the scenarios highlighted in **bold** above as key scenarios for initial piloting and told us that:

- Information sharing breaks down where there are issues of interoperability across local borders.
- Transition from paediatric to adult services is a key scenario for consideration as well as sharing of the national eye screening grading result.
- GPs and hospital consultants have different information requirements from self-management devices (in terms of the resolution/ granularity of data needed).
- Sharing tests results is a major issue.
- Remote monitoring using self-management data could be considered

“A lot of the time the GP's got their own record on one side and the hospital’s got their own records, in some cases even still paper-based records in a separate filing cabinet or silo, and none of the data talks to each other. So, you'll be getting things like duplicate tests and patients being unnecessarily inconvenienced. So that kind of stuff, the data sharing would be a big thing [to test in piloting].” **– Systems supplier**

Candidate proposals

The interview output led us to propose the following key scenarios for initial piloting:

- Sharing a care plan
- Sharing self-management data
- Sharing investigation (pathology test) results

Workshop findings

Workshop attendees told us that:

- They agreed with piloting of the candidate scenarios.
- Self-management data including food and nutrient intake (e.g., carbohydrates and calories) needs to be shared with health care professionals to support diabetes treatment/ management.
- It is important to differentiate between type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), impaired glucose tolerance (IGT) and gestational diabetes.
- It is important to ensure consistency/ interoperability of care plans used by the multidisciplinary team (MDT) and the care home professional team.

"Where scenarios refer to community settings it is important to remember that some people are living in residential care rather than their own homes. It is important that the EHCH support plan and the care home plan "match". **– Anonymous mentimeter response**

"…looking at improving the care of diabetes in care homes…it's very important to consider glucose monitoring…I know that some ICSs are using things like the blue box and care home staff can send things like glucose readings to a clinical portal, which is then available to the MDT to view, but I don't see how that is then shared in the person's care plan…[in some cases] they were actually printing off the care plan for the care home and that's not really satisfactory… it's really important that we do consider how the data can be captured at the point of care, but then shared to the MDT for review, but also captured in the person's care records and the care home at the same time so that everything is aligned and there is no risk of misunderstanding." **– Director, social care software**

After the workshop the project team provided further examples of where information sharing could break down for people with diabetes including where use of paper is involved:

"[There is] the issue of PWD [(people with diabetes)] who still choose or have to carry bits of paper with information that needs to enter the record. [For example] the person transferring information between secondary and primary care, e.g., a discharge note, yellow prescription or test result that is needed immediately but may also be included in a letter. [Another issue] is the person [with diabetes] who is perhaps not tech savvy so brings their [fingerstick] results or other information to the GP on a bit of paper…in both cases there may be assumptions that it will enter the record eventually via another electronic route…" **– Project citizen lead (post workshop comment)**

Final proposals

Overall, the consultation led us to the following recommendations for theme 1:

- Consideration **should** be given to piloting the candidate scenarios [R1A].
- PRSB **should** demonstrate that the diabetes record information standard supports recording of food and nutrient intake [R1B].
- The care plan used by the care home and MDT should be the same. The sections (Care and support plan, Contingency plan and Additional support plan) of the diabetes record information standard **should** be used to structure care plans in both care homes and the MDT to ensure consistency and interoperability [R1C].

Theme 2: Approaches to sharing data now and in the future

Interview findings

We asked diabetes systems suppliers at interview:

- What approaches do you use now for sharing the data in scenarios? (e.g., Summary Care Record, Eye Screening Service data, Shared Records Systems (ICS or local collaborative), Event Management Service, National Record Locator (NRL) Service, Patient Held Records e.g. NHS App)
- What will you move to in the medium and longer term (1-3 years)?

Interviewees told us that:

- **Now**: Shared Care Record at ICS or local collaborative is a priority for all suppliers currently. Might be easiest as there may already be some interoperability within the ICSs.
- Event Management Service can be lengthy to agree and implement.
- Eye screening service data seems robust. Inability to retrieve eye screening data (grading result) was also identified as a significant gap for record systems.
- Summary Care Record would stop being a summary and become someone's *de facto* care record.
- **Moving forwards**: People with diabetes should have access to their interoperable diabetes record including via person held apps allowing them to bring their record with them (this would help with information sharing across borders where treatment is unplanned e.g. person with diabetes from England uses their app to share with healthcare professionals when treated in Scotland.

"That ICS or local collaborative is a priority for all suppliers currently. That might also be easier as there may already be some interoperability within the ICSs. We then don't have to worry about aligning timescales and capture of standard information." **– Systems supplier**

"I'd say event management service concerns me slightly as that's a lengthy process to agree and implement information sharing." **– Systems supplier**

"[Regarding] eye screening service data I feel that's fairly robust and would be keen to identify how that could be progressed." **– Systems supplier**

"I think one good example [of a scenario] would be potentially eye screening, because there's no way of getting data [the grading result] from the national eye screening service out in any sort of format and into other systems, and that's a big sort of gap in our data at the moment … So having some sort of new interface to get eye screening data out of their systems and using an agreed format and FHIR would be great [for that]." **– Systems supplier**

"Regarding [use of] the summary care record my only issue is then it stops being a summary and becomes someone's *de facto* care record. We need to improve the others e.g. shared care record… If the patient has their own record, then the summary care record is defunct because if they share the patient will share the full record… My slight hesitation would be is this pursuing familiarity rather than reality going forwards? In the medium term I think patient held information has much greater credence, I wouldn't expect people to start cold from a record on a patient's phone, but this should be interoperable." **– Systems supplier**

"From the patient perspective, what about handheld apps for patients? On the NHS app, there's patient access, there's Evergreen and moving forwards patients should be able to access and share their diabetic record. Where there are issues of interoperability across local borders information sharing breaks down and patient held records can mitigate this. Where care is unplanned, e.g. English residents hopping over the border to Wales, then patient held records are important." **– Systems supplier**

After the workshop, the project team raised an unresolved issue regarding how a diabetes record dependant on integration with the shared care and/ or summary record would be supported in cases where people with diabetes opt out of information using these platforms:

"[Regarding] people who have opted out of sharing information at both levels [(summary care/ shared care records)]. Will this mean they have neither a shared care [n]or summary care record? Where will their diabetes record sit and if a patient chooses to have that shared how will this happen?" **– Project citizen lead (post workshop comment)**

Candidate proposals

The interview output led us to the following candidate recommendations:

- **Now:** Data sharing via shared care record systems including national eye screening grading result data should be encouraged and explored.
- **Moving forwards**: People with diabetes **should** have access to their interoperable diabetes record, which may include via person held apps This would allow them to bring their record with them when traveling across borders for unplanned treatment.

Workshop findings

Workshop attendees told us that:

- They supported the use of shared care records for sharing diabetes information but that currently some of these might not support the granularity of data required.
- In the long-term system-to-system transfer should be implemented across borders/ boundaries.

"You might need to consider and evaluate all ways which data could be shared e.g., External portals since not all shared care record would include the granular data required." **– Anonymous mentimeter response**

"Shared care records seem the most natural home [for this information] … the NRL is still on unstructured data. Events result from record, and [are] not a permanent home. The National Record Locator will point to the shared care records so it's just an index for pointing things out and it doesn't maintain it…and right now it only points at PDF documents which are unstructured data. So, it's not, I don't think setup to support this more detailed work...I'm not saying never [but] the events by their nature would be volatile and I think the data we don't really want to be volatile…I don't think there's a straightforward answer to this, I'm just saying why I think the shared care record is probably the most natural home at the moment." **– Healthcare interoperability expert**

Final proposals

Overall, the consultation led us to the following recommendations for theme 2:

- **Now:** Data sharing via shared care record systems including national eye screening grading result data **should** be encouraged and explored. The data shared must be of a sufficient granularity to allow for effective professional decision making [R2A].
- **Moving forwards**: People with diabetes **should** have access to their interoperable diabetes record, which may include via person held apps This would allow them to bring their record with them when traveling across borders for unplanned treatment [R2B].
- A national architecture for sharing diabetes data with a roadmap for achieving this **should** be developed and maintained to enable sharing of a person's diabetes record within the UK including across local and national borders/ boundaries [R2C].

Theme 3: Current and future use of APIs, standards and interfaces

Interview findings

We asked diabetes systems suppliers at interview:

- What APIs/ standards / interfaces will be/ are used with these systems? (e.g., Locally maintained FHIR (Fast Healthcare Interoperability Resources) profiles, FHIR UK core profiles, comma-separated values (CSV) files, Clinical Data Architecture

(CDA) Documents, locally defined Application Programming Interfaces (APIs), Health Level Seven Version 2 (HL7v2), International Organization for Standardization 11073 (ISO 11073) for devices, GP2GP, GP Connect)

Interviewees told us that:

- A standard using FHIR (facilitating a strategic move towards a common set of FHIR profiles) would be useful in the medium term but there is a pragmatic need to support other interfaces now (shorter term).
- GP connect view is new but can link to hospital systems.
- APIs may already exist to support sharing this information.
- Being clear about the data items (and codes) required is the priority as suppliers can work out how to share.
- Standardised data items allow mapping of the data items into various interoperability capabilities e.g. CDA or HL7v2
- Linking with the International Patient Summary (IPS) could be explored.
- Proprietary diabetes devices (e.g., continuous glucose monitors are less likely to conform to standards (e.g., ISO 11073). Stakeholders held a range of views with some wanting to move as soon as possible to nationally mandated FHIR and some wanting pragmatic use of existing interoperability approaches, allowing the market to make the decisions.

Stakeholders held a range of views with some wanting to move as soon as possible to nationally mandated FHIR sharing and some wanting pragmatic use of existing interoperability approaches, allowing the market to make the decisions on how the information is shared. (see quotes below and under theme 5).

“Everyone is moving towards FHIR [internationally] but all the other standards and APIs are being used currently and I don’t see that changing in the near future. A standard for FHIR would be great moving forwards. CSV files are a nightmare (if still considerably used). For me FHIR is the way forward. I wonder if we have defined APIs now that could be useful in sharing this information – I would imagine we have APIs that would handle this sharing. Where APIs are used, we should be working towards FHIR (if slowly) and perhaps the capturing of the standard information would be my priority and then worry about sharing and be confident it can be.” **– Systems supplier**

“[Diabetes device manufacturers] are less likely to conform to these standards. They generally just have their own way of transmitting data. The data is formatted in their own way, which is why we [diabetes data aggregator platform] approach our integrations on a case-by-case basis. We do our evaluations, and we translate those into a true common format on our side…if there was a standard, then it would make our lives a lot easier…everything’s been custom with our APIs anyway, it is more laborious, but it’s about the only way you can do it in terms of working with all the separate markets that are out there.” **– Systems supplier**

“What’s happening in the UK at the moment is [that glucose data from devices is often pushed into the electronic health record (her) as] a PDF [(Portable Document Format)] report…which has all the key graphs and charts on there, and then they’ll upload that into the NHS system to provide context to why whatever it is that they’re changing, whether that be insulin doses or introducing new medications [etc.] …” **– Systems supplier**

“[For] an internationally recognised standard like FHIR and I know that's the direction of travel… If you asked me this question five years ago when we'd not done the integration with the primary care systems, I would have said one mandated standard that allows the transfer of data

from all systems would be the ideal, but we live in the real world and all the suppliers have their own different ways of transforming or sending data over. And because now five years later, we've set up those connections…so we wouldn't necessarily want to change those… moving forward… if there's an agreed standard, then we would certainly look to comply with that for our day-to-day issuing. [Compliance should] not necessarily be mandated but recommended…" **– Systems supplier**

"One of the things that interests me is how much diversity and variation there is in the way that people are using FHIR [and] is it being consistently used or not. [When mapping the diabetes standards to FHIR] with NHS digital they're seeing quite a lot of choices you can make, and I could imagine that if each ICS has got its own set of FHIR interfaces they might be making different choices than the ones we are making." **– Healthcare interoperability expert**

"Not so many organizations are doing flat CSV files anymore, but we have had experience using those as well. So yeah, I mean, there's wide and varying ways in which people and in which systems allow access to their data. All of those in the list there, we've had experience with in the past…. if we can get the data we need [for care] we don't mind what format but if everybody was using a standardised FHIR profile, then it would make life much easier." **– Systems supplier**

Candidate proposals

The interview output led us to the following candidate recommendations:

- Short-term: Where information is already being shared, continue to do so
- Long-term: Converge on standardised sharing using SNOMED CT and FHIR (with connectors for legacy systems)

Workshop findings

Workshop attendees told us that:

- They agreed with the candidate recommendations.
- It is important in the medium-term to explore use of existing interoperability standards to develop information sharing aligned to the PRSB standards.
- Linking with the IPS (which allows sharing of an electronic health record extract containing essential healthcare information about the subject of record for unplanned care across international borders) could be considered.
- Short term implementations based on HL7v2 might be "wasted work" as the direction of travel is use of FHIR.

"I think the International Patient Summary is really, really interesting because I've seen that driving a lot of countries and to think about structured data differently…it's the way that [data] can be instantiated that can be generated in a FHIR format, it can be generated in a CDA [(Clinical Data Architecture)] which is a HL7v3 kind of format and I think I've even seen an openEHR implementation of the [IPS]. So, they're just, if you like, the kind of ways that people can access it and so I think it's useful to look at the [IPS] for what it contains with respect to

diabetes information. I suspect it'll be higher level and less detailed than you would like for research and for real direct patient care but a useful summary for a diabetes patient to carry around with them internationally…" **– Healthcare interoperability expert**

"If this project is going to take more than 18 months to implement, then going to HL7v2 would be wasted work. Also, the direction of travel to webservices would almost force this down a FHIR route…. definitely don't do HL7v2, because that will lock your data in somewhere. Try to build a model that is referenceable by FHIR and the rest will follow… you'll be able to feed into the IPS naturally that way" **– Healthcare interoperability expert**

Final proposals

Overall, the consultation led us to the following recommendations for theme 3:

- **Short-term:** Where information is already being shared, continue to do so [R3A].
- **Medium-term:** Use existing interoperability specifications and infrastructure, modified where necessary to align with PRSB standards [R3B].
- **Long-term:** Converge on standardised sharing using SNOMED CT and FHIR (with connectors for legacy systems) in line with the strategic direction of travel for sharing health information in England [R3C].

Theme 4: Technical guidance or artefacts to support implementation

Interview findings

We asked diabetes systems suppliers at interview:

- What technical artefacts or guidance would help support implementation?

Interviewees told us that:

- NHSE should provide each supplier with a set of clear and unambiguous requirements and expectations to ensure consistent interpretation by suppliers.
- Suppliers need to be aware of changes to SNOMED CT codes and **coding requirements** (what codes to use to transfer data) so that they can update their systems to support new codes and coding requirements.
- There is a need for suppliers implementing the diabetes standards to know what is a **must have** and what is a **should have** (and when a **should have** will become a **must have**).
- There should be a standard format whether you're pulling data from EMIS (Egton Medical Information Systems) or TPP (The Phoenix Partnership) etc.

- Standardised high level summary views should be available for professionals to enable efficient care but also standardised granular data views for use by specialists should also be developed. It was felt it would be useful to test stakeholder group/ speciality specific views of the data in piloting (e.g., for GP versus diabetes specialist) as GPs and diabetologists have different information requirements e.g., glucose/ insulin data from self-management devices (in terms of the resolution/ granularity of data needed). It would be helpful to have Royal College approved content for summary screens with flexibility for customers to modify the UI as they would like to.

"[An example of helpful guidance would be] a traffic light system [where] the red data points…are the ones that we absolutely need to have. Then there's the amber ones which are 'you will be a preferred system if you have these' and then there's the green ones that 'if you can provide these that would be awesome but they're not essential." **– Systems supplier**

"The priority has to be to provide each supplier with a standard set of requirements even if this is in different flavours. That specification is required from NHSE. I know colleagues from [another EHR supplier] would say the same otherwise you have [our] users doing something different to them and we can't have that. Requirements and expectations need to be clearly understood to suppliers. We need to be aware of changes to SNOMED codes [and] the particular coding requirements. When we get specifications, it needs to be very clear and unambiguous, we need to know what is a must have and what should be had. There must be no ambiguity or things will get missed and then we get to pilot and realise we need to go back and add in elements. Or is it you must do x but should do y if z happens." **– Systems supplier**

"[We have to keep] an eye on all of the relevant codes that we need to take now and in the past that are relevant to diabetes… [for example] things like cholesterol, systolic blood pressure. There are so many codes that could potentially align to [those]... It would be useful from a recommendation perspective to say here are all the codes for a specific data item and here's the one we recommend if you're going to be transferring data around the ecosystem… the main thing is the code lists and having an accurate centralized repository that says, 'here's your diabetes standard coding'. I'm coming at this very much from a technical angle. So that's the sort of stuff that would help me do my job more easily." **– Systems supplier**

"In terms of the content of summary screens customers would like an approved royal colleges standard. This gives suppliers the opportunity to give out a product useful and supported and endorsed. There is flexibility for customers to modify the UI as they would like to. So, some sort of form design – these are the data items we would expect to see – the content of what should be included in a summary from a clinical perspective… Standardised forms endorsed by [for e.g.] NICE would help to bridge the gap between a record and a care pathway." **– Systems supplier**

Candidate proposals

The interview output led us to the following candidate recommendations:

- Clear articulation of data items to be supported (must/should haves)
- Development and maintenance of SNOMED CT guide for code use
- Approved content for a diabetes summary screen (not UI design)

Workshop findings

Workshop attendees told us that:

- They agreed with the candidate recommendations.
- The pulling of data from care home records should be explored so that care homes can manage, record and share key information about residents with diabetes with MDTs, which would support monitoring.
- Standard codes for unplanned admissions should be built into software used by care homes to facilitate analysis by ICSs to inform provision of services. (i.e. for ICSs to identify how frequently residents underwent urgent unplanned transfer(s)/ admission (s) from care home to hospital). [*NB*: Relevant SNOMED concepts (SNOMED CT ID: 507241000000105 and 507281000000102 already exist for this and care home software should in the longer term be SNOMED CT enabled for interoperability of this information with NHS systems]. One of the outstanding issues is to understand the challenges for national adoption of SNOMED and what can be done to enable and accelerate that. This would require local authority and the Department of Health and Social Care (DHSC) to work with local health authorities to synchronise reporting.

"If the person providing POCT [(point of care test)] data is resident in a care home, how is the data captured in the person's care plan in the home while, at the same time, being shared with the MDT? Current initiatives appear to use devices that just send data to a clinical portal. Discussions on NHS Futures seem to indicate that this is an issue that needs addressing. It is unsafe to expect care staff to manually transcribe results to the care plans in the care home… GP Connect supports sharing from the GP record to care homes. Is there any plan to allow data to be pulled from care home records to facilitate monitoring of LTCs [(long term conditions)] such as diabetes?" **– Healthcare interoperability expert**

"It would be useful to have standard codes for unplanned hospital admissions built into all software used by care homes. This would facilitate analysis by ICSs to inform provision of services to help to prevent unnecessary admissions." **– Anonymous mentimeter response**

"[Development of SNOMED CT guidance] must be led by clinical teams and then developed by coders." **– Anonymous mentimeter response**

"[When developing] a dashboard specifically for diabetes [for shared care records] it needs to work for everyone and we get a lot of comments from users [about] not overwhelm[ing] them with too much information so that they can't find what they need quickly. But also, there are people who are diabetes specialists who really want to see the detail about their specific area and designing something that does both is really, really tricky. [Developing a solution where] you can address the different resolution of data issue and who needs to see what and the best way to show it to different people [is] quite tough. [It] could be really helpful [to test summary views for different stakeholders in the piloting]." **– Digital Programme Manager, ICB**

"[There] is always the eternal struggle between the expert view of the data and the summary view…If you build a data model which doesn't support the expert view then you'll always end up having to go and build that data model later…so it's better to get the granularity to offer the right level of detail to the experts and then filter it out or simplify it for people who want to take a simplified view….If you really want to make a difference in data for diabetes, the data model has to be able to capture [granular data], particularly if you want to do any kind of advanced analytics on it or [in future] machine learning….[T]he structure [of the data] is one thing because that gives you the vehicle to access it, but the actual content of the data and the ontology and the codification [is] almost more important because once you dig that data out if it's not rightly

coded then you will find it hard to use and you'll forever be making mapping. Ontology [is] the best place to start," **– Healthcare interoperability expert**

"The resolution of data should be detailed enough to support the most detailed work of experts. If a summary view is needed, it can be prepared separately - or a consumer application can formulate a summary view based on the detailed data. That is why a good information model and data model is essential." **– Healthcare interoperability expert**

Final proposals

Overall, the consultation led us to the following recommendations for theme 4:

- Guidance to support implementation **should** be produced that clearly articulates the data items to be supported (must/should haves) [R4A].
- There **should** be central development and maintenance of SNOMED CT guide for suppliers defining concept use (in PRSB diabetes standards implementation guidance) [R4B].
- There **should** be approved content for a diabetes summary screen (not UI design). This **could** be explored as candidate examples (e.g. person facing, general practitioner and diabetes specialist summary screens) in the piloting phase of the diabetes standards. If validated these **could** be standardised and endorsement/ ownership sought from professional bodies in a subsequent phase [R4C].
- Exploration of information sharing from care home records **should** be done including profiles of the diabetes record information standard for care home recorded data [R4D].

Theme 5: Helping to drive uptake and adoption of the diabetes standards

Interview findings

We asked diabetes systems suppliers at interview:

- What would help to drive uptake and adoption of the standard?

Interviewees told us that:

- Frameworks and contracts should:
    - mandate that data collected and displayed must be shared with NHS systems (or third-party systems in use in the NHS) at a level of detail necessary (detailed or summary data) e.g. where calculated summary glucose and insulin dosing metrics are exposed for sharing, the system MUST make the underlying data used for the calculation available for consumption by these other systems.

    - recommend that the data is shared in conformance with the diabetes standards (as defined in the Information Standards Notice (ISN).
    - mandate that there are data sharing agreements in place between suppliers – this would help avoid the situation where a system stops sharing data because they have partnered with a different supplier or exited the UK market etc.
- There needs to be clarity about the benefits of sharing the data in particular scenarios – who is going to use it and how it is going to be used (particularly detailed data) – where the benefits of use cases are clearly articulated it was felt that this would help business cases to be developed locally where trusts are commissioning software.
- There should be a clear accreditation process so that conformance with the diabetes standard(s) can be demonstrated.

Stakeholders held a range of views with some wanting to move as soon as possible to nationally mandated FHIR sharing and some wanting pragmatic use of existing interoperability approaches, allowing the market to make the decisions on how the information is shared. (see quotes below and under theme 3).

"[The centre (NHS Diabetes Programme and PRSB) should not say that you can't sell in this market if you don't support this (or one of these two or three) messaging standards]…the better way [would be for the centre to say] we're not bothered by if you need to do custom APIs and you guys figure out a different way of doing that…but this is the data that is required if you're going to be on the market. If you're going to connect with our clinic, you need to provide us this data... then the market will figure out whatever the easiest API is [for sharing data between a data aggregator and EHR] to meet those needs." **– Systems supplier**

"There is a middle way, which is '[the centre says] these are the data items we want, and this is an API that we know is widely supported in the country…If you need to pick an API, choose this one. If you've got good reason to do something else, [then] do something else.'" **– Healthcare interoperability expert**

"We sign [data sharing] agreements with each of the [device manufacturer] companies…you'd probably want to [mandate this] in the standard as well…purely because…there's history, not so much in the UK but elsewhere of… hacking the devices to get the data out…[whereas with a data sharing agreement] the device companies we work with will provide all the technical documentation [for device integration] so that will cover future versions of that device if they update things like firmware, it ensures the ongoing integrity of the data that's being passed through…[but] if you're just hacking devices, you haven't got that guarantee, so you would need to have an agreement with industry…Generally they're global agreements [where] the company will state [that] patients can download the data to us and that will be shared with clinical providers for the purposes of clinical decision making… It means that the [device company] can't just turn off the data [or if somebody goes out of business or pulls out of the UK market] …So, I think for this you would have to mandate that it needs to be shared through a non-competitive route and supported by a legal agreement that states that…[Some companies e.g., insulin pump manufacturers have done] a managed exit [from the market] where they found [patients] an appropriate solution as an alternative…they didn't just pull out and go… and that might be a stipulation to include as well." **– Systems supplier**

"NHS England, if [it is] procuring any sort of devices into the market and making use of it within the NHS, they should be mandating that data sharing must be possible and one of the things we've had major problems with is about collecting all this fantastic information on CGM through

the Libre monitors and…they don't want to share the data. We can get data out of Libre view if people go through a concave process of exporting their data and then uploading it into our system [hacking], which is OK, but it's not ideal. There's no way of getting data directly or connecting our patients directly as you can do with Fitbit and then pull that data through on a periodic update. So that sort of thing is what NHS, Digital and NHS generally should be mandating when they procure any new devices for use within the service and alongside that would be nice to say, 'here's a recommended standard for how you share that data…" **– Systems supplier**

"Our product manager would be very delighted to see lots of use cases, so we can help map out the journey when he's designing parts of the system." **– Systems supplier**

Candidate proposals

The interview output led us to the following candidate recommendations:

- Mandate that all data collected and displayed must be accessible for use in software for NHS systems (or third-party systems in use in the NHS) as appropriate. This means that where calculated summary glucose and insulin dosing metrics are exposed for sharing, the system **MUST** also make the underlying data used for the calculation available for consumption by these other systems.
- Mandate or recommend as appropriate that information sharing is aligned to the diabetes standards (as defined in the Information Standards Notice (ISN)
- Mandate that there are data sharing agreements in place between suppliers. These agreements **should** ensure that the person with diabetes has ownership of their data and has access to it.
- Provide example use cases with benefits

Workshop findings

Workshop attendees told us that:

- They agreed with the candidate recommendations.
- Additionally, they agreed with a recommendation emergent from point-of-care work conducted in parallel with implementation support (this document) that the process for Data Protection Impact Assessments (DPIAs) should be simplified. Currently DPIAs must be completed by suppliers separately for each implementation project. Stakeholders agreed that this should be done once for a piece of software and should be reused across the system so that separate questionnaires do not have to be filled out each time the software is implemented in a particular area, Trust, or ICS.

Final proposals

Overall, the consultation led us to the following recommendations for theme 5:

- Mandate that all data collected and displayed must be accessible for use in software for NHS systems (or third-party systems in use in the NHS) as appropriate. This means that where calculated summary glucose and insulin dosing metrics

are exposed for sharing, the system **MUST** also make the underlying data used for the calculation available for consumption by other systems [R5A$_1$].

- Investigate how to incorporate the diabetes standards as a requirement for access to purchasing frameworks for systems (including software and devices) [R5A$_2$].
- Mandate or recommend as appropriate that information sharing is aligned to the diabetes standards (as defined in the Information Standards Notice (ISN) [R5B].
- Investigate if it is possible to mandate that there are data sharing agreements in place between suppliers to facilitate the person with diabetes having access to and the ability to share their data in human and machine-readable forms. [R5C].
- Explore whether a standardised data protection questionnaire (Data Protection Impact Assessment (DPIA)), see Data sharing from point of care systems report) could be nationally agreed [R5E$_1$].
- Investigate how DPIA responses could be stored to reduce duplication across organisations and providing access to Trusts and suppliers when needed (see Data sharing from point of care systems report) [R5E$_2$].
- Example use cases with benefits **should** be developed/ provided to support implementation [R5D].

5 Conclusion and Recommendations

In conclusion, there was good agreement from stakeholders, including diabetes systems suppliers, interoperability experts and others around scenarios for testing the diabetes standards and the technical artefacts and guidance needed to support their delivery; including products on implementation, conformance and coding/ terminology requirements and clinically endorsed summary screens of the diabetes record.

This work recognised shared care records to support information sharing as a priority now, with pragmatic use of a variety of standards, APIs and interfaces in the near term, and a strategic direction of travel towards FHIR messaging in the medium to long term.

The promise of utilising interoperable patient held information for cross-border information exchange in future was considered. It is suggested that it is investigated that whether it is possible to include in procurement frameworks that:

- all data collected and displayed must be accessible for use in NHS and other software/ systems as appropriate (in use within the NHS estate)
- there should be data sharing agreements between device and systems suppliers
- recommendation that data is shared in conformance with the ISN.

We now need to build on this work in the next phase of focused implementation.

6 Appendices

6.1 Appendix A - Project team

Team member name	Title / Responsibility
Ben McGough	NHS England and NHS Improvement, Digital Lead NHS Diabetes Programme.
Mark Brodigan	Commissioner, NHS England and NHS Improvement.
Sarah Jackson	PRSB, Project Manager
Neel Basudev	Lambeth GP/ Project Clinical Lead
Iain Cranston	Consultant Physician, Diabetes and Endocrinology Portsmouth Hospitals NHS Trust/ Project Clinical Lead
Ojaih Willow	Project Citizen Lead
Charlie McCay	PRSB, Project Technical Lead/ Non-executive Director
James Critchlow	PRSB, Analyst Researcher/ Lead Analyst
	PRSB, Membership and Stakeholder Manager
Louis Martin	Ramsey Systems, Technical Analyst
Alison Brown	PRSB, Project Co-ordinator

6.2 Appendix B - Consultation event attendance

- Three semi-structured interviews were held with system suppliers in August 2022.
- A workshop was held on 22nd September 2022 (n = 21 participants)

Interview 1 (17/08/22)

Organisation	Title / Responsibility
PRSB	Project Manager
PRSB	Non-executive Director/ Project Technical Lead
PRSB	Analyst Researcher
EMIS	Head of Clinical Safety
EMIS	Senior Clinical Director
EMIS	Senior Informatics Pharmacist

Interview 2 (17/08/22)

Organisation	Title / Responsibility
PRSB	Project Manager
PRSB	Non-executive Director
PRSB	nalyst Researcher
Glooko	Partnerships Manager – Europe, the Middle East and Africa
Glooko	Sales Director – Northern Europe

Interview 3 (25/08/22)

Organisation	Title / Responsibility
PRSB	Project Manager
PRSB	Non-executive Director
PRSB	Analyst Researcher
MyWay Digital Health	Chief Operating Officer
MyWay Digital Health	Chief Technical Officer

Workshop participants (22/09/22)

Organisation	Title / Responsibility

PRSB	Project Manager
PRSB	Non-executive Director
PRSB	Analyst Researcher
PRSB	Membership and Stakeholder Manager
Ramsey Systems	Technical Analyst
Quic (Quality in Care) Ltd	Medical Director
Trumonix Ltd	Principal Consultant
MyWay Digital Health	Development Manager
Dietary Assessment Ltd/ University of Leeds	Professor
Aire Logic	Enterprise Architect
Malaffi	Director
Norfolk and Norwich University Hospitals NHS Foundation Trust	Consultant
MyFood24	Marketing Manager
N/A	Workshop participant
Gloucester Health and Care NHS Foundation Trust	Senior Business Intelligence Analyst
Gloucestershire Integrated Care Board	Digital Programme Manager
Royal College of Paediatrics and Child Health	National Paediatric Diabetes Audit Manager
Abbott	Business Development Manager – Digital and IT Solutions
Aire Logic	Solution Architect
Insulet	Head of Market Access
MyWay Digital Health	Chief Executive Officer (CEO) and Chief Medical Officer