DAPB4085 Diabetes Record Information Standard

(DAPB4085 Amd 59/2022)

High Level Implementation Guidance v1.0

Data Alliance Partnership Board

The Data Alliance Partnership Board (DAPB), which holds delegated authority from the Secretary of State for Health and Social Care, has approved a new information standard for publication under Section 250 of the Health and Social Care Act 2012.

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Standards Assurance Service (DSAS) and endorsed by the Data Alliance Partnership Sub Board (DAPSB). This information standard comprises the following documents:

- Requirements Specification
- High Level Implementation Guidance

An Information Standards Notice (DAPB4085 Amd 59/2022) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the information standard.

The controlled versions of these documents can be found on the NHS England website. Any copies held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

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Glossary of terms

Term / Abbreviation	What it stands for
CIS	Core Information Standard
DAPB	Data Alliance Partnership Board
DAPB4085	The Diabetes Record Information Standard
FHIR	Fast Healthcare Interoperability Resource. A method for exchanging healthcare information electronically
ISN	Information Standards Notice
PRSB	Professional Record Standards Body
SLA	Service Level Agreement
SNOMED CT	Structured clinical vocabulary for use in an electronic health record. SNOMED CT has been adopted as the standard clinical terminology for the NHS in England

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1. Purpose

The purpose of this document is to provide guidance on the implementation of the Diabetes Record Information Standard. The standard was developed by the Professional Record Standards Body (PRSB) during 2021 and 2022 under a commission from NHS England. The purpose of the standard is:

1. To improve sharing of key information about a person's diabetes with health and care professionals involved in the care and support of that person across primary, secondary, community and social care. This includes information like eye screening results, insulin dosing information, foot check results, test results, assessments and care plans.

2. To improve sharing of self-management information (that a person has recorded and is using to manage their diabetes) with their health and care team to enable better support to be provided. This includes information like weight and blood pressure as well as from glucose monitoring and insulin delivery devices.

Through implementation of the information models and use of associated implementation guidance and other supporting materials, the standard will enable the consistent recording and sharing of key information:

- that the health and care team need to know about the person's diabetes to support the person; and

- information that the person records and wants to share with their health and care team.

This stage covers standardised recording of information about a person's diabetes in IT systems across primary, secondary, social care and community settings.

Technical specifications are in progress with NHS Digital which, through a further release of DAPB4085, will allow providers and their systems to be able to share this information between IT systems in a standardised way in the future.

This High Level Implementation Guidance is to be read alongside documents outlined in Section 1.3 of the DAPB4085 Diabetes Record Information Standard Requirements Specification.

2. Implementation checklist

The following is a sequence of steps, set out to help organisations understand the implementation process, enabling them to ask the right questions and engage with the right people within their respective organisation.

Step 1: Read the Information Standards Notice (ISN)

This is the official notification of the information standard, published by the Data Alliance Partnership Board (DAPB). It provides an outline of the approved standard and timeframe for compliance.

NB: Compliance with information standards will normally be included in contracts between NHS Providers and their system suppliers; review your existing contracts with system suppliers to confirm this is the case.

Step 2: Read the Diabetes Record Information Standard documentation

Documents (High Level Implementation Guidance and the Requirements Specification) will be hosted on the DAPB web page and will be linked to from the PRSB web page.

The PRSB hosts the information models (version 1.0) which provide a detailed description of the diabetes record information standard including explanations about the data items and values that can be recorded. There are two information models: one for the diabetes record and one for diabetes self-management information. The self-management information is a subset of the diabetes record and is designed for medtech and app suppliers providing systems that enable self-management data to be recorded, to understand how the data should be exposed so that it can be imported by record systems.

The information models include detailed implementation guidance at Section and data item (Element) level primarily for IT system suppliers and providers implementing the standard. The implementation guidance for the self-management information model is designed to support the recording of self-management information so that it can be shared with record systems whereas the implementation guidance for the diabetes record information model covers recording in any setting.

Further guidance on the Sections and Elements in the information models that may be relevant to specific situations e.g. a child's record or data sharing from Continuous Glucose Monitors is available on the PRSB web page along with further supporting materials including the clinical safety case and examples. This will be updated as more situations are considered during testing and piloting.

In the future, release notes for updates to the standard will be available. These should be read alongside the information models.

Step 3: Familiarity with the Core Information Standard (CIS)

It is highly recommended that providers are aware and familiar with the PRSB Core

Information Standard (CIS) which underpins shared care records. The Diabetes Record Information Standard is based on the CIS which means that many components of the CIS, such as medications, allergies, demographics, have been reused. This is to ensure that the information is structured in the same way across systems and therefore can be shared between systems. Some extensions have been developed for key diabetes information such as structured education, diabetic eye screening, insulin dosing and glucose metrics.

The Sections of CIS most relevant for diabetes are listed below:

- About me
- Care and support plan (also part of the PCSP)
- Contingency plans (also part of the PCSP)
- Additional support plans (also part of the PCSP)
- Problem List
- Social Context
- Medications and medical devices
- Investigation results
- Examination findings and observations
- Assessments
- Admission details
- Pregnancy status
- Vaccinations

Detailed descriptions and specifications supporting implementation of the PRSB Core Information Standard are hosted on the PRSB web page.

Step 4: Read the Personalised Care Support Plan (PCSP) Standard documentation and About Me standard

It is highly recommended that providers are aware and familiar with the PRSB Personalised Care and Support Plan (PCSP) Standard and the PRSB About Me Standard. In future when an individual's PCSP is available to all who need to access it (both read and create/update), health and care professionals caring for a person with diabetes may be able to contribute to a single holistic plan covering goals and actions related to multiple co-morbidities. However, until then, the Care and support plan Section (and Contingency plans and Additional support plans Sections) from the PCSP are used in the Diabetes Record Information Standard for recording the person's strengths, needs, goals, actions and activities in a structured way, meaning these are done in the same person-centred way as they are for personalised care and support planning.

Detailed descriptions and specifications supporting implementation of the PRSB Personalised Care and Support Plan are hosted on the PRSB web page.

The About Me standard is included in the diabetes standard. Additional information to

support the implementation of the standard can be found on the PRSB web page.

Step 5: Discuss with current IT systems suppliers

If commercial systems are in use, discuss with the suppliers to confirm the timescale for any necessary changes to the system. In most cases these changes will be part your Service Level Agreement (SLA). Ensure any future SLAs, via re-procurement or contract refreshes etc, cover adherence to ISNs impacting your service.

Discussions with systems suppliers should help inform subsequent steps.

Where an in-house solution is in place, discussions need to start early to ensure all changes can be incorporated within the implementation timetable.

Step 6: Stakeholder engagement

It is essential to engage with those who are involved in collecting, recording, using and sharing the data items detailed within DAPB4085. This includes health and care professionals and people with diabetes and their carers.

Step 7: Check current state of readiness

Providers should check the current state of readiness for implementation of the information standard. This includes (but is not limited to):

IT Systems (Software)

- Many of the data items (Elements) in the information models may already be recorded electronically and structured as defined in the information models.
- Check what changes are required to comply with the new standard. For example, does the IT system require any additional fields for capturing or displaying data?

It is recommended that providers identify whether:

- There are any changes required to clinical/business processes in order to implement DAPB4085.
- There are any additional training needs for health and care professionals to be able to implement and use DAPB4085.
- There are any changes for people with diabetes (and their carers) related to the information that they may choose to digitally share with their health and care team and, therefore, whether specific engagement and communication is needed to implement and use DAPB4085.

Step 8: Plan implementation

Each provider’s approach to implementation may vary to suit their individual

circumstances. At a high level, the following factors should be considered when assessing and enacting any business change:

- Scope of change
- Finance
- Change governance
- Change manager requirements
- Change resource requirements
- Timescales
- Key milestones
- Benefits
- Training requirements/resource
- Key stakeholder engagement
- Key risks/barriers to change
- Success measures.

3. Implementation plan

Compliance with Version 1.0 of DAPB4085 will follow a phased approach from March 2023.

PRSB standard and DAPB information standard

As outlined in Section 1.3 of the requirements specification, DAPB4085 comprises the High Level Implementation Guidance (this document) and the Requirements Specification. They are published on the DAPB website.

The PRSB standard comprises the information models (version 1.0) and associated detailed implementation guidance.

There are two information models for:

- the diabetes record; and
- diabetes self-management information

They are published on the PRSB website.

Dates by which providers **should** be compliant with the information standard have been set out below in addition to dates by which providers **must** be compliant. The timescales take into account the wide range of providers involved in the care of people with diabetes and their wide-ranging record systems, digital maturity and funding. Work with pilot sites will be used to gather learning which will be shared to support others with implementation and will inform the final compliance dates.

The implementation will be phased to incorporate the flows of diabetes information using standardised messages (using FHIR, the NHS messaging standard) at a later stage.

Phase 1 is compliance with the diabetes information models for the standardised recording of information. This will support health and care professionals working with people with diabetes with systems to create, edit and view records to support their work. Where there are existing flows of this information between systems, these are expected to continue, and where new flows of information are planned, the interfaces used should align to the diabetes information models.

Phase 2 (to be defined in a revised ISN) is standardised sharing of information using FHIR messaging. Details and dates for phase 2 will be provided when they are available in the revised ISN.

The implementation timetable is:

Action	Date
Communicate the DAPB4085 standard (this standard) to providers	March 2023

Action	Date
Work with pilot sites	January 2022 – September 2023
Phased compliance schedule	
Phase 1a: Primary care	**Should** be compliant by March 2024 **Must** be compliant by March 2025
Phase 1b: Secondary and community care (including mental health, ambulance and urgent and emergency care)	**Should** be compliant by June 2024 **Must** be compliant by June 2025
Phase 1c: Social care (including care homes (nursing and residential) and hospices)	**Should** be compliant by September 2024 **Must** be compliant by September 2025
Phase 2: Will be defined in an update to this ISN	TBD

It is envisioned that the work with pilot sites (above) may result in additional guidance that will be incorporated within the PRSB implementation guidance or other supporting materials from April 2023 onwards.

The DAPB information standard is a DAPB approved standard under the Health and Social Care Act. The PRSB standard that this standard refers to provides the information models and detailed guidance for those implementing this standard. It is approved under its own governance and future releases of the PRSB information model for use in this standard will require DAPB approval.

NB – The timescales for the next release of DAPB4085, in terms of detailing the mechanism of interoperability; ISN publication; and provider implementation, are currently to be defined. It is possible that specific data flows may be required in later releases of DAPB4085.

3.1. Support and maintenance

Where additional advice in implementing the standard is required, please contact the PRSB support service at support@prsb.org. The PRSB is responsible for managing any updates to the information models and implementation guidance document through established assurance processes and release cycles (see Section 7 below) at the PRSB and DAPB. If possible, please include "Diabetes Record Information

Standard ISN" in the subject header of your message so that it can be identified appropriately.

Maintenance releases for PRSB standards are currently planned for 3-year cycles, however these may be updated on a more regular basis based on need and clinical and professional review. Issues raised may also affect the date for future releases.

The above email address can also be used should you have any suggested enhancements or amendments to any aspect of this standard. The management of such items is summarised in Section 7.1, below.

4. General guidance for PRSB standards

4.1 The structure of PRSB standards

PRSB record standards are organised into Sections made up of several Elements (data items), with Record Entries and Clusters (sub-Sections) to support repeated sets of information and grouping of data items.

The set of rules and instructions governing the type of information expected within a Section, Cluster, Record Entry and Element and how it is communicated is defined in the information model under the titles of Description, Cardinality, Conformance and Valuesets.

The PRSB information model structure and rules are explained in Table 1 and the annotated example below.

Information Components	Model Description
Section	A Section groups together all the information related to a specific topic e.g. 'Medications and medical devices' and 'Person demographics'. It is the highest level to logically group data Elements that may be independent or related. For example: - 'Legal information' includes a set of independent Elements or data items, grouped in a logical Section. - 'Medications and medical devices' includes sets of related Elements with dependencies between the Elements to create a full set of information about a medication or device.
Record Entry	A Record Entry within a Section is typically used where a set of information is repeated for a particular item, and there can be multiple items. For example, for each medication there is a set of information associated with that medication. Other examples are allergies or adverse reactions and procedures. A Record Entry has contextual information associated with it. The data model for the context information is determined by the Information Type of the Record Entry. There are two information types used: "Record" and "Event.Record". For "Record" entries, the provenance data includes the author of the data, and the time it was recorded. For "Event.Record" entries, it

Information Components	Model Description
	details of the performer of the event, the location, and the time the event happened in addition to the author.
Cluster	This is a set of Elements put together as a group and which relate to each other; e.g. medication course details Cluster which is the set of Elements describing the course of the medication.
Element	The data item. An Element can appear in one or more Sections e.g. medication name and date.

Information model rules and instructions	Explanations
Description	This is the description of the Section, Record Entry, Cluster or Element. For an Element, it describes the information that the Element should contain in plain English.
Cardinality	Each Section, Record Entry, Cluster and Element will have a statement of cardinality. This clarifies how many entries can be made i.e. zero, one or many entries. The number of entries expected and allowed are displayed as: 0…* = zero to many entries are allowed 0…1 = zero to one entry is allowed 1…1 = one entry is expected 1…* = one to many entries are expected For example, the 'Medications and medical devices' Section may have zero to many medication item records in it and is displayed as 0… *.
Conformance	Conformance defines whether the information is 'mandatory', 'required' or 'optional' and applies to Sections, Record Entries, Clusters and Elements. The following set of rules apply to enable implementers to cater for the requirements of the end users of the information: ❖ **Mandatory** – the information must be recorded or shared ❖ **Required** – if it exists, the information must be recorded or shared ❖ **Optional** – a local decision is made as to whether the information should be recorded or shared These rules apply at all levels and give the flexibility to allow local clinical or professional decisions on some information that is recorded or shared, while being clear on what is important information. For example, a person subject to a referral may have many assessments, but not all of these will be relevant to the referral. The conformance can be used to allow just relevant assessments to be shared with the referral.

Information model rules and instructions	Explanations
	Assessment Section – Required – i.e. it is important information you must share assessments if they have been recorded. Record entry level – Optional – allows a local decision on which assessments are shared, so only relevant ones are included based on clinical or professional needs. Assessment Elements – Conformance set on the normal basis of which Elements for an assessment are mandatory, required or optional. **NB:** It is permitted to upgrade a conformance rule but not to downgrade one. For instance, a Section that is classed as optional in the standard can be upgraded to required or mandatory in local implementations. However, one that is classed mandatory or required cannot be downgraded to required or optional.
Valuesets	Valuesets describe precisely how the information is recorded in the system and communicated between systems. This is required for interoperability (for information to flow between one IT system and another). The information can be text, multi-media or in a coded format. If coded it can be constrained to SNOMED CT and specific SNOMED CT reference sets, NHS Data Dictionary values or other code sets.

Table 1: PRSB information model structure

In the annotated example shown below for Allergies:

- The standard has a Section for ‘Allergies and adverse reactions’, its conformance is ‘mandatory’ and the cardinality is ‘1 only’ (or 1...1) i.e. there must be just one allergies Section
- It has a Record Entry to allow for multiple allergies, which is also ‘mandatory’ so with a cardinality of 1 to many (or 1...*). The Record Entry contains a set of Elements, i.e. the set of information for each allergy and there must be at least 1 Record Entry.
- The Record Entry also includes a Cluster (reaction details Cluster), which groups the reaction details together.
- Each Element has a description, conformance, cardinality and valueset. e.g. Causative agent, which is mandatory with a cardinality of 1 only (or 1…1) and a valueset with two options, coded value with a constrained set of SNOMED codes (including an option for “No known allergy”) or free text if coded values are not available. Other Elements are required in this example i.e. the set of information for each allergy or adverse reaction must have a causative agent, and where available should have the other information such as reaction details, substance, severity etc.

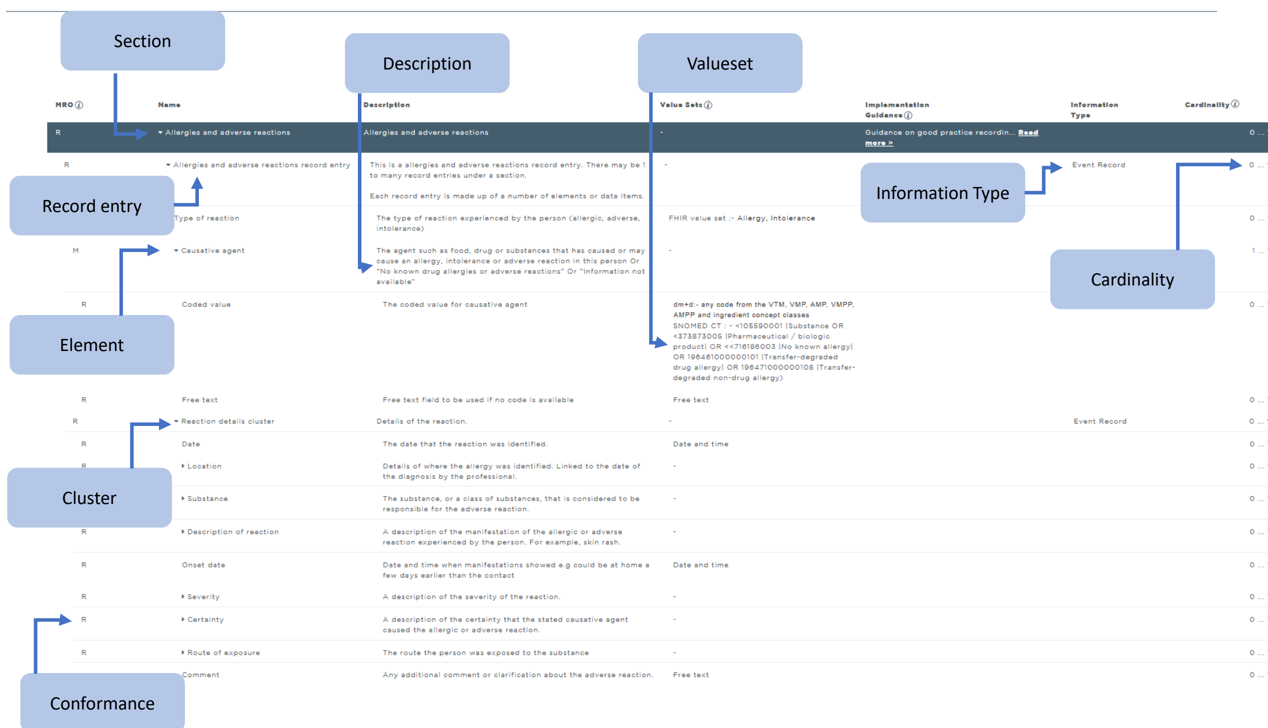

Figure 1: Diagram showing key terms used in the DAPB4085 standard with the example for allergies and adverse reactions (from the PRSB Diabetes Information Standard)

4.2 Context of the information

It is vital for use of the data that all contextual information is maintained and should not be lost on exchange or import of information. For example, if a frailty assessment was undertaken at the care home two days before the individual was admitted to hospital, it is important that the full context of the information is known (where and when the assessment was done and by whom).

The principle, for PRSB standards, is that for clinical safety and efficacy of communications, the following key contextual data should be shared where specified by the "Information Type" of the Record Entry in any PRSB standard (see Figure 1 above):

- **Performing Professional** - is the person who performed the activity for example conducted the procedure, assessment etc. It has various attributes that are expected to be completed, name, role, specialty, organisation of the professional. If the professional is not known but the organisation and specialty are known they should be included as contextual information. In some situations, the action or event may be performed by the patient or a device. In these situations, a Performing Person or Performing Device may be recorded. Alternatively, a more generic "Performer" may be specified with the same content model as "Performing Professional".

- **Location** – the place in which the activity took place e.g. observations were made.

- **Date** - the date on which the activity took place e.g. the assessment was performed.

- **Author** - is the person, device or application that recorded the information and has various attributes; name, role, speciality and organisation and the date the record was completed. This is expected to be automated and linked to audit trail (see Section 4.3).

Note that although 'Professional' contains the Element 'speciality' it is recognised that this only applies to some professionals so only needs to be included where relevant.

The principle applied in the information model is that where it is important (from a professional perspective) to know who undertook the activity and who recorded the activity, an Information Type of "Event.Record" or "Record" is included in the information models. For every item of information shared it is important that an audit trail is recorded (even if not explicitly stated in the information model). This is set out below.

The provenance information model is available on the PRSB website.

4.3 Time stamp and audit trail

It is important that an audit trail is recorded for every item of information recorded or shared (even if not explicitly stated in the information model).

Each Record Entry will need to be time stamped from the source system with date and time recorded and the identity of the person (or device) making the record. This needs to be viewable in the records themselves where appropriate and via a full audit trail which may be viewable by the end user to enhance transparency.

4.4 PRSB reference library

The content of DAPB4085 is based on a reference library of components used for all PRSB standards, maximising reuse of existing components and ensuring consistency across standards to support interoperability between records, systems, professionals and people.

4.5 SNOMED CT

This standard uses SNOMED CT coding where appropriate. Where this is not appropriate, national coding from the NHS Data Model and Dictionary has been used. The supplier systems must be compliant with the SNOMED CT codes set out within the information models.

Compliance is based on the scope of the standard SNOMED CT SCCI0034.

Further information on SNOMED CT, including mapping to and from other clinical terminologies, can be found in the SNOMED CT Editorial Guide.

4.6 Format

If national codes have been defined, then the format will match that of the NHS Data Model and Dictionary; this will be shown in the “Valuesets” column. The field describes the valid formats that will be accepted for this data item. For dates and times, it specifically refers to the exact formatting. For other data items it describes the data type required and the max/min field lengths.

For the majority of data items, SNOMED CT is permitted as well as a free text option for those who are not yet SNOMED CT compliant.

4.7 National codes

If no SNOMED CT codes have been identified, then certain Elements provide a list of the valid formats that will be accepted for this data item (if there are any). For example, a field may only allow values of "Y", "N" and "X", which equate to "Yes", "No", "Don't Know".

For ease, the information model contains hyperlinks to referenced Data Dictionary formats in columns: “National Codes (if applicable)” and “National Description (if applicable)”.

4.8 Free text fields

Free text will be available where there is a clear clinical requirement. It is also appreciated that many systems are not yet compliant with SNOMED CT and so the ability to use free text where SNOMED CT is not available has often been allowed.

Free text field size will be appropriate to support the clinical requirement. All free text documentation should be completed in accordance with professional record keeping standards, being clear and accurate.

4.9 Use of terms

The term ‘role’ has been consistently used rather than ‘designation’ throughout PRSB standards to apply to the role the professional had in an activity. It is the term used in the NHS Data Dictionary.

The term ‘organisational role’ means the role the professional has in their employer organisation.

Some Clusters such as referrer details have Elements for one or more of specialty, team, service and department. This is to allow for all situations across health and care where different terms are required. Where possible specialty and service should be used and coded as detailed in the Valueset for the Element.

4.10 Dependencies

The implementation of PRSB information standards is often dependent on the following:

- The national and local Information Governance frameworks which will determine information access and sharing controls and legitimate relationships between health and care provider organisations.
- Technical standards e.g. FHIR APIs (to support the standardised transfer of information between systems).

4.11 Data quality

Data quality and accuracy of coded data entry should be managed in local 'source' systems to ensure that information shared with people and professionals through other systems is accurate and complete.

5. Clinical safety

We recommend system suppliers and local implementers apply further risk mitigations when implementing PRSB standards by addressing the risks that have been flagged in the clinical safety case report and hazard log for each standard. Suppliers and implementors should aim to reduce the risk scores to 2, or better, when carrying out clinical risk assessments and developing safety cases for their implementations with respect to DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems and DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems.

As more practical implementation issues may vary from provider to provider, it is recommended that all providers implementing the PRSB standards must still follow their local clinical safety processes to assess the local impact.

6. Information governance

Sound principles of information governance and respecting the privacy of people and their information is paramount. NHS England has published Information Governance guidance which needs to be considered when planning implementation.

Local agreements should be drawn up between organisations to define information requirements for communication.

As more practical implementation issues may vary from provider to provider, it is recommended that all providers implementing the PRSB standards must still follow their local information governance and security review processes to assess the local impact.

7. Future changes

7.1 Release cycles and governance

DAPB4085 will be enhanced as necessary based on need. Enhancements could be based on further clinical requirements, clinical safety feedback, technical feedback from Subject Matter Experts or supplier implementation findings, for example.

The DAPB4085 information standard (including guidance) provides the structure and content for a diabetes record; the Sections and Elements of the information models define what information should be recorded and made available to health and care professionals. The need for standardising sharing of data flows will be considered in a later version of DAPB4085.

Throughout the implementation process, any lessons learned and feedback from implementers will be documented and used to influence future releases.

A formal log will be maintained and managed by the PRSB to analyse, assure and prioritise any enhancements or amendments elicited from the feedback channels detailed above. The information standard will follow a three-yearly release cycle by default. Ongoing feedback and review will take place throughout the implementation period through the PRSB support service. All feedback is reviewed on a quarterly cycle, and it is possible that enhancements are made to DAPB4085 as a result of the assessment of the feedback on a regular basis.

8. Full links for referenced resources

1. DAPB4085 Diabetes Record Information Standard:

2. PRSB Diabetes Record Information Standard: https://theprsb.org/standards/diabetesstandards/

3. PRSB Core Information Standard: https://theprsb.org/core-information-standard-v2-0/

4. PRSB Personalised Care and Support Plan Standard: https://theprsb.org/standards/personalisedcareandsupportplan/

5. PRSB About Me Standard: https://theprsb.org/standards/aboutme/

6. Health and Social Care Act 2012: https://www.legislation.gov.uk/ukpga/2012/7/section/250

7. PRSB Support Email Address: support@theprsb.org

8. Provenance data standard: https://theprsb.org/standards/provenance/

9. SNOMED CT SCCI0034: http://www.digital.nhs.uk/isce/publication/scci0034

10. DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems: https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems

11. DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems: https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems

12. NHS England Information Governance: https://transform.england.nhs.uk/information-governance/