



Professional
Record
Standards
Body

DAPB4085 Diabetes Record Information Standard (DAPB4085 Amd 59/2022)

Requirements Specification 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.

Date of publication: 6 April 2023

Glossary of Terms

Term / Abbreviation	What it stands for
DAPB	Data Alliance Partnership Board
DAPB4085	The Diabetes Record Information Standard
FHIR	Fast Healthcare Interoperability Resource. A method for exchanging healthcare information electronically.
HL7	Health Level Seven® International (HL7®) is the global authority on standards for interoperability of health technology.
ISN	Information Standards Notice
PRSB	Professional Record Standards Body
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. Introduction

The number of people living with diabetes in the UK is estimated at 4.8 million (including approximately 1 million that do not know they have it) and is expected to rise to 5.3 million by 2025. Ninety percent of those are living with type 2. Uncontrolled diabetes can lead to serious health complications like heart disease, stroke and kidney failure.

As the number of people with diabetes is so large and expected to rise rapidly, the [NHS Long term plan \(January 2019\)](#) sets out accelerated 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.

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.

In March 2019, NHS England published national arrangements outlining that all people with type 1 diabetes in England would be offered flash glucose monitors and at least 34% of the type 1 population now have one. 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. Recently NICE has updated guidelines expanding the cohort of people entitled to devices to help them to manage their diabetes.

For health and care staff to advise and support a person with the self-management of their diabetes they require access to information about the person's diabetes and related conditions. This information isn't always available to those that need it, when they need it. For example:

- information recorded by community nurses or podiatrists is not always available to GPs or hospital doctors
- information such as latest HbA1c test results is not always shared across systems (which can mean that a person is asked back for repeat tests)
- eye screening data is available to the GP but not the hospital team
- self-management data recorded in medical devices (such as continuous glucose monitors) cannot be easily shared with the health and care team

The PRSB was tasked by NHS England with standardising information recorded for the management of a person's diabetes so that it can be shared across care settings with those involved in the care and support of the person.

The purpose of the standard is:

- To set out the information that is needed by the health and care team to advise and support a person with diabetes to manage their diabetes. (This

includes information that may be recorded by the person for self-management.)

- To set out how this information should be recorded in a consistent way so that it can be shared across care settings and between IT systems.
- In the future, information recorded as part of routine care aligned to this standard could be extracted to support both population health management and the National Diabetes Audit (NDA) and National Paediatric Diabetes Audit (NPDA). This would be set out in a separate Information Standards Notice.

The development involved consultation with health and care professionals, people with diabetes (and their carers) as well as IT system and medtech suppliers. The final report of the development as well as other supporting documents to aid implementers are available on the [PRSB's web page](#).

This first version (v1.0) of the Data Alliance Partnership Board (DAPB) approved Information Standard (DAPB4085 Amd 59/2022) which has been approved for publication by the Department of Health and Social Care under [section 250 of the Health and Social Care Act 2012](#) is to mandate the use of the [PRSB Diabetes Record Information Standard \(version 1.0\)](#). This will prepare providers and their systems to be able to share information by standardising the recording of information. Standardised sharing of the information will be facilitated through a further release of DAPB4085.

1.1. Purpose

The purpose of this document is to detail the requirements for providers and their IT system suppliers to implement DAPB4085 (this standard). This will prepare providers and their systems for standardised sharing of the information in the future via mechanisms currently under development by NHS England, for example using HL7 FHIR messages. The requirement for standardised sharing will be included in an update to this standard.

This document provides the specification of the [PRSB Diabetes Record Information Standard version 1.0](#).

NHS England commissioned the PRSB to develop the standard into a DAPB approved information standard.

Through this application, the standard will be referred to hereafter as DAPB4085 (DAPB Diabetes Record Information Standard). Please see section 1.3 which describes the key documents required to implement DAPB4085.

1.2. Definitions

It is important to understand the key terms used to describe the data hierarchy of the information models for PRSB standards. Details are provided in the High Level Implementation Guidance document which is also part of DAPB4085.

1.3. Supporting documents

Supporting documents for DAPB4085 include:

- DAPB4085 Diabetes Record Information Standards Notice (ISN)
- DAPB4085 Diabetes Record Information Standard Requirements Specification (this document)
- DAPB4085 Diabetes Record Information Standard – High Level Implementation Guidance
- PRSB Diabetes information models (v1) and associated detailed implementation guidance which are hosted and maintained on the [PRSB's web page](#).

PRSB items

The following items will be published on the PRSB website.

Document Name	Purpose
PRSB Diabetes information models v1	Provides the information models setting out the detailed content and structure needed for a provider to implement the standard. Provides the SNOMED CT codes for the information models. Includes detailed implementation guidance at Section and Element level. There are two information models : 1. the diabetes record; and 2. diabetes self-management information
PRSB Diabetes Record Information Standard Clinical Safety Case Report	Details the hazards identified for the standard along with mitigations for use by IT system suppliers and implementors in their implementations and their own safety cases.
PRSB Diabetes Record Information Standard Final Report	Describes the development of the standard including the methodology, stakeholder consultation, findings, conclusions and recommendations.

Please note that additional supporting documents may be added to the [PRSB website](#) over time as a result of feedback from implementation.

DAPB items

The following items comprise the DAPB information standard and will be published on the [DAPB website](#).

Document Name	Purpose
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DAPB4085 Information Standards Notice Amd 59/2022	The Information Standards Notice provides confirmation of the standard details, implementation date, whether it is mandated or voluntary, the legal or contractual basis upon which the data are being requested and details of key contacts.
DAPB4085 Diabetes Record Information Standard High Level Implementation Guidance v1.0	Provides high level guidance and context to providers involved in care planning on the implementation of DAPB4085 (this information standard).
DAPB4085 Diabetes Record Information Standard Requirements Specification v1.0 (This document)	Details the requirements for providers involved in caring and supporting people with diabetes and their system suppliers to implement DAPB4085.

1.4. Scope

This information standard defines the fields (structure) needed for implementation of a diabetes record through:

- The [PRSB Diabetes information models v1](#) with detailed implementation guidance.

The obligations to providers and their IT system suppliers to comply with these requirements when implementing DAPB4085 are presented through:

- The DAPB4085 Information Standard Notice
- The DAPB4085 Diabetes Record Information Standard Requirements Specification v1.0 (this document)
- The DAPB4085 Diabetes Record Information Standard High Level Implementation Guidance v1.0.

[Note: the obligations do not apply to health and care professionals within provider organisations.]

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 website](#). This will be updated as more situations are considered during testing and piloting.

This release of DAPB4085 (this information standard) applies to the implementation of the PRSB Diabetes information models (v1). There are two information models for:

1. the diabetes record; and
2. diabetes self-management information

They are published on the [PRSB website](#).

The diabetes self-management information model is a subset of the diabetes record information model but with slightly different information guidance specific to recording

self-management information.

The scope of DAPB4085 (this information standard), with regards to providers and their respective levels of compliance with the PRSB Diabetes information models (v1) is as follows:

- **Phase 1:** All health and care staff involved in the care of someone with diabetes should have the capability to record information in conformance with the diabetes information models. The requirements are set out in section 2 below.
- **Phase 2:** (to be defined in a revised ISN) is expected to include the ability to send and receive information in a standardised way using technical standards.
- The implementation and compliance for phase 1 will be further phased to take account of the range of providers involved in the care and support of a person with diabetes and their wide-ranging record systems, digital maturity and funding. Details of the phasing are defined in the DAPB4085 Diabetes Record Information Standard High Level Implementation Guidance v1.0.

(NB – the terms “MUST”, “SHOULD” and “MAY” are defined in section 2.1, below).

- All service providers involved in the care and support of people with diabetes **MUST** conform to this information standard including:
 - Ambulance services
 - Care homes (nursing and residential)
 - Community-based services
 - General Practice
 - Hospices
 - Acute care services
 - Mental health services
 - Urgent and emergency care

This information standard (DAPB4085 Amd 59/2022) will impact:

- All health and care IT systems suppliers providing information and systems used by health and care staff to provide care and support for people with diabetes.

The above scope is the result of guidance from clinical, technical and governance subject matter experts.

1.5. Implementation plan

Compliance with Version 1.0 of DAPB4085 will be phased from March 2023. Details about the phasing are provided in the DAPB4085 Diabetes Record Information Standard High Level Implementation Guidance v1.0.

PRSB standard and DAPB information standard

As outlined in section 1.3 above, the DAPB4085 standard includes the Requirements Specification (this document) and the High Level Implementation Guidance document. They are published on the [DAPB website](#).

The PRSB standard (which is referenced by this information standard) comprises the Diabetes information models (version 1.0) including detailed implementation guidance. They are published on the [PRSB website](#).

The implementation plan is provided in the DAPB4085 Diabetes Record Information Standard High Level Implementation Guidance.

1.6. Support and maintenance

Where additional advice in implementing DAPB4085 is required, please contact the PRSB support service at support@theprsb.org. The PRSB is responsible for managing any updates to the information models and implementation guidance through established assurance processes and release cycles 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 the DAPB information standard.

1.7. Related standards

It is highly recommended that providers are aware of the [PRSB Core Information standard](#), which defines the minimum content for shared care records, the [PRSB Personalised Care and Support Plan Standard](#) and the [PRSB About Me Standard](#) which were used in the development of the Diabetes Record Information Standard. Please note that this information standard does not mandate compliance with PRSB’s Core Information Standard, Personalised Care and Support Plan Standard or About Me Standard. More details about the relevance of these standards are provided in the DAPB4085 High Level Implementation Guidance Document v1.0.

2. DAPB4085 Diabetes Record Information Standard requirements

2.1. Requirements definition

This document defines the specification that health and care providers (termed the PROVIDER), need to work with their suppliers of IT systems (termed the SYSTEM) to implement the requirements of DAPB4085 Diabetes Record Information Standard Notice (STANDARD).

NB: the onus is on PROVIDERS to instruct their SYSTEM suppliers to comply with the STANDARD via their local contracts.

The requirements within this specification are assigned levels using the following terms:

MUST - This word, or the term "SHALL", mean that the definition is an absolute requirement of the specification.

SHOULD - This word, or the adjective "RECOMMENDED", mean that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

MAY - This word, or the adjective "OPTIONAL", mean that an item is optional. One provider may choose to include the item because their local processes require it or because they feel that it enhances the product, while another provider may omit the same item.

2.2. Provider requirements

Reference	Requirement
P01	Providers MUST read the Requirements Specification (this document) in conjunction with the DAPB Diabetes High Level Implementation Guidance, PRSB Diabetes information models (version 1.0) including detailed implementation guidance.
P02	Providers MUST review their system compatibility against this standard to identify any changes required to current practice and systems to ensure compliance with this standard.
P03	Providers MUST ensure that where their current system enables recording of information that is included in the PRSB Diabetes information models (including implementation guidance), version 1.0 , it is recorded in conformance with the information models. This may require the system to be updated.
P04	It MUST be possible to validate any mandatory items at the point of data entry to prevent a user from not recording mandatory information.
P05	Providers SHOULD provide adequate training for all staff involved in collection and recording of this data.

Reference	Requirement
P06	Where there are suggested changes to either the PRSB Diabetes information models, or implementation guidance, the provider SHOULD contact the PRSB support and maintenance service.
P07	Providers MUST have ensured that supplier organisations are compliant with 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 .
P08	Providers MUST ensure that any new flows of information between systems comply with the PRSB Diabetes information models (including implementation guidance), version 1.0 .

2.3. IT system requirements

NB: the onus is on PROVIDERS to instruct their SYSTEM suppliers to comply with the STANDARD via their local contracts.

Reference	Requirement
ITS01	The system MUST support the implementation of a relevant information governance and privacy model that meets local and national requirements as detailed in NHS England's Information governance guidance .
ITS02	The system supplier MUST be compliant with 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 .
ITS03	The system MUST be able to protect the gender identity of transgender persons. The person's Sex (phenotypic) and Gender (self-reported) must be displayed in a way that does not inadvertently reveal protected information.
ITS04	Where information, included in the PRSB Diabetes information models (including implementation guidance), version 1.0 , is recorded in the system, the system MUST enable the recording in conformance with the information models.
ITS05	Where the system is used by a health or care professional, it MUST offer configurable viewing of the information as per the provider's internal workflow requirements.
ITS06	For any new flows of data, the system MUST enable the exposure (for importing by other systems) and import of diabetes information in conformance with the PRSB Diabetes information models (including implementation guidance), version 1.0 .
ITS07	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 importing by other systems.

Reference	Requirement
ITS08	Where the system uses terminology products, it MUST conform to regular updates of terminology releases.
ITS09	The system MUST ensure that the provenance of the information is recorded and visible. For each activity performed by a professional (or person or device) the performer, the date, time and the location MUST be recorded and stored. The PRSB provenance information model provides guidance on this.
ITS10	The system MUST ensure that when information is recorded, the author (a professional, person or device) and date is recorded and stored. The PRSB provenance information model provides guidance on this.
ITS11	There MUST be a full audit trail maintained of changes to the information (including strikethrough) which MUST include date, time, and the author (which could be a professional, person or device/application).
ITS12	It MUST be possible to view the audit trail in the records where appropriate.
ITS13	The interface MUST be compliant with NHS England's Accessible Information (AIS) standard .
ITS14	Where changes are made to how a user interacts with the system (for example the user interface) the IT system supplier SHOULD produce appropriate guidance to be made available to the health and/or care organisation.
ITS15	The system SHOULD use the Patient Demographic Service (PDS) as the source of GP practice information where available.
ITS16	The system SHOULD use the Patient Demographic Service (PDS) as the source a person's demographic information where available.
ITS17	Where blood glucose measurements are available as a mixture of laboratory test results, Point of Care test results and patient self-reported results (including from connected devices) it MUST be easy to distinguish between the different types of results with the source of data clearly indicated.
ITS18	The volume of blood glucose Point of Care test results and self-reported data MUST not cause other test results to be difficult to view in the system.
ITS19	Summary metrics and trends SHOULD be used to present large volumes of glucose measurements and insulin administration data.

Reference	Requirement
ITS20	The device type, manufacturer and model used for a measurement or action MUST be easily visible when viewing data from a glucose or ketone monitoring or insulin delivery device.
ITS21	Data recorded using a connected device MUST be easily distinguished from data that has been manually entered (including data transcribed from a device).

2.4. Provider and IT system conformance criteria

This section describes the tests that can be measured to indicate that the information standard is being implemented correctly.

Reference	Criteria
PITSCC01	<p>Providers have read the following documents:</p> <ul style="list-style-type: none"> - DAPB4085 Diabetes Information Record Standard Requirements Specification (this document) - DAPB4085 Diabetes Information Record Standard – High Level Implementation Guidance - PRSB Diabetes information models (v1) including detailed implementation guidance <p>This relates to P01.</p>
PITSCC02	<p>The provider has reviewed the system and working practices to identify changes needed to conform with DAPB4085.</p> <p>This relates to P02.</p>
PITSCC03	<p>The provider has ensured that the where system supports the recording of information included in the PRSB Diabetes information models (including implementation guidance), version 1, it enables the recording in conformance with the information models. This relates to P03; P04 and ITS04.</p>
PITSCC04	<p>The provider has ensured that relevant staff can evidence that they have completed training on the use of the system to record and use the information set out in DAPB4085. This relates to P05.</p>
PITSCC05	<p>The provider has ensured that the PRSB is made aware of any suggested changes to either the PRSB Diabetes information models or the implementation guidance, through the PRSB support and maintenance service. This relates to P06.</p>
PITSCC06	<p>The provider has ensured that their system suppliers are compliant with the clinical safety standards DCB0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems and that the providers are compliant with DCB0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems. This relates to P07 and ITS02.</p>
PITSCC07	<p>The provider has ensured that the exposure or importing of diabetes information for any new information flows between systems comply with the PRSB Diabetes information models (v1). This relates to P08 and ITS06.</p>
PITSCC08	<p>The provider has ensured that the system supports the implementation of a relevant information governance/privacy model that meets local and national requirements. This relates to ITS01.</p>

Reference	Criteria
PITSCC09	The provider has ensured that the system protects the gender identity of transgender persons. The person's Sex (phenotypic) & Gender (self reported) must be displayed in a way that does not inadvertently reveal protected information. This relates to ITS03
PITSCC10	The provider has ensured their system supplier can offer configurable viewing of the record as per the provider's internal workflow requirements. This relates to ITS05.
PITSCC11	The provider has ensured that a system exposing summary glucose and insulin dosing metrics also exposes the underlying data for importing by other systems. This relates to ITS07.
PITSCC12	The provider has ensured their system supplier conforms to regular updates of terminology releases. This relates to ITS08.
PITSCC13	The provider has ensured that for each record entry, the system supplier allows provenance (specifically the performer, author, date and location details) to be recorded and stored. This relates to ITS09 and ITS10.
PITSCC14	The provider has ensured that the system allows for a viewable audit trail of information recorded, including time(s), date(s) and author(s). This relates to IT10; ITS11 and ITS12.
PITSCC15	The provider has ensured that the interface is compliant with NHS England's Accessible Information (AIS) standard . This relates to ITS13.
PITSCC16	The provider ensures that it has been made aware of any functional changes, by the system supplier, that may impact the recording of the information (for example user interface changes) and they provide appropriate support to the end users. This relates to ITS14.
PITSCC17	The provider has ensured that the system can link to the Patient Demographic Service (PDS) for demographic information and information about the GP practice where applicable. This relates to ITS15 and ITS16.
PITSCC18	The provider has ensured that where blood glucose measurements are displayed, it is easy to distinguish between the different sources (e.g. laboratory test results, Point of Care test results and patient self-reported results (including from connected devices)) and the source of data is easily identifiable. This relates to ITS17.
PITSCC19	The provider has ensured that the display of large volumes of blood glucose measurements does not obscure other test results. This relates to ITS18.
PITSCC20	The provider has ensured that summary metrics and trends are used to present large volumes of glucose and insulin data administration data. This relates to ITS19.

Reference	Criteria
PITSCC21	The provider has ensured that details of the device (type, manufacturer and model) are visible when viewing data from a device. This relates to ITS20.
PITSCC22	The provider has ensured that it is possible to distinguish between data recorded from a connected device and data manually entered. This relates to ITS21.

2. Full links for referenced resources

1. Health and Social Care Act 2012:
<https://www.legislation.gov.uk/ukpga/2012/7/section/250>
2. NHS Long Term Plan: <https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf>
3. DAPB4085 Diabetes Record Information Standard:
4. PRSB Diabetes Record Information Standard:
<https://theprsb.org/standards/diabetesstandards/>
5. PRSB Support Email Address: support@theprsb.org
6. PRSB Core Information Standard: <https://theprsb.org/core-information-standard-v2-0/>
7. PRSB Personalised Care and Support Plan Standard:
<https://theprsb.org/standards/personalisedcareandsupportplan/>
8. PRSB About Me Standard: <https://theprsb.org/standards/aboutme/>
9. 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>
10. 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>
11. NHS England Information Governance:
<https://transform.england.nhs.uk/information-governance/>
12. Provenance data standard: <https://theprsb.org/standards/provenance/>

13. NHS England Accessible Information Standard:

<https://www.england.nhs.uk/about/equality/equality-hub/patient-equalities-programme/equality-frameworks-and-information-standards/accessibleinfo/>

14. Patient Demographic Service (PDS): <https://digital.nhs.uk/services/demographics>