Professional Record Standards Body

Better records for better care

Digital Maternity Record Standard Release 2 General Implementation Guidance

July 2024

Document Management

Revision History

Version	Date	Summary of Changes
0.1	25-08-21	First draft as general “Guidance for all PRSB standards”
1.0	02.02.2022	First version after incorporating reviewer comments
1.1	25/05/2022	Updated for changes to how provenance data is held in PRSB information models
1.2	31/01/2023	Minor updates
1.3	27/03/2023	Minor update to Section 1.1
1.4	15/08/2023	Update to include new version numbering scheme
1.5	25/07/2024	Updated to add Section 3

Reviewers

Reviewer name	Title / Responsibility	Date	Version
Sandip Kaur	Architect	Sep-2021	0.1
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Approved by

Name	Date	Version
PRSB Task and Finish Group	May-2022	1.1

Glossary of Terms

Term / Abbreviation	What it stands for
DAPB / DCB / SCCI	Data Alliance Partnership Board, formerly Data Co-ordination Board and Standardisation Committee for Care Information. Acts on behalf of SoS health to approve health and care data and information standards
dm+d	Dictionary of medicines and devices
EPR	Electronic Patient Record
FHIR	Fast Healthcare Interoperability Resources
GMT	Greenwich Mean Time
GP	General Practitioner
HL7	Health Level 7
IT	Information Technology
Metadata	A set of data that describes and gives information about other data
MSDS	Maternity Services Data Set
NHS	National Health Service
NHSDD	NHS Data Dictionary
NHSE/ NHSEI	NHS England/ now NHS England Improvement
NICE	The National Institute for Health and Care Excellence
NRLS	National Record Locator Service
ODS	Organisation Data Service
PDS	Personal Demographic Service
PRSB	Professional Record Standards Body
SNOMED-CT	Systematized Nomenclature of Medicine - Clinical Terms

Contents

1 Introduction

1.1 Purpose of This Document

This document provides general guidance to support the implementation and use of all PRSB standards.

Specific implementation guidance for specific standards at section and element level is available as part of the information model for that standard.

In addition, each standard will have a safety case and hazard log developed and approved in accordance with the DCB0129: Clinical Risk Management standard. This guidance should be used in conjunction with section 0 Risk Mitigation.

1.2 Audience

This guidance is intended for anyone implementing and using PRSB standards. This will include health and social care professionals, IT system suppliers, developers, and implementors.

2 General Guidance

2.1 Structure of the PRSB Standards Explained

An information standard is organised into sections made up of several data (information) elements, with record entries and clusters (subsections) to support repeated sets of information and grouping of related 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 information items, grouped in a logical section. - 'Medications and medical devices' includes sets of related elements with dependencies between the elements.
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 person recording the data, and the time it was recorded. For “Event.Record” entries, details of the performer of the event, the location, and the time the event happened are also included in the provenance data.
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. name, 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 as plain English as possible.
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 records expected and allowed are displayed as: 0……* = zero to many record entries are allowed 0……1 = zero to one record entry is allowed 1……1 = one record is expected 1……* = one to many records 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 what information is ‘mandatory’, ‘required’ or ‘optional’ and applies to sections, record entries, clusters and elements. The IT system must be developed to handle all the information elements that are defined in the Standard but not all the information is required for every individual record or information transfer. The following set of rules apply to enable implementers to cater for the end users (senders and receivers) requirements: ❖ **Mandatory** – the information must be included

	❖ **Required** – if it exists, the information must be included ❖ **Optional** – a local decision is made as to whether the information is included These rules apply at all levels and give the flexibility to allow local clinical or professional decisions on some information that is included, while being clear on what is important information to include. 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 included. Assessment Section – Required – i.e. its important information you must include if you have it. Record entry level – Optional – allows a local decision on what assessments are included, 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 down grade 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 standard data structure

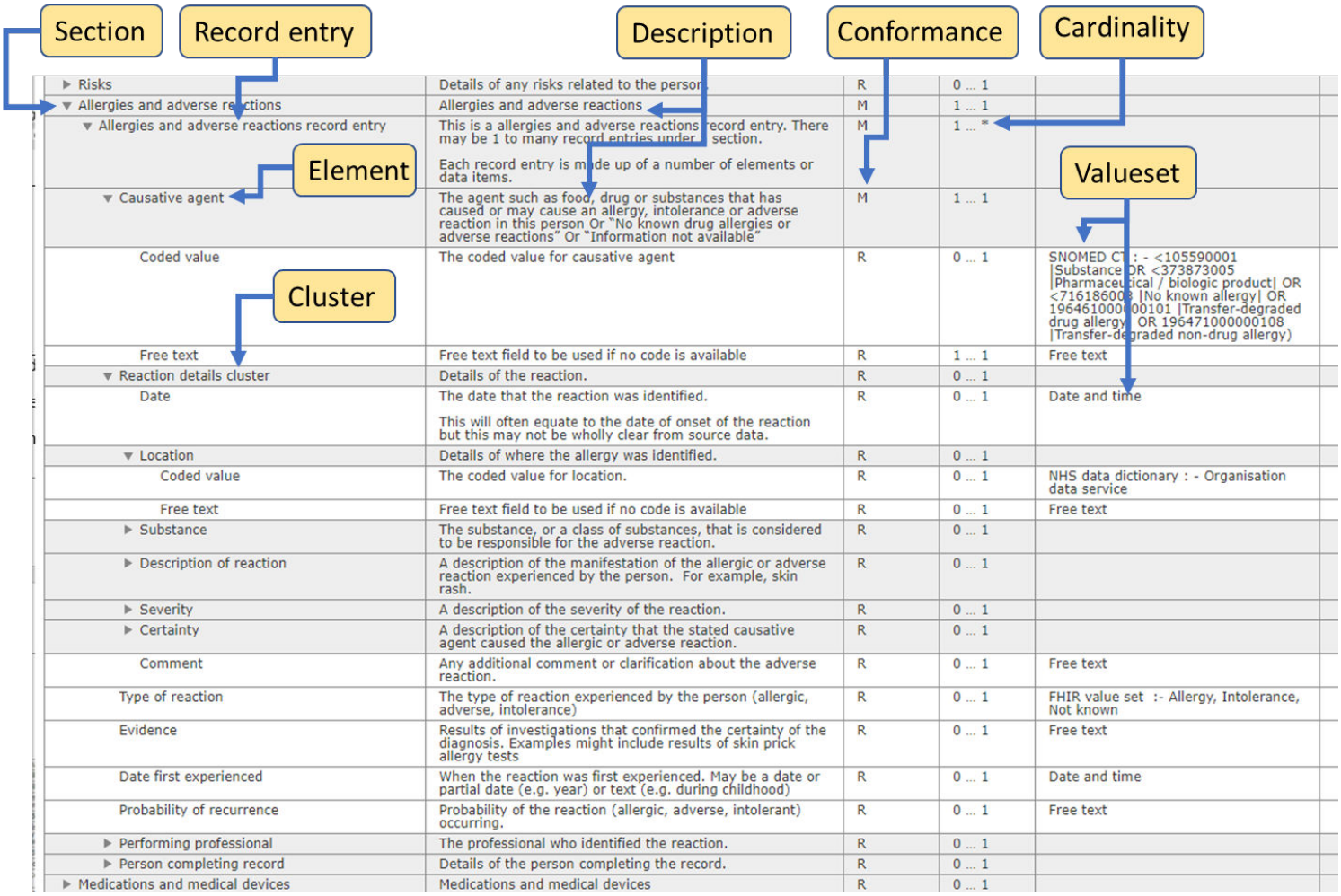
In the annotated example shown below for Allergies:

- The standard has a section for 'Allergies and adverse reactions', it's conformance is 'mandatory' and the cardinality is '1 only' (or 1...1) i.e. there must be just one allergies section

PRSB Methodology and Standards.pptx

- 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.



▶ Risks	Details of any risks related to the person	R	0 … 1	
▼ Allergies and adverse reactions	Allergies and adverse reactions	M	1 … 1	
▼ Allergies and adverse reactions record entry	This is a allergies and adverse reactions record entry. There may be 1 to many record entries under a section. Each record entry is made up of a number of elements or data items.	M	1 … *	
▼ Causative agent	The agent such as food, drug or substances that has caused or may cause an allergy, intolerance or adverse reaction in this person Or “No known drug allergies or adverse reactions” Or “Information not available”	M	1 … 1	
Coded value	The coded value for causative agent	R	0 … 1	SNOMED CT : - <105590001 |Substance OR <373873005 |Pharmaceutical / biologic product| OR <716186003 |No known allergy| OR 196461000000101 |Transfer-degraded drug allergy| OR 196471000000108 |Transfer-degraded non-drug allergy)
Free text	Free text field to be used if no code is available	R	1 … 1	Free text
▼ Reaction details cluster	Details of the reaction.	R	0 … 1	
Date	The date that the reaction was identified. This will often equate to the date of onset of the reaction but this may not be wholly clear from source data.	R	0 … 1	Date and time
▼ Location	Details of where the allergy was identified.	R	0 … 1	
Coded value	The coded value for location.	R	0 … 1	NHS data dictionary : - Organisation data service
Free text	Free text field to be used if no code is available	R	0 … 1	Free text
▶ Substance	The substance, or a class of substances, that is considered to be responsible for the adverse reaction.	R	0 … 1	
▶ Description of reaction	A description of the manifestation of the allergic or adverse reaction experienced by the person. For example, skin rash.	R	0 … 1	
▶ Severity	A description of the severity of the reaction.	R	0 … 1	
▶ Certainty	A description of the certainty that the stated causative agent caused the allergic or adverse reaction.	R	0 … 1	
Comment	Any additional comment or clarification about the adverse reaction.	R	0 … 1	Free text
Type of reaction	The type of reaction experienced by the person (allergic, adverse, intolerance)	R	0 … 1	FHIR value set :- Allergy, Intolerance, Not known
Evidence	Results of investigations that confirmed the certainty of the diagnosis. Examples might include results of skin prick allergy tests	R	0 … 1	Free text
Date first experienced	When the reaction was first experienced. May be a date or partial date (e.g. year) or text (e.g. during childhood)	R	0 … 1	Date and time
Probability of recurrence	Probability of the reaction (allergic, adverse, intolerant) occurring.	R	0 … 1	Free text
▶ Performing professional	The professional who identified the reaction.	R	0 … 1	
▶ Person completing record	Details of the person completing the record.	R	0 … 1	
▶ Medications and medical devices	Medications and medical devices	R	0 … 1	

2.2 Version Numbering

PRSB standards published with the detailed implementation guidance in the information model use a 3-segment version number, e.g., V3.01.02, while older standards published before the detailed implementation guidance was put into the information model retain the previous 2-segment version number, e.g., V2.02 until their next maintenance release or revision.

2-segment version numbers take the form of major version.minor version, e.g., V2.02 where the information model is major version 2 and minor version 01.

3-segment version numbers use the format Va.bb.cc where:

- a - is the major version number of the information model, incremented on significant revisions or enhancement of the information model
- bb – is the minor version number of the information model, incremented on minor updates such as changes or issue resolutions
- cc – is the implementation guidance version number, incremented whenever the implementation guidance is updated, which can be with or independent from an

information model update. At a major revision of the information model this will restart at version 01.

2.3 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 messaging standards e.g., FHIR profiles (to support the transfer of information between systems).
- The availability of other sources to access some of the person's care information such as the national record locator service (NRLS), GP records and shared care records.

2.4 Risk Mitigation

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 and DCB0160.

2.5 Information Governance

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

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

2.6 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 dependent on the source data quality.

2.7 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 2 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 data item in any PRSB standard.:

- **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. In some instances, this would be start and end dates.

- **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 2.8).

Note that although both 'Performing professional' and 'Author' contain 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" will be included in the model. 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 published on the PRSB website Provenance data – PRSB (theprsb.org)

2.8 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 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.

2.9 Links to Other Records and Documents

The person may have multiple detailed records or documents held on local systems, e.g. there may be a mental health record for a person at a particular trust or shared care records such as an end of life care plan. PRSB record standards do not define all these possible links. It is expected that the local areas will define the requirements for accessing other records or documents, and where applicable and provide access through the shared care record for authorised professionals.

2.10 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 value set for the element.

2.11 Coding

The *Personalised Health and Care 2020 framework for action* (https://www.gov.uk/government/publications/personalised-health-and-care-2020) recommends the use of SNOMED CT and the dictionary of medicines and devices (dm+d). Local decisions need to be made about when these codes are to be used, depending on local system functionality and plans. The current ambition is for SNOMED CT and dm+d to be the primary clinical coding schemes in use in the NHS.

2.12 Accessibility

The design of user interfaces for health and care record systems should follow guidance for specific PRSB standards and should comply with the NHS England Accessible Information Standard (https://www.england.nhs.uk/ourwork/accessibleinfo/). This sets out the rules for accessible patient information in patient literature and clinical systems.

3 Digital Maternity Record Standard Release 2 General Implementation Guidance

3.1 Sending Newly Recorded Data

Only send information recorded at a point in time, not what was recorded previously as this information will already be available in the record.

3.2 Null Records

Where no information has been recorded, a blank record should not be sent, except for mandatory items where a ‘null’ record should be sent, with explanatory coded text e.g. ‘no information recorded’.

3.3 Time Stamps

Time stamps in the record should be GMT.

3.4 Movement Between Services

Any transfer of care or movement between services, e.g. during labour, can be recorded using existing sections and data elements. Some systems may decide to create a template for transfers of care using the sections and data elements.

3.5 Metadata

It is expected that for any information recorded under the record sections that there will be some minimum mandatory information (audit trail) which will essentially be derived in the

background from the IT system the data is recorded in. This audit data is essential as it will allow for information which is not defined as being mandatory in the Digital Maternity Record Standard Data Model Specification and specified in the structured sections to be recorded.

It is not expected that this data should be carried across into the clinical record, but this should form part of an audit trail which will display in a system workflow. The metadata will differentiate between the person who performed an action and the person who inputted the data.

If recording SNOMED CT clinical findings, the date/time from the clinical finding entry must indicate the time something was recorded. The default recording of a clinical finding should relate to something recorded to the present time, but this may be backdated. Systems should have the ability to record the time of recording and the time it applied.

3.6 Fetal Identifier

The fetal identifier should be used in all circumstances where information is being recorded in the maternal record which is directly related to the fetus e.g. a diagnosis as a result of screening such as downs syndrome. This information should always be transferred to the baby's NHS Number in the result of a live or still birth. In England, a baby born (live or still born) on or after 24 weeks gestational age must be registerable and issued with an NHS Number.

As the fetus will not have a medical record, suppliers may wish to record information and link to a local fetal identifier as a way of distinguishing information which pertains to the fetus during the pregnancy episode. This recommended implementation of how this should be recorded is something which suppliers may wish to use in their system design. This is also something that suppliers will need to consider to comply with the data submissions required as part of the Maternity Services Data Set (MSDS).

3.7 Use of Person

Throughout this document and in the accompanying record sections and associated data model, we refer to the person in relation to who the information is recorded against. In most instances, this will be a reference to the woman / birthing person but the decision to use this term is based on the Equality Act 2010 and the Gender Recognition Act which is currently under review. The decision to use person ensures compatibility with discrimination law and aligns with the NHS Data Model and Dictionary definition which references 'An individual human being about whom information is maintained'.

3.8 Screening Incidents

In the event of an incident during a screening, it is recommended to complete a Screening Incident Assessment Form and forward it to the relevant parties for review, or follow local procedures.

3.9 Newborn Examination Checklist

It is mandatory to complete The Newborn Examination Checklist within 72 hours after birth.