Professional Record Standards Body

Community Pharmacy Information Standard (DAPB4008 Amd 5/2023)

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:

- Information Standards Notice (ISN)
- Requirements Specification
- High Level Implementation Guidance (this document)

An Information Standards Notice (DAPB4008 Amd 5/2023) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the 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: 26 June 2023

Glossary of terms

Term / Abbreviation	What it stands for
CIS	Core Information Standard
CPCF	Community Pharmacy Contractual Framework
DAPB	Data Alliance Partnership Board
DAPB4008	The Community Pharmacy Information Standard
FHIR	Fast Healthcare Interoperability Resource. A method for exchanging healthcare information electronically
ISN	Information Standards Notice
PRSB	Professional Record Standards Body
Refset	In the context of this Standard, a Refset is a group of SNOMED clinical terms that is represented by a single reference, rather than a list of all the terms contained therein
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

Contents

1. Purpose

The purpose of the standard is to support the expanding use of community pharmacies and pharmacists as part of the NHS providing services under the Community Pharmacy Contractual Framework (CPCF). The standard will provide consistency in recording information which can be shared with other parts of the health and care system and support a more integration overall system. It will support people by integrating information about their care from all parts of the system. The standard:

- defines the information that should be recorded in a community pharmacy
- the information which should be sent to the person's general practice about the care provided to be added to their primary care record and potentially with shared care records

Through implementation of the structured information model content and use of associated implementation guidance and other supporting materials, the standard will enable key information to be recorded consistently about services provided in community pharmacies and be added to their general practice record.

This stage covers the information to be recorded in all community pharmacy systems. Technical specifications are planned within NHS England which through a further release of DAPB4008 will allow providers and their systems to be able to share information with general practice in the future through structured coded messages. In the mean-time information can be shared with the person's general practice through existing mechanisms such as email.

This High Level Implementation Guidance is to be read alongside documents outlined in section 1.3 of the DAPB4008 Community Pharmacy 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. If unsure, it is recommended that you liaise with your system supplier to establish what their intentions are regarding implementation of the DAPB4008 and the timescales they are working to (as per Step 4, below).

Step 2: Read the Community Pharmacy 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 webpage.

The Community Pharmacy information model provides a detailed description of the PRSB standard including explanations about the data items, definitions, formats and values which can be recorded. It also includes implementation guidance at section and element level primarily for system suppliers and providers implementing the standard. There are further supporting materials on the PRSB website including the general implementation guidance (including definitions of the content and structure of PRSB standards), clinical safety case, examples, and release notes for updates. These should be read alongside the Community Pharmacy information model.

Step 3: Read the 111 referral standard

It is highly recommended that providers are aware and familiar with the 111 referral standard (part of the Booking and Referrals Standard (BaRS)) for referrals from 111 services into community pharmacy.

Step 4: 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. These are becoming increasingly available to community pharmacies as they are developed in each of the ICBs in England.

The sections of CIS most relevant for Community Pharmacy are listed below, although other sections may also have useful information for the pharmacist:

- About me
- Individual requirements
- Care and support plan
- Contingency plans
- Additional supporting plans
- Problems List
- Medicines and medical devices
- Allergies and adverse reactions

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

Step 5: Discuss with current IT systems supplier

If a commercial system is in use, discuss with the supplier to confirm the timescale for any necessary changes to the system. In most cases these changes will be part of 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 and subsequently using the data items detailed within DAPB4008.

For example, you may find it useful to share the contents of this High Level Implementation guidance document, and other documents relating to DAPB4008 including (but not limited to) the information model and section-level implementation guidance, with all staff groups and organisations directly impacted, such as frontline staff, commissioners and representative groups for people with lived experience.

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 elements in the Community Pharmacy Standard may already be recorded electronically
- Check what changes are required to meet the new standard. For example, does the IT system require any additional fields?

It is recommended that providers identify whether:

- There are any changes required to clinical/business processes in order to implement DAPB4008.
- There are any additional training needs for professionals to be able to implement and use DAPB4008.

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 DAPB4008 must be achieved no later than March 2025. Compliance to DAPB4008 Version 1 is a prerequisite for compliance to the planned next release of the information standard (Version 2.0).

PRSB Standard and DAPB information standard

As outlined in section 1.3 above, the DAPB4008 information standard comprises the high-level implementation guidance (this document) and the requirements specification. They are published on the DAPB website.

The PRSB standard comprises the Community Pharmacy information model (version 3.0.1) and the associated detailed implementation guidance. They are published on the PRSB website.

Implementation of the information standard will follow a phased approach, identifying early adopters and publishing the results of trials to embed learning ahead of the planned full compliance date:

Action	Date
Communicate the DAPB4008 standard (this standard) to providers	June 2023
Suppliers start development (due to full development roadmaps)	Jan 2024
Work with early adopters	Jul – Sep 2024
Publicise early adopter findings	Oct – Dec 2024
Suppliers compliance	December 2024
Full compliance of community pharmacies	March 2025

It is envisioned that the work with early adopters (above) may result in additional guidance that will be to be incorporated within the PRSB implementation guidance from Q3 24/25 onwards.

This DAPB information standard (version 1.0) refers to the PRSB Community Pharmacy standard: which is comprised of the Community Pharmacy information model (version 3.0.1) including detailed implementation guidance.

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 structure 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 DAPB4008, in terms of detailing the mechanism of interoperability; ISN publication; and provider implementation, are currently to be defined. It is possible that data flows may be required in later releases of DAPB4008.

3.1. Support and maintenance

Where additional advice in implementing the standard is required, the PRSB support service can be contacted using support@theprsb.org. The PRSB is responsible for managing any updates to the information model and implementation guidance document through established assurance processes and release cycles (see section 7 below) at the PRSB and DAPB. If possible, please include “Community Pharmacy 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 more frequent 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, below.

4. General guidance for PRSB standards

4.1. The structure of PRSB standards

PRSB information standards are 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 entries are allowed 0…1 = zero to one 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…… *.

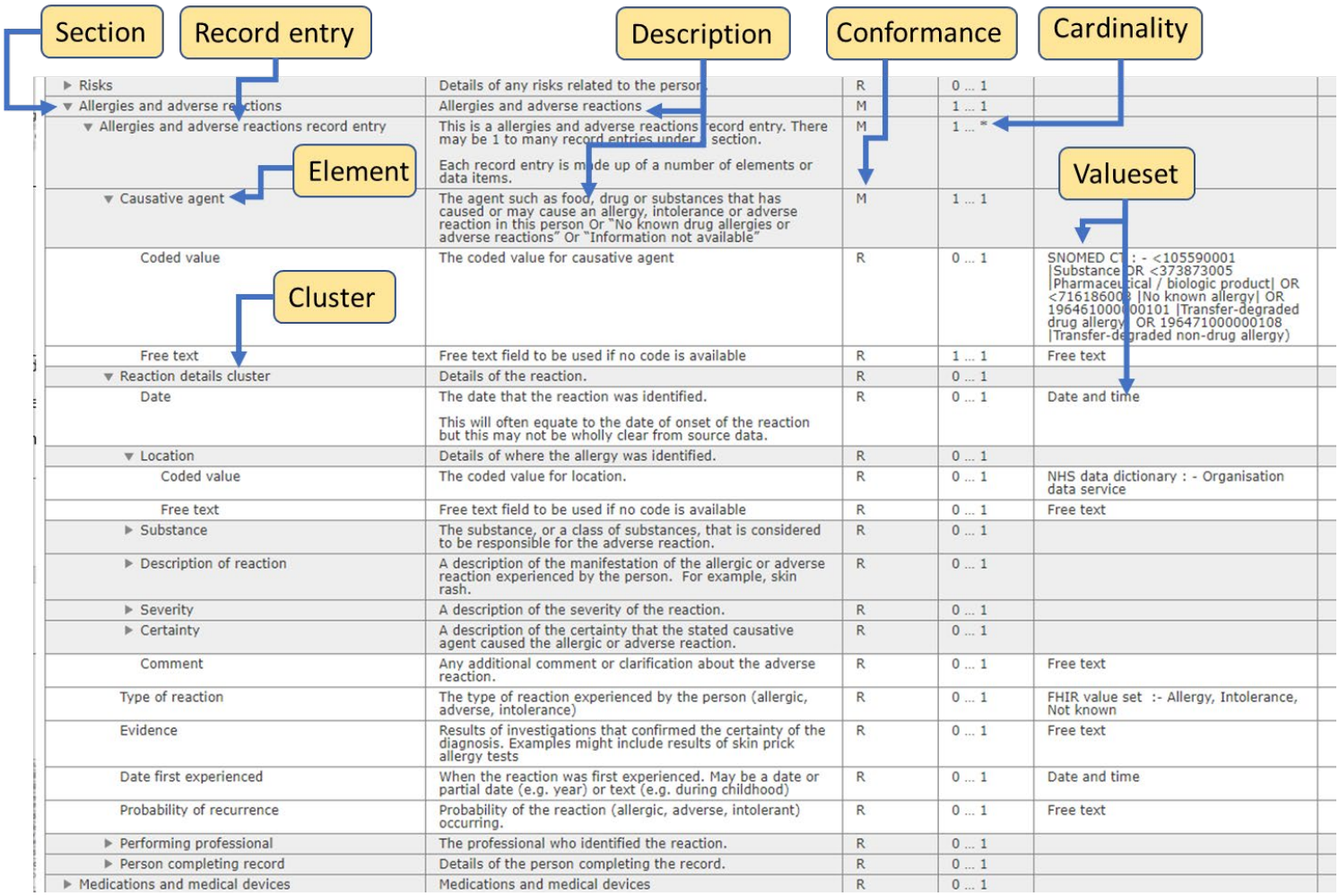
Information model rules and instructions	Explanations
Conformance	Conformance defines what information is 'mandatory', 'required' or 'optional' and applies to sections, record entries, clusters and elements. The IT system should be developed to handle all the information elements that are defined in 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: 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', 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.



▶ 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 1964610000000101 |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	

Figure 1: Diagram detailing key terms used in the DAPB4008 standard with the example for allergies and adverse reactions (taken from the Core 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 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 4.3).

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.

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 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 DAPB4008 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 Community Pharmacy information model.

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 has 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 value set 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 messaging standards e.g. FHIR specifications (to support the 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 dependent on the source data quality.

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 and DCB0160.

As more practical implementation issues may vary from provider to provider, it is recommended that all providers implementing the PRSB information 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 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.

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

One example for local review is:
How third-party information is managed (justification and lawful basis for processing), e.g. the handling of sensitive data pertaining to the mother's next-of-kin.

7. Future changes

DAPB4008 will be enhanced as necessary based on need. Enhancements could be based on further clinical requirements, clinical safety feedback, technical SME feedback or supplier implementation findings (for example).

The DAPB4008 information standard (including guidance) provides the structure and content for a Community Pharmacy record; the sections and elements of the Community Pharmacy information model define what information should be recorded. The need for data flows will be considered for later versions of DAPB4008.

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 DAPB4008 as a result of the assessment of the feedback on a regular basis.

8. References

DAPB4008 webpage:
https://theprsb.org/standards/communitypharmacy/

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

Information Governance Framework:
https://transform.england.nhs.uk/information-governance/guidance/summary-of-information-governance-framework-shared-care-records/

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

PRSB Community Pharmacy Information Standard webpage:
https://theprsb.org/standards/communitypharmacy/

PRSB Provenance data:
https://theprsb.org/standards/provenance/

PRSB support service:
https://theprsb.org/standards/support/

SNOMED CT SCCI0034:
https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/scci0034-snomed-ct

SNOMED CT Editorial Guide:
https://confluence.ihtsdotools.org/display/DOCEG/SNOMED+CT+Editorial+Guide

PRSB 111 Referral Standard:
https://theprsb.org/standards/111referralstandard/

Booking and Referral Standard:
https://digital.nhs.uk/services/booking-and-referral-standard