Classification: Official

NHS England

Pathology and Laboratory Medicine Reporting Information Standard

Implementation Guidance

Publication reference: DAPB4101 Amd 63/2023

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:

- Implementation Guidance
- Requirements Specification (this document)

An Information Standards Notice (DAPB4101 Amd 63/2023) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled copies 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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Version	Date	Summary of Changes
0.1	30/01/2024	Initial draft
0.2	22/02/2024	Minor editorial corrections – move to updated templates
1.0	15/04/2024	Final
1.1	16/04/2024	Minor editorial corrections – updated links

Contents

1. Introduction

The Pathology and Laboratory Medicine Reporting Information Standard (DAPB4101 Amd 63/2023) supports the interoperable sharing of pathology reports from laboratories to Primary Care for the purpose of direct care.

DAPB4101 has been designed to replace the legacy ISB 1557 EDIFACT Pathology Messaging Standard (Amd 39/2003 EDIFACT v1.003), thereby replacing the Pathology Messaging EDIFACT integration with the Pathology Messaging - FHIR integration.

The purpose of this document is to provide general implementation guidance and signpost to more detailed technical guidance to support conformance with DAPB4101. Specifically, this document is intended to support system suppliers to develop the required functionality to enable a system to electronically communicate and exchange a generic pathology report.

2. Key requirements

In the pathology report sent from laboratories to GP practices, and to support complex pathology reporting structures containing fully atomic, coded results, DAPB4101 mandates the use of:

- Pathology FHIR specification
- Concepts included in SNOMED CT Pathology specific Reference sets:
  - ❖ Pathology Bounded Code List (PBCL) observables simple reference set
  - ❖ PaLM (pathology and laboratory medicine) procedure simple reference set
  - ❖ PaLM (pathology and laboratory medicine) observable entity simple reference set
- Additional mandatory data elements such as patient demographic information, report identifiers, and organisation data. These are governed by their own Information Standards and the Pathology FHIR specification details their use.

3. Related documents

This document should be read alongside:

- DAPB4101 Pathology and Laboratory Medicine Reporting Information Standard Requirements Specification

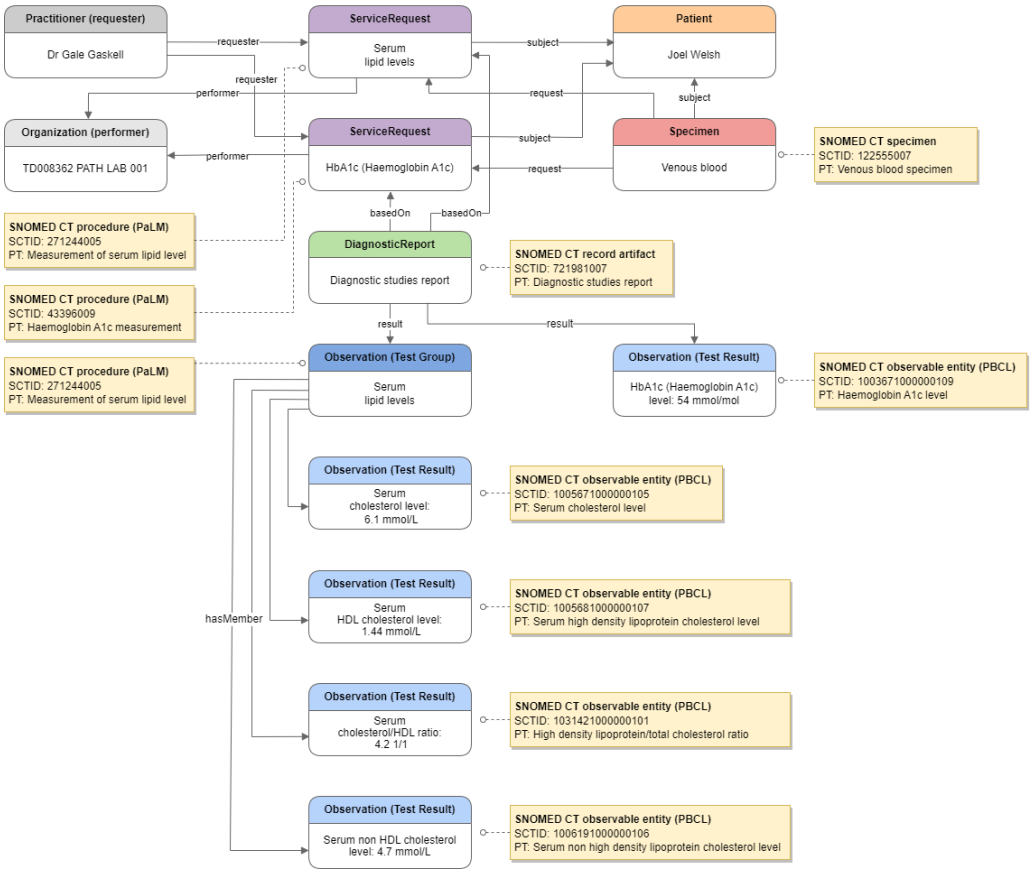
4. Pathology FHIR Specification

Fast Healthcare Interoperability Resources (FHIR) is a standards framework that is used for healthcare data exchange. In this context, it is used to define the structure of pathology laboratory test reports.

As noted in section 1, the PMIP EDIFACT (NHS003) specification is to be replaced by a specification based on FHIR. Each pathology report will be represented by a FHIR UK Core R4 'bundle'.

- LIMS/Middleware systems will need to support the creation of **outbound** FHIR UK Core R4 laboratory test report messages in place of PMIP EDIFACT.
- GP systems will need to implement the ability to receive **inbound** FHIR UK Core R4 laboratory test report messages in place of PMIP EDIFACT.

Example diagram illustrating the structure of an HbA1c and serum lipid level laboratory test report using FHIR UK Core R4, showing how various data elements are populated.



The Pathology Standards and Implementation team have created pathology-specific FHIR UK Core R4 profiles and an accompanying implementation guide (IG). This IG provides the detailed guidance system suppliers will need to implement the profiles. Regularly updated, this IG is the source of truth for implementors.

5. SNOMED CT for pathology reporting

SNOMED CT is the recognised NHS standard terminology for clinical data entry in electronic health and care records. In addition to representing many different types of clinical information, SNOMED CT provides an interoperable and machine-readable mechanism for sharing pathology request and result data.

5.1. Mandated SNOMED CT data elements

The data elements represented using SNOMED CT in the pathology report that are mandated by DAPB4101 fall into three categories, or SNOMED CT concept 'hierarchies':

- Procedures
- Observable entities
- Record artifacts

5.2. Procedures

Within this context, Procedure concepts represent laboratory test request codes. These are known colloquially as 'requestables' or 'orderables'.

Within the report, they are used for two purposes:

- a single data item used in the Service Request FHIR Profile identifying the specific laboratory test(s) initially requested that led to the generation of results.
- a single data item used in the Observation (Test Group) FHIR Profile to represent test panels/batteries.

The Procedure concepts mandated for use in DAPB4101 are contained in the PaLM (pathology and laboratory medicine) procedure simple reference set.

5.3. Observable entities

Within this context, Observable entity concepts represent laboratory test result codes. These are known colloquially as 'resultables' or 'reportables.'

Within the report, they are used for a single purpose:

- a single data item used in the Observation (Test Result) FHIR Profile identifying the specific laboratory test to which a value(s) and interpretation can be assigned.

The Observable entity concepts mandated for use in DAPB4101 are contained in the Pathology Bounded Code List (PBCL) observables simple reference set and PaLM (pathology and laboratory medicine) observable entity simple reference set.

5.4. SNOMED PBCL and SNOMED PaLM

The Observable entity concepts referenced in 5.3 relate to two legacy national catalogues of pathology laboratory test codes, the Read v2 Pathology Bounded Code List (PBCL) and the Unified Test List (UTL). These concepts fall into two categories:

- SNOMED PBCL
- & SNOMED PaLM

The PBCL was originally, a subset of Read v2 codes for use in laboratory to GP messaging. Semantically equivalent SNOMED PBCL concepts have since been created.

SNOMED PaLM concepts are more detailed than SNOMED PBCL concepts and their human-readable descriptions conform to the editorial principles used in the development of the UTL. Where feasible within the constraints of the SNOMED CT concept model design, all SNOMED PaLM concepts are fully modelled; the modelled components logically define each concept and allow for machine processing, enabling clinical decision support, and improved analysis of the data. Due to SNOMED CT's concept model, some of the information about a laboratory test is carried inherently in the terminology, with Observable entities carrying defining coded attributes relating to measurable characteristic, substance, specimen, and technique.

To ease transition to SNOMED CT and support timely conformance with DAPB4101, the standard allows less detailed, ontologically suboptimal SNOMED PBCL concepts to be used in addition to more detailed, granular, ontologically sound SNOMED PaLM concepts.

5.5. Record artifacts

Within this context, Record artifact concepts are used to identify electronic artefacts.

Within the report, a single concept serves this purpose:

- 721981007 Diagnostic studies report (record artifact) is a single data item used in the Diagnostic Report FHIR Profile to identify the FHIR message.

5.6. Non-mandated SNOMED CT data elements

In its initial iteration, DAPB4101 allows, but does not mandate the use of other types of SNOMED CT concepts to represent other data elements in the report, including laboratory test result values and specimens. The Pathology FHIR specification details how these concepts can be used, and their use is governed by the overarching SCCI0034: SNOMED CT Information Standard.

NB. If the Pathology Standards Programme is commissioned to standardise these data elements and mandate their use, DAPB4101 would be amended to support this requirement.

5.7. How to access SNOMED CT

The SNOMED CT reference sets that support pathology reporting are included in the SNOMED CT UK Clinical Edition which can be accessed via the NHSE TRUD website, or via the NHS England Terminology Server.

Suppliers must use of the latest version of the SNOMED CT UK Clinical Edition to ensure they can send / ingest newly introduced concepts and no longer send / ingest outdated concepts.

Further information on how to implement SNOMED CT into a system can be found on NHSE's Delen website.

6. Additional data elements

The Pathology FHIR specification details how additional mandatory/non-mandatory, non-SNOMED CT data elements included in the pathology report, such as patient demographic information, organisation data, units of measure and clinician data should be used. These data elements are governed by their own Information Standards.

7. Data exchange mechanism

NHS England's Message Exchange for Social Care and Health (MESH) service supports the ability to share data directly and securely between health and care organisations. MESH is the nationally recognised mechanism for message-based data sharing and is currently used to transport PMIP EDIFACT reports from laboratory systems to GP systems.

In addition to MESH, FHIR supports other methods of exchanging data, including the use of RESTful APIs. This approach may be considered for pathology reporting in the future, but until an alternative national messaging architecture is mandated, MESH will be used to transport FHIR UK Core R4 pathology reports.

8. Implementation approaches

Implementation of the Pathology Messaging – FHIR integration will be determined and managed locally.

8.1. Mapping to SNOMED PBCL

To support PMIP EDIFACT, laboratories currently map their local laboratory test result codes to Read v2 PBCL codes. DAPB4101 allows the use of PBCL derived content, thereby allowing the current LIMS output to map to SNOMED PBCL in a simple step, using assured, one to one Read v2 PBCL to SNOMED PBCL maps published by NHS England.

8.2. Mapping to SNOMED PaLM

Laboratories can take steps to map their local laboratory test result codes to SNOMED PaLM Observable entity concepts directly.

NHSE's Pathology Standards and Implementation team are currently developing mapping solutions facilitated by NHSE's Terminology Server. Please visit the NHSE Pathology Standards and Implementation website for the latest information.

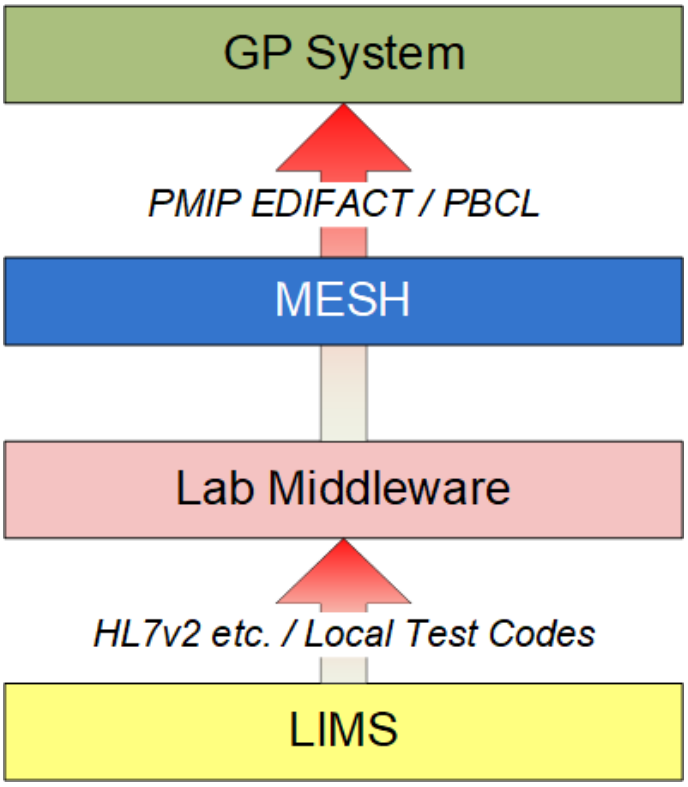
8.3. Transition from SNOMED PBCL to SNOMED PaLM

Relationship components that exist within SNOMED CT link SNOMED PBCL and SNOMED PaLM concepts together in a logical hierarchy. These 'parent/child' relationships support technical mapping between SNOMED PBCL and SNOMED PaLM. Similarly, these relationships support historical trending and data migration.

8.4. Middleware transform

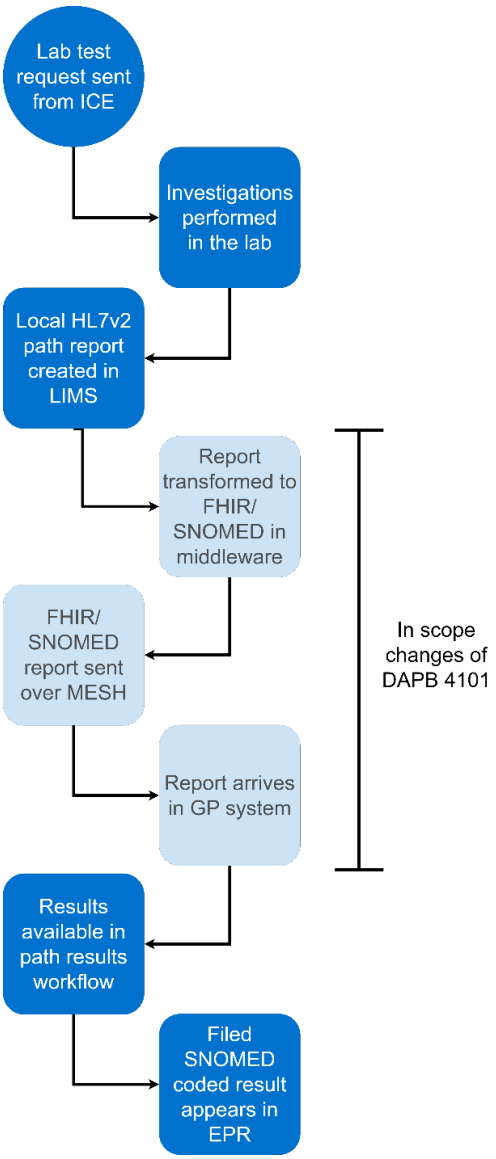
The systems and messaging/coding protocols currently used to support PMIP EDIFACT are depicted opposite. Of note is the use of middleware. This software is currently used to perform two key functions:

- To transform the pathology reporting output from LIMS (typically based on supplier specific HL7v2 formatted messages) into PMIP EDIFACT formatted messages.
- To map locally defined laboratory test result codes to Read v2 PBCL coded equivalents.



To make adoption of FHIR/SNOMED pathology reporting as straightforward as possible, one approach would be to use middleware to transform the output from LIMS into a FHIR/SNOMED conformant report.

This process map illustrates such a method - steps **4, 5** and **6** being affected by DAPB4101.



Requester launches Order Comms to create laboratory test request.

1. Investigations performed on specimen in laboratory as per request.
2. Report generated in LIMS containing local, lab-specific result codes, result values, interpretations, and units of measure (UoM), then sent to middleware via supplier-specific formatted HL7 v2 message.
3. Result codes and initial request codes mapped to SNOMED PBCL/PaLM concepts and HL7 v2 message transformed to FHIR R4 message in middleware.
4. Report sent over MESH in FHIR R4 format.
5. FHIR R4 format report arrives with GP EPR system and ingested as SNOMED CT.
6. Results presented to user in the GP system pathology results workflow.
7. Filed coded results appear in EPR.

8.5. Flowing FHIR/SNOMED pathology reports directly from LIMS.

An alternative method of generating and sending FHIR/SNOMED pathology reports would be to do it directly in the LIMS, negating the requirement for middleware.

9. Implementation support

9.1. Informatic support

Implementation guidance, advice, and supporting artefacts will be regularly updated and published on the NHSE Pathology FHIR Implementation Guide and Pathology Standards and Implementation website throughout the period between initiation and conformance with DAPB4101. Please bookmark these websites and check for the latest updates.

In addition, the Pathology Standards and Implementation team are available to offer informatic support. Please contact the team via the following email address pathology.standardsandimplementation@nhs.net.

9.2. Provision of test message packs

The Pathology Standards and Implementation team are creating test message packs for developers to use. Please visit the NHSE Pathology Standards and Implementation website to access these artefacts when they are made available.

9.3. Validation tool

It is envisaged that a validation tool to assure FHIR R4 pathology reports sent and received will be developed by NHSE, similar to the National Messaging Assurance Service (NMAS) used to support PMIP EDIFACT. Please visit the NHSE Pathology Standards and Implementation website for the latest information.

Appendix A: Useful web links

Content	URL
Delen: Implementing SNOMED CT	https://nhsengland.kahootz.com/t_c_home/view?objectId=45956592
FHIR	https://digital.nhs.uk/services/fhir-apis
ISB 1557 EDIFACT Pathology Messaging Standard (Amd 39/2003 EDIFACT v1.003)	https://webarchive.nationalarchives.gov.uk/ukgwa/20150107154542/http:/www.isb.nhs.uk/documents/isb-1557
Message Exchange for Social Care and Health	https://digital.nhs.uk/services/message-exchange-for-social-care-and-health-mesh
NHS England Terminology Server	https://digital.nhs.uk/services/terminology-server
Our API technologies	https://digital.nhs.uk/developer/guides-and-documentation/our-api-technologies
Pathology Messaging EDIFACT integration	https://digital.nhs.uk/developer/api-catalogue/pathology-messaging-edifact
Pathology Messaging - FHIR integration	https://digital.nhs.uk/developer/api-catalogue/pathology-messaging-fhir
Pathology FHIR Implementation Guide	https://simplifier.net/guide/Pathology-FHIR-Implementation-Guide/Home
Pathology standards and implementation	https://digital.nhs.uk/services/pathology-standards-and-implementation
Read v2 PBCL	https://digital.nhs.uk/services/terminology-and-classifications/read-codes#pathology-bounded-code-list-pbcl-
Read v2 PBCL Read Code to SNOMED Translation Table	https://isd.digital.nhs.uk/trud/users/guest/filters/2/categories/9/items/270/releases
SCCI0034: SNOMED CT Information Standard	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 for pathology reporting	https://digital.nhs.uk/services/pathology-standards-and-implementation/snomed-ct-for-pathology-reporting
TRUD	https://isd.digital.nhs.uk/trud/users/guest/filters/2/categories/26
Understanding our data elements	https://digital.nhs.uk/services/pathology-standards-and-implementation/understanding-our-data-elements