DAPB4017 Pathology Test and Results Standard Implementation Guidance

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Data Alliance Partnership Board

Acting on behalf of the Data Alliance Partnership Board (DAPB), which holds delegated authority from the Secretary of State for Health and Social Care, the Data Alliance Partnership Sub Board (DAPSB) 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 approved by the Data Alliance Partnership Board (DAPB).

This information standard comprises the following documents:

- Specification
- Implementation Guidance

An Information Standards Notice (DAPB4017 Amd 44/2020) 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 Digital 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: 17 August 2021

NOTE: From 1 February 2023, Delen - the information sharing and collaboration platform for Terminology and Classifications products - has migrated from https:///hscic.kahootz.com to https://nhsengland.kahootz.com. URLs in this document have been corrected to ensure continuity of access. No other changes have been made.

Glossary of Terms

Term / Abbreviation	What it stands for
EDIFACT	Electronic Data Interchange for Administration, Commerce and Transport
HL7 FHIR	Health Level Seven Fast Healthcare Interoperability Resources
LIMS	Laboratory Information Management Systems
NLMC	National Laboratory Medicine Catalogue
PBCL	Pathology Bounded Code List
UCUM	Unified Code for Units of Measure
UTL	Unified Test List

Contents

1. Introduction

To meet future NHS needs for interoperability and secondary care use within the Pathology domain, three inter-related specifications have been identified to standardise information exchanged with clinical pathology laboratories and their laboratory information systems (LIMS) to enable the sharing of Pathology Results across the NHS.

1.1 Related documents

This document should be read in conjunction with:

- DAPB4017 Pathology Test and Results Standard Consultation Report which also includes the background to this work, and
- DAPB4017 Pathology Test and Results Standard Specification.

2. Scope

Implementation of the three, inter-related specifications in systems will differ depending upon the level of system maturity and Pathology specialist areas serviced, therefore, implementation guidance is provided for both:

- Systems already utilising the international standards on which these are based (SNOMED, UCUM & FHIR)
- New market entrants and/or systems not using the above or who only wish to implement the Pathology specific specifications.

2.1 Standards Implementation Guidance

The Pathology Test and Results Standard makes use of three distinct and established standards:

- Unified Test List (UTL) is a Pathology ontology, based upon SNOMED CT which is already widely used throughout the NHS
- Units of Measure (UoM) is based upon UCUM, which is established as an embedded standard within HL7 including FHIR
- Pathology Profiles (and associated Pathology Information Model) are based upon HL7 FHIR, and these profiles are currently employed within overlapping programmes of work including GP2GP, GP Connect and the National Integration Adaptor.

The following sections provide links to implementation guidance and further information for each of the above standards and where these have been incorporated into complementary programmes of work.

2.2 Pathology Implementation Principles and Blueprint

The following documents provide Pathology Test and Results Standard specific implementation guidance to aid suppliers, researchers, and other stakeholders.

- Implementation Principles contains details of the current pathology digital landscape and provides a high-level roadmap for standards adoption.
- The Pathology Implementation Blueprint contains a phased implementation proposal based upon consultation with existing GP primary care and LIMS suppliers.

2.3 Message Specification Implementation Guidance

- The national HL7 FHIR Care Connect Profiles provides Implementation Guidance applicable for Pathology information flows within all the following FHIR profiles included in the Specification:

ProcedureRequest; DiagnosticReport; Specimen; Observation; Practitioner; Organization; & Patient.

These profiles were developed by the NHS Digital Interoperability Standards Service in collaboration with GPConnect, GP2 GP and GP IT Futures Systems and Services as centralised standards that can be used by all so that anyone implementing will have a common solution that allows interoperation with all others.

Each has wider implementation guidance, incorporating the above in current and future developments, however, additional implementation guidance is available related to the FHIR profiles used in the Pathology Domain as follows:

- Use of the FHIR pathology profiles for GP Connect is part of the GP Connect API (specifically the Access Record Structured component of that API) and Pathology National Integration Adaptor (EDIFACT-FHIR). The pathology specific implementation is included in the Investigations guidance
- GP2GP HL7v3- FHIR adaptor message spec / API implementation guidance: National Integration Adaptor for the GP2GP API
- National Integration Adaptor EDIFACT-FHIR adaptor to access the Pathology and Screening laboratory results via an easy-to-use FHIR-compliant queue interface.

The NHS Digital Interoperability Standards Service will provide further implementation guidance as part of their maintenance and support of the development of Interoperability Standards in the Health and Social Care sector, for use by the FHIR community and collaborate at the National and UK level to develop centralised standards.

- Full HL7 FHIR Implementation guides are available internationally at http://fhir.org/guides/registry/

This guidance includes any implementation from older HL7 standards and specifically includes the implementation/use of UCUM in FHIR profiles which have been adopted in the Pathology domain.

2.4 Units of Measure Specification Implementation Guidance

A tri-partite agreement between HL7, Regenstrief (owners of UCUM) and SNOMED International enables an open-source set of units, via a Creative Commons licence which includes Pathology units required by users (Commonly Used UCUM Codes), so this has been adopted.

- Full UCUM implementation guidance is available if required and/or
- Implementation guidance including the use of UCUM with all national HL7 FHIR CareConnect profiles.

2.5 Test and Results Specification Implementation Guidance

SNOMED CT is widely used across the NHS for national data set and Spine services and has been implemented by suppliers under preceding programmes of work (Connecting for Health, GP Systems of Choice, etc including the Unified Test List for Pathology.

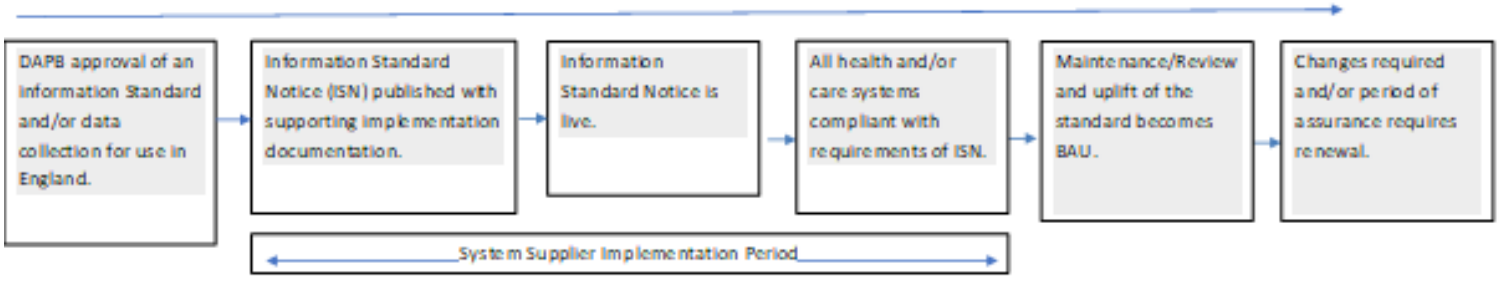
The full SNOMED CT Technical Implementation Guide can be found at http://snomed.org/tig.

3. Implementation Support

As the standards are developed iteratively, the above will be extended and elaborated to support additional diagnostic specialisms.

Once approved, the standards will be included in the NHS Standard Contract (fiscal year 2022-23) and be mandated for new system procurements and used by key stakeholders to support their related strategic transformational initiatives for the wider health and care system in line with the current Data Alliance Partnership Board, post approval process for an Information Standards Notice (ISN).

The ISN will inform policy and contracts for new suppliers.



3.1 Education and Training

Pathology specific materials are available from the Pathology Training and Education collaboration site.

Additional materials can be found at the following sites:

- SNOMED CT Implementation support
- FHIR Online Training Courses
- FHIR Teaching and Online Training Courses - HL7
- Education Outreach – UCUM.

3.2 Demonstrator Report

The Professional Records Standards Body (PRSB) were commissioned to build demonstrators to show the feasibility of implementing the new standards, and then to engage with stakeholders to gather their feedback on the feasibility of implementing those standards.

These demonstrators are detailed within section 1 of the PRSB Report.

3.3 Proof of Concept Reports

In addition, NHSX and NHS Digital commissioned South, Central and West CSU in April 2021 to perform an end-to-end test of the combined UTL, UoM and Pathology FHIR Profiles with existing suppliers to confirm the standards applied and identify lessons which could be incorporated into the implementation guidance.

- Test Report: provides an overview of the tests that were performed and a summary of the outstanding issues.
    - The Proof of Concept didn't raise any issues with regard to the FHIR profiles or UTL content. All issues raised during the Proof of Concept related to configuration, handshaking with the test server and clarifying understanding of FHIR STU3.
    - The Proof of Concept highlighted a need to utilise existing clinical coding for findings and noted the potential for an asynchronous acknowledgement to provide a useful improvement (acknowledgements are supported by ITK in FHIR but aren't currently utilised by legacy pathology messaging).
- Case Study describes the scope of the Proof of Concept, testing approach and key lessons learned.

3.4 Additional Test and Clinical Safety Reports

- Clinical Safety Case for the Curation of National FHIR Interoperability Standards is the assessment of the curation of the jointly curated national FHIR profiles including Pathology.

Additional Use of Pathology Related FHIR Profiles

In addition to their use as part of the Pathology Message Specification, the pathology related FHIR STU3 profiles are also used by several other NHS Digital projects and programmes. These are summarised below.

- **National EDIFACT-FHIR Adaptor**: this provides a way for GP systems to receive EDIFACT (NHS003) based lab test result messages using a FHIR interface. Further details can be found here: https://digital.nhs.uk/developer/api-catalogue/lab-results-adaptor

  The following document is also of note:

  Test Report: provides an overview of the tests there were performed by a GP system supplier during testing of the adaptor and a summary of the outstanding defects.

  GP Connect: a GP Connect variant of the pathology related FHIR STU3 profiles are used to support the retrieval of pathology lab results from GP systems. This forms part of the GP Connect Access Record Structured FHIR API. Further details can be found here: https://digital.nhs.uk/developer/api-catalogue/gp-connect-access-record-structured-fhir and here: https://developer.nhs.uk/apis/gpconnect-1-5-0/accessrecord_structured_development_pathology_guidance.html

  The following document is also of note:

  Test Report: provides an overview of the tests there were performed by a GP system supplier during testing of the GP Connect API and a summary of the outstanding defects.