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PATHOLOGY STRATEGIC ACTIVITIES:

Phase 2 Final Report V 1.1

17 March 2021

Document Management

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Glossary of terms

Term	Description
CCRI	Care Connect Reference Implementation
EPR	Electronic patient record
FHIR	Fast Healthcare Interoperable Resources Overview - FHIR v4.0.1 (hl7.org)
HCPs	Health and care professionals
ICE	Integrated Clinical Environment
LIMS	Laboratory Information Management Systems
MESH	Message Exchange for Social Care and Health
NHS	National Health Service
PBCL	Pathology Bounded Code List
PRSB	Professional Record Standards Body
PHR	Patient held record
PMIP	Pathology Messaging Implementation Programme
PQAD	Pathology Quality Audit Dashboard
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
UCUM	Unified Code for Units of measure
UoM	Units of Measure
UTL	Unified Test List

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1. Executive summary

Pathology tests are a vital part of healthcare with over 1 billion test results reported across the NHS each year. The standards used for primary care test results (about 100 million a year) are based on a retired coding standard and a transport standard which does not support the NHS approved terminology standard. Across the rest of the NHS there is no single set of standards used for pathology results. This is inefficient and a safety risk in particular when converting between coding systems and when interpreting results using different Units of Measure.

NHSX/Digital have a programme to implement new standards for pathology test requests and results across the NHS. These new standards will enable safer use and sharing of test results across the NHS and other organisations with which it works. A single coding system used by all will define the test results, standards for Units of Measure and will enable safer use and understanding of result values. Both of these will facilitate easier use, decision support and have wider benefits for population health management among others. This will also help support people's access to test results and enable additional information to enhance their understanding and management of their care.

PRSB was commissioned to support the NHSX/Digital programme and asked to develop 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.

The standards selected by NHSX/Digital are:

- A Unified Test List (UTL) using SNOMED CT (the NHS approved standard for terminology) to define the list of test requests and results for everyone across the NHS. The UTL available only contains results for blood sciences and microbiology, and so the focus was in those areas rather across the full range of pathology disciplines.
- The Unified Code for Units of Measure (UCUM) as the coded primary Unit of Measure, together with a human readable version of that code.
- A technical standard (HL7 FHIR) to electronically transport the details of the test, the result and its Units of Measure across the NHS and other organisations needing the information.

The work was conducted in 2 phases.

1. Phase 1 developed demonstrators to show how the 3 standards could work.
2. Phase 2 engaged with stakeholders using the demonstrators or the outputs of them to gather feedback on the feasibility of implementing the new standards.

1.1 Phase 1 - Demonstrators

1.1.1 UTL-PBCL mapping

This demonstrator looked at the feasibility of mapping the current coding scheme in primary care for test results (PBCL) to the new UTL. The purpose was to identify gaps in the new UTL, and support implementation of the new UTL in primary care.

A process was developed to produce mappings using some limited existing mappings and several different algorithms. Candidate mappings were reviewed by relevant

specialists, pathologists, scientists and clinicians, to produce a first pass set of mappings and identify gaps, with the results fed back to NHS Digital so they could address the gaps.

From this a process for producing approved mappings was proposed along with how the mappings could be communicated so their usefulness to support implementation of the UTL could be tested with stakeholders in phase 2.

1.1.2 Units of Measure

Units of Measure standards are used so that there is a consistent method of describing the test results of each test. Phase 1 looked at the options for Units of Measure (UoM) and how the UoM could be associated with a UTL test result code and incorporated into the FHIR message for sharing the information between systems.

An analysis of the UoM used in real data extracts showed that quite a range of different UoM were used for most test results. Ideally a single preferred UoM would be used for each test result, and a process was proposed for how those “preferred UoM” could be defined and approved, starting from those most commonly in use.

Three options were proposed for how particular UoM could be associated with a specific UTL code but, also allowing the use of more than one UoM for any test result, and the use of other standards for defining results which aren't numeric values:

1. Exactly one preferred Unit of Measure in the UTL as a data field (using UCUM, SNOMED CT or proprietary code list)
2. UoM provided as a list (constraint table listing the allowed UoM) for the potentially usable UoM for the individual test and the constraint table reference stored in the UTL as a field
3. Both a preferred unit code and a constraint table reference is stored in the UTL

The process for defining preferred Units of Measure and the options for association with the UTL and implementation were tested with stakeholders in phase 2.

1.1.3 FHIR messages

An electronic demonstrator was developed to show the feasibility of transmitting pathology test results using the HL7 FHIR standard to transport the UTL code, the result and the associated UoM. The example test result messages were generated by the Ramsey Systems CADE (Care pathway Analysis and Design Environment) simulation engine using configuration files that are freely available. The demonstrator showed how the messages could be generated, be validated as conforming to the National Pathology Messaging FHIR profile, sent over the NHS network and validated using NHS Digital message validation tools. The existing NHS Digital (XSLT) validation suite could be extended to validate against the UoM constraint tables, and so identify any messages that are not using the appropriate UoM or datatype for the result.

The demonstrator showed that HL7 FHIR as the transport standard was feasible, but also highlighted issues with the specification and test environment and raised a number of issues and options which were then tested with stakeholders in phase 2.

1.2 Phase 2 – Stakeholder consultation

Phase 2 engaged with stakeholders across the NHS, including citizens, to gather their

feedback on the feasibility of implementing these standards. The consultation used the outputs from the phase 1 work to derive the proposals to test and the questions to ask. Stakeholders were engaged through three streams. Overall, 63 stakeholders attended one or more of the six webinars with good coverage across the targeted range of disciplines and organisations. The three streams were:

1. Technical stream. Aimed at technically aware clinicians, pathologists, lab scientists, and those implementing the standards including system suppliers, IT staff from labs and provider organisations. Three webinars were held with largely the same attendees and the discussion continuing across all three.
2. Clinical users of test results including research and public health. Aimed at understanding the needs of users, the benefits, issues and risks of implementing the standards.
3. Citizens. A single webinar was held with a small group of knowledgeable patients so the benefits and implications for patients could be understood and used to inform the development and implementation.

1.3 Conclusions

The full conclusions are available in section 8 and are summarised below:

- A UTL-PBCL mapping was considered to be useful to support implementation and transition from the current systems, for informing local mappings and for analysing results over time for direct care and research. Stakeholders found the proposed method for development and assurance acceptable. A number of suggestions and recommendations were made about how the mappings should be made available and changes managed for both the UTL and the mappings.
- The use of a preferred UoM was accepted along with the process for deriving and approving them.
- The combination of including the preferred UoM in the UTL and the constraint table reference (option 3 above) is the preferred option, allowing the use of alternative UoM for a transition period during and following implementation.
- Driving the adoption of preferred UoM should be through existing infrastructure such as the pathology quality audit dashboard.
- Human and machine readable UoM is important to support human checking and oversight and decision support respectively.
- The National Pathology FHIR Messaging Specification can be used with the UTL and UCUM Units of Measure to convey pathology results.
- For test results that have non-numeric values, the datatype of the value needs to be specified as part of the additional constraints table in a similar manner to the way that Units of Measure are constrained.
- An idea from the patient's webinar that all 'up-front' (as opposed to routine) test results should be considered to be potentially 'life changing' and patient access to the test result should be agreed by the healthcare professional. Any 'routine' test results (less likely to be 'life changing') should be provided straightaway to the individual. This was considered a good starting point.
- The consultation included representation from Scotland and Wales (Northern

Ireland representation was invited) and the outputs of this work can be considered to apply UK wide, certainly for Wales and Scotland.

1.4 Recommendations

The full recommendations are available in section 8 and are summarised below:

- The UTL-PBCL mappings should be completed and made available and communicated to stakeholders as suggested, along with a system to report and log issues or suggested changes and a process for updates.
- Define the preferred UoM and allow alternatives to be specified where necessary for each test result code in the UTL.
- Use incentives and existing infrastructure to drive adoption of preferred UoM, including UoM frequency analysis and the pathology quality audit dashboard.
- Further work should be carried out with the standards development organisations to address the lack of a human readable representation of the UoM in UCUM and its proprietary governance and restrictive license arrangements.
- Develop the technology-independent information model for pathology with clear definitions so it's clear what information goes where in the message fields, and for the capture and tracking of new requirements from stakeholders, whether those are expressed as information items, business rules, risks or benefits. The Information should also support a structured Example Authoring and Maintenance Process. The information model would also be standard for handling investigation results in users systems and for transferring information between systems or for shared care records, ensuring alignment and consistency across systems beyond just the user and laboratory interface.
- A set of detailed recommendations are provided for FHIR implementation, implementation guidance and the use of constraint tables.
- Healthcare professionals need to be aware of a person's rights to access test results and the (increasing) level of detail they will expect to see.
- Implementation plans should include access for patients with supporting information for them.
- The stakeholders were very keen to engage and support the programme and use their front-line knowledge and lived experience to help shape the standards and guide the implementation so that it can deliver new standards resulting in safe and effective implementation which will make a real difference to pathology testing and care. It is strongly recommended that further and continued stakeholder engagement is used to validate the development and shape the plans for testing and implementation.

2 Introduction

2.1 Background and context

2.1.1 National Pathology Strategic Standards

NHSX and NHS Digital (NHSD) have a programme to implement standards for pathology messaging of test requests and results throughout the NHS and for the standards to be UK wide. Overall benefits for the consistent use of common standards will support:

- Easier sharing of test requests and results between all users and laboratories
- A replacement for the out-dated primary care standards for pathology messaging
- Reducing the need for re-testing when patients move between care providers
- Safer use of test results
- Facilitate the use of decision support
- Promote selfcare through better understanding of test results by citizens/ patients/ carers
- Enabling nationwide laboratory data collection/sharing and comparison

2.1.2 Current position and the need for change

At present pathology messaging in the UK is not standardised except in primary care, which is partially standardised, where the standards are based on the Pathology Bounded Code List (PBCL) for the test requests and results with EDIFACT as the transport mechanism. The PBCL is the national pathology test result code database, with approximately 3900 Read v2 and v3 codes specifying the data used within the ISB 1557 EDIFACT Pathology Messaging Standard, transferring approximately 100 million pathology test results from NHS labs to GPs each year.

Primary care has moved to SNOMED CT replacing Read codes which was retired in 2016, therefore it is no longer possible to update the PBCL with new tests. The EDIFACT platform is old technology and does not support SNOMED coding. The lack of standards outside of primary care and gaps in the PBCL mean local code systems and a lot of translations are used with the associated risks. This inhibits the sharing of results and has implications for monitoring such as performed by Public Health England for population health management. Units of measure (UoM) in use are not standardised for all tests and are not always machine readable limiting the ability of safely exchanging messages between clinical systems and safely interpreting results.

NHSD has confirmed the schedule for the retirement of Read v2 and V3 (CTV3) clinical terminologies and informed relevant organisations to commence preparations to make use of SNOMED CT for clinical data. In support of these preparations NHSX and NHSD programme has selected strategic standards to use to address the situation.

These are:

- A Unified Test List (UTL) using SNOMED CT (the NHS approved standard for terminology) to define the list of test requests and results. This is to replace the PBCL and meet the reporting requirements of all pathology specialists.
- The Unified Code for Units of measure (UCUM) as an international standard and both machine and human readable for the Units of Measure.
- HL7 FHIR (Fast Healthcare Interoperability Resources) as the messaging system to transport laboratory test requests, results, Units of Measure and all associated

metadata. FHIR is an international standard adopted by the NHS for use in all IT system communications.

At present the plans or timetables for implementation are not finalised. The outputs and feedback from this project will be used to shape implementation plans.

2.1.3 Pathology Standards development to date

The Unified Test List, first published by NHS Digital in 2018/19, is a list of SNOMED CT coded terms, initially focused on providing relevant codes to migrate from the former “Read code” based PBCL to SNOMED CT coding for primary care reporting. So far, the development includes over 1800 results covering blood sciences and starting to cover a few microbiology results. The list is being expanded over time and is expected to eventually encompass over 5000 codes or more across all pathology disciplines.

Progress on UoM, for the test result, included the development of the Interim Units Guide (IUG) and several scoping projects to identify the variance of UoM used in practice.

Initial FHIR profiles have already been developed by NHSD but prototype testing has not been achieved.

2.1.4 PRSB input to pathology strategic activities

The Professional Record Standards Body (PRSB) were engaged to develop prototype products to support the introduction of these selected standards, building on the work already achieved by NHSD (Phase 1). Following this, stakeholder consultations were conducted to gauge the overall feasibility of developing these products for national roll out and implementation (Phase 2). PRSB collaborated with MetadataWorks and Ramsey Systems Ltd for product development.

2.2 Project background and context

As discussed above, this project was conducted into two sequential phases over a six month period: in Phase 1 the demonstrator products were developed (delivered in October 2020) and phase 2 conducted consultations with key stakeholders to gain feedback on the feasibility of implementing these products at scale nationally. The purpose was to inform the next stage of development and implementation planning by NHSX and NHSD.

Section 2.2.1 and 2.2.2 is a recap of the project’s overall aims, objectives, and scope. Section 2.2.3 is a recap of Phase 1 and section 2.2.4 introduces phase 2 of the project.

2.2.1 Aim

The overall aim is to showcase that the strategic standards (SNOMED based UTL, UCUM for Units of Measure and FHIR messaging to transmit the test result), are feasible to develop and implement, and provide feedback from key stakeholders, gathered through consultations, to demonstrate the feasibility of their implementation.

2.2.2 Objectives

The objectives are:

Phase1:

- Develop mappings for the existing PBCL to the UTL for common and complex test requests and results, showing how the mappings can be developed and assured and how they could be provided as a table or centrally managed service accessed through APIs.
- Develop a scheme to allow Units of Measure to be added to the UTL for each UTL element using UCUM codes.
- Develop a demonstrator showing how FHIR messages can be developed from the UTL and UoM using independent tables to validate the UTL, associated UoM and values of the results units.
- Develop an Excel Spreadsheet with benefits, risks and issues

Phase 2:

- Use the demonstrators to engage key stakeholders and collate their feedback on the feasibility of the standards and how they could be implemented.
- Provide a final report identifying the gaps and where further work is required, lessons learned and evidence for potential implementations and suitable as evidence to support a DCB application.

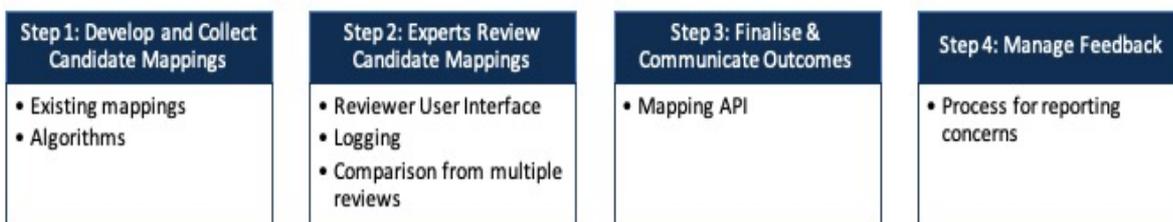
2.2.3 Phase 1 recap

PBCL to UTL mapping tool

Between July and September 2020, the PRSB partnered with MetadataWorks to provide NHS Digital with guidance, documentation, and deployable software tools to demonstrate the feasibility of a PBCL to UTL mapping, to meet the requirements for milestone 1 (Phase 1 deliverable).

MetadataWorks proposed that the outcomes of milestone 1 could be achieved through the deployment of an instance of the MetadataWorks Exchange (MDX), a secure, web-based cloud-deployed knowledge base specifically developed to support clinical organisations manage data evolving standards, and support interoperability and integration. The proposal was a mapping utility tool provided with the knowledge base.

At the end of Phase 1 MetadataWorks presented a proposed mapping process with four steps, a list of candidate mappings and a ‘first pass’ mapping review of the PBCL to UTL.



Units of measure strategic options

The PRSB delivered strategic options for deriving a preferred UoM for a test result and how that UoM might be communicated in the FHIR message taking into consideration the National standards adopted for pathology. The UoM options included direct inclusion of the (preferred) UoM in the UTL structure, message-bound valueset/constraint tables or a hybrid of the two. Further details can be found under Chapter 3.2.3.

FHIR message demonstrator

RamseySystems Ltd delivered a demonstrator to send test results from laboratory to end user (e.g. GP). This is the live prototype described in the proposal. The demonstrator [1] used an agent-based modelling engine to generate example messages [2] with a simple pathway [3] and set of example patients. The UTL codes, units and values for the “interesting cases” were set in a comma separated file [4]. The pathway is edited using the publicly available Camunda Modeler [5], and the other configuration files are all text formats that can be modified with a text editor. Fixed values for other parts of the result message such as health professional’s and specimen details are set in a json configuration file [6]. These could be made dynamic and determined by the pathway if broader aspects of the message were to be tested. The simulation can be run using docker, with instructions in the github project front page [1]. The “interesting cases” csv file [4] was populated with selected items from the statistical patient data that was obtained during the project, and if further anonymized or statistically-derived data becomes available, this file could be modified to use the new data. Indeed, all of the attributes populated with soft-coded fixed values from the json file, can also be populated from appropriately named comma separated files. This allows for the simple generation of test data using anonymized data or data derived from statistical analysis of live systems.

Constraint Tables (Tactical Solution) Demonstrator

An example of a constraint table was provided as a spreadsheet with a report describing its use. This established how sets of Units of Measure could be defined and associated with line items in the Unified Test List. This mechanism can be extended to express other co-occurrence constraints (such as constraining the values for “interpretation” or the datatype for values that are not quantified measurements) based on the test result code from the Unified Test List. The constraint tables could be used as input to generating the XSLT stylesheets used in the NHS Digital validation tooling, and so ensure that the Pathology Messaging specification is maintained alongside all the other FHIR profiles developed and supported by NHS Digital.

The example spreadsheet included a table for expressing constraints on valueQuantity, allowing constraints on the Unit of Measure to be expressed. In order to support test results that are not expressed as measured qualities (such as “++” and “+++” for glucose levels) additional tables could be added to specify the value datatypes supported for each UTL test result code and further tables to express constraints for specific datatypes such as valueCodeableConcept (which would be appropriate for the insulin example mentioned above).

Constraint Tables (Standards-based Strategic Solution)

The project team explored the current work of national and international standards groups, including HL7UK, HL7 International, ISO TC215 (Health Informatics) and SNOMED International, and established that there is no clear consensus on how such co-occurrence constraints should be expressed, and they are not expressed consistently across different specifications. Progress in these discussions was reported to NHS Digital during the weekly FHIR calls, and it was suggested during the BSI IST35 that further work could be undertaken to establish national and/or international standards in this space.

These products were delivered with associated draft products including example constraint tables and interesting cases of test types, results and UoMs that must be explored, and solutions agreed because they may pose problems in the message transfer.

A ‘benefits, risks and issues’ log was developed and delivered as an Excel Spreadsheet to NHSD.

2.2.4 Phase 2: stakeholder consultations

The remainder of this document focuses on the Phase 2 of the project: consultation methods, results, discussion of the findings with recommendations and conclusions. This should be read in conjunction with the outputs and deliverables submitted to NHSD from Phase 1.

3 Methodology and consultation approach

3.1 Phase 2 Aims, Objectives and Scope

3.1.1 Phase 2 Aim

Gathering stakeholder feedback on the feasibility of implementing these standards for test results:

- The feasibility of the prototype/ process for mapping the PBCL to the UTL (identifying gaps as appropriate) with an API to communicate mappings and support transition
- Using FHIR to send test results (UTL code, result, Units of Measure) with validation tables
- Exploring options for implementing Units of Measure and the proposed process for identification of preferred UoM
- Gathering benefits, risks and issues from implementing these standards

3.1.2 Scope Inclusions

Gathering stakeholder feedback on the feasibility of implementing the following standards for test results:

- The feasibility of the prototype/ process for mapping the PBCL to the UTL (identifying gaps as appropriate) with an API to communicate mappings and support transition
- Using FHIR to send test results (UTL code, result, Units of Measure) with validation tables
- Exploring options for implementing Units of Measure and the proposed process for identification of preferred UoM
- Gathering benefits, risks, and issues from implementing these standards

3.1.3 Scope Exclusions

- Producing final products – Phase 1 products developed were only demonstrators or proposed processes to support stakeholder engagement and understand feasibility
- Considering the other attributes required in the FHIR messages beyond the result code, values and Units of Measure (e.g., reports, reference ranges, specimen information etc.)
- Appraise the capability of system suppliers, laboratories and NHS providers to implement these solutions

3.1.4 Project team

A mixed team was established for the work to bring the right skills and expertise. PRSB partnered with MetadataWorks for the UTL-PBCL mapping work, whose Metadata Exchange product is designed for loading and mapping datasets and code systems, and with Ramsey Systems for the FHIR messaging bringing their experience of implementing and simulating health standards and systems.

The work was led by pathologist and GP clinical leads and a citizen lead to guide the direction and approach to the stakeholders, as well as provide expert advice.

The full team is shown in Appendix 9.1

3.2 Consultation Approach

The aim of the consultation was to gain participant feedback on the feasibility of implementing the selected strategic standards supported by the development and products from phase 1.

A stakeholder mapping exercise was done to identify and list all the relevant stakeholders. For the consultation three separate streams were identified for engagement through a series of webinars. Given the complex nature of pathology and these standards, the three groups were based on technical understanding:

1. Technical stream. Aimed at technically aware clinicians, pathologists, lab scientists, and those implementing the standards including system suppliers, IT staff from labs and provider organisations

For this group, three webinars were held with largely the same attendees and the discussion continuing across all three. These sessions looked in some detail at the selected methods and processes from the phase 1 work and sought feedback on some of the areas where the phase 1 work revealed options for how implementation could be done.

2. Clinical users including research and public health.

Two webinars were held with some continuity and some new attendees for the second webinar. These webinars focussed more on the needs of the users, how the standard could improve usability and care for patients and the implications of the new standards including risks that would need to be considered and addressed.

3. Citizens

A single webinar was held with a small group of knowledgeable patients so the benefits and implications for patients could be understood and used to inform the development and implementation.

Details of the stakeholder attendees and the webinars are shown in Appendix 9.2. Overall 63 stakeholders attended the webinars, with many attending 2 or 3, with good coverage across the users from GPs to hospital clinicians, public health and researchers, pathologists, scientists, system suppliers, provider IT and patients.

3.2.1 PBCL to UTL mapping tool

In the webinar consultation process, we presented stakeholders with the following:

- The assumptions we'd made about the usefulness of the mappings
- The proposed mapping process, its risks and benefits
- The suggested methods of communication: API, file for download
- Questions about how to report and manage queries and concerns
- What other issues/problems need to be considered in addressing it?

We engaged stakeholders on the following:

- Agreeing a process for mapping that could be utilized for related/similar mapping tasks
- How to implement a mapping
- How to manage the mapping process on an ongoing basis (managing updates, issues etc.)

3.2.2 Options for Units of Measure (UoM)

For the consultation the following were presented as the key areas for consideration:

- The proposed process for creating a preferred UoM
- Options for UoM associated to UTL or assembled in FHIR message

Table 1 shows how the feasibility of the preferred UoM was developed and showcased for feasibility with consultees.

Table 1: Testing the methodology for empirically deriving the preferred UoM for a test result

Collated sample frequency tables of UoM used for tests	Identified preferred UoM for a test result from tables	Sense checked tables with other code systems	Consulted on empirically derived preferred UoM
<ul style="list-style-type: none"> • Used mainly blood sciences with some microbiology raw anonymised lab results data • Sample data sources were: NPEX, GP data and hospital lab data • 155,372 test results used: 93,711 from hospital, 168 NPEX and 61,493 GP 	<ul style="list-style-type: none"> • Counted UoM used for a test (UTL code) from the sample • Displayed frequency of UoM as percentages • Developed prototype constraint tables/ value sets for preferred and allowable UoMs 	<ul style="list-style-type: none"> • Conducted high level comparison between sample results and UCUM, NPU, LOINC • Checked if UoM identified for a test is the same/ in agreement with these systems <p>Identified approach uses, benefits, issues and risks</p>	<ul style="list-style-type: none"> • Included relevant current literature to inform findings, potential uses, benefits, risks and issues • Gained stakeholders views via Webinars • Consulted with technical, laboratory, clinical, research, patient/ lay audiences

The options derived from Phase 1 for communication of the UoM in the FHIR message specification was presented, to consultees, as follows:

1. Preferred Unit of Measure hard coded in the UTL as a data field (using UCUM, SNOMED CT or proprietary code list)
2. Units of Measure coded as a value set list (used as constraint map) for the

potentially usable UoM for the individual test and the constraint map reference stored in the UTL as a field

3. Both a preferred unit code and a constraint map reference is stored in the UTL

All approaches assume that the clinically used UoM is sent within the FHIR message.

3.2.3 FHIR message demonstrator

The Ramsey Systems CADE (Care pathway Analysis and Design Environment) Simulation engine was used to generate example messages. The CADE tool supports pathway-driven agent based modelling, the generation of digital outputs using industry-standard Jinja2 templates, and the posting of those outputs to webservices, files, or other endpoints using locally configured adaptors.

A set of configuration files for the CADE simulation engine were posted to github. The focus of this simulation is the representation of the observation information, and in particular the Unit of Measure and the attributes of the observation that are constrained by extended Unified Test List. The simulation generated a set of results based on the contents of a csv file (observations.csv) that defined the relevant attributes. The demographics, timestamps and identifiers were generated by the CADE tooling following a simple BPMN pathway for the test requesting and reporting process. Items could be added to the observations.csv file to illustrate how the observations should be populated for interesting cases.

The simulation generated FHIR resources for the actors (patient, health care professionals and organisations) as well as the request and result. These were posted as individual resources into a generic HAPI FHIR server. This was a simple way to demonstrate that the resources conformed to the basic FHIR specifications.

A bundle as defined in the National Pathology Messaging Specification was also composed and validated using an instance of the Care Connect Reference Implementation (CCRI). The CCRI automatically imported the National Pathology Messaging FHIR profile and validated the bundle against these.

The bundle was also saved to a file and submitted using the MESH client to the NHSD OpenTest FHIR validation service. This included validating the bundles using the NHSD rules engine implemented using XSLT stylesheets. It is anticipated that the constraint tables can be used to generate additional XSLT stylesheets to test the constraints expressed in the constraint tables, although this could not be tested in the timeframe of the project due to issues with OpenTest availability.

3.2.4 Citizen Consultation

Whilst not forming part of the contracted deliverables, the PRSB felt it worthwhile to gain patient and citizen views on this work in order to ascertain any potential impacts on both the feasibility and implementation of any revised solution. We wanted to know whether there would be any degree of interest in any proposed changes in this area and whether the proposed solutions or implementation considerations potentially supported or conflicted with citizen/patient aspirations. As one citizen commented “After all, we are both the subject matter of the tests and the real end user of the test results”.

A semi-structured two hour workshop was undertaken with citizens on 24th November 2020. Core themes discussed included:

- Experience of receiving test results currently
- Whether the results were currently straight-forward to access and understand
- How they would like to access test results in future
- Whether supplementary explanation would be necessary
- Future format of information presented to patients
- Patient Concerns

3.2.5 Consultation findings

The findings are reported in the following four chapters:

Chapter 4: Mapping PBCL to UTL tool

Chapter 5: The proposed methodology for identification and implementation of the preferred UoM for a test result and the options for sending the UoM in the FHIR message

Chapter 6: The feasibility of sending the test result using HL7 FHIR and issues to be considered to ensure a safe and effective transmission, receipt and end user interpretation

Chapter 7: Patient consultation

4 Findings and discussion: PBCL to UTL mapping tool

4.1 Mapping PBCL to UTL tool

4.1.1 Lessons learnt from the mapping process:

1. Initial intention was to split the review of the ~1500 UTL codes into randomized batches of an estimated effort of 1-2 days' work, amongst a small number of reviewers (~5).
2. Feedback from early reviewers was that they were not able to review many of the randomly assigned codes and required codes that matched their areas of specialisations.
3. Batches were revised into UTL codes of specialisation areas.
4. Some reviewers were able to complete large batches over time, however the majority of reviewers were not able to dedicate full days to the reviewing task, resulting in needing to recruit further experts to complete the reviews.
5. The average reported time taken to review a code and the candidate matches was around 1-2 minutes per UTL code.

4.1.2 Feedback from reviewers

6. There is a learning curve associated with being a reviewer, and reviewers noted that they felt more confident once they had “got into it”.
7. Despite the evidence below that the search was not required in the majority of cases, reviewers felt that the search added to their confidence that the code they had selected as the match was the right one.
8. Reviewers were often keen to give feedback on the UTL code itself (the user interface and system design enabled feedback on the proposed candidate matches but was not intended to collect feedback on the authoring of the UTL codes). A feature to enable reviewers to feedback on the UTL code could be incorporated into future versions if desired.

4.1.3 Improvements to be made to the prototype/demonstrator code matching system

These are supplementary recommendations for the code mapping system requirements presented in Phase 1, milestone 1):

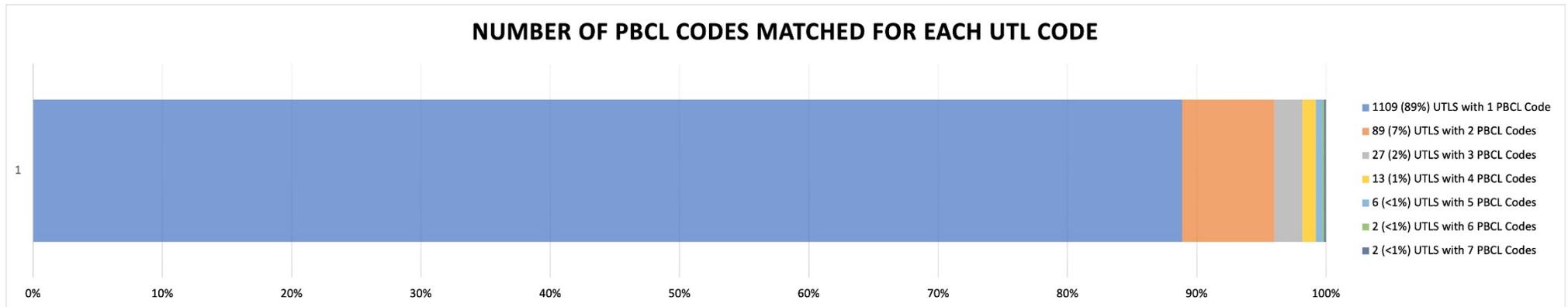
9. The ability to assign or name code batches for reviewers (in order to indicate which batch, they should review)
10. Improvements required to the search (***) Noting that the search didn't result in many matches – get analysis/numbers, but helped reviewers feel confident about their choices)
11. Perhaps introduce an option in the user interface to indicate “no matching code”, rather than just “no suitable matches identified here”
12. When commenting or rejecting codes, the page re-loads from the top. Users would like it to return to the section (i.e. the position of

the code on the list) that they were last looking at.

4.1.4 Results of how successful the algorithm was:

1424 candidate matches were approved in the first pass, covering 1248 unique codes

13. Of the 1248 unique UTL codes, 1109 UTL codes have only one related PBCL code. The remaining 139 UTL codes have between two and six approved PBCL matches (see chart below).



14. In 759 cases, the approvers identified a “correlation id”. In the remaining 717 cases, the approvers selected the default ‘related’ correlation. The correlation ids identified were:

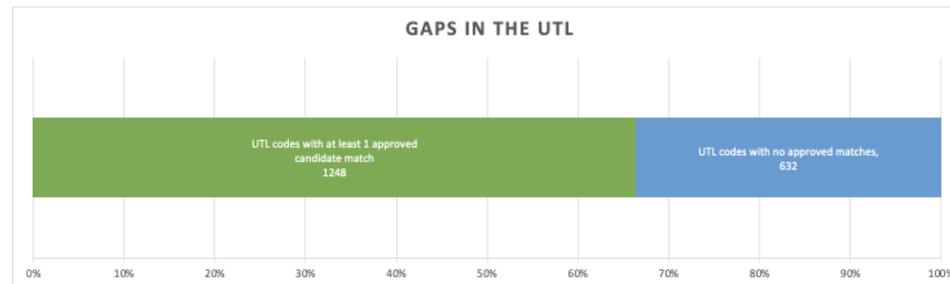
- Exact Match (n=470)
- Narrow to Broad Match (n=212)
- Partial Overlap (n=62)
- Broad to Narrow Map (n=15)

15. 96.5% of the matches approved were sourced from the algorithm, with only 52 of the approved matches identified using the search function. However, when these search suggestions were compared with the initial candidate matches, 42 of these had been identified by the algorithm and included in the initial list of candidate matches (meaning that the user had searched and selected a match already presented in the screen above). Therefore, in total 99.3% (1466) of the matches were sourced from the text matching algorithm.

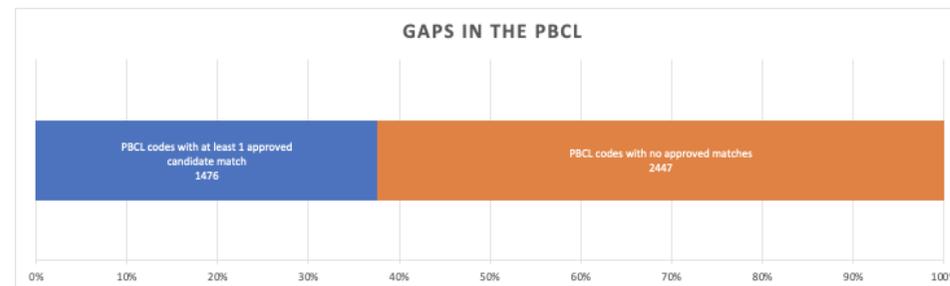
16. The algorithm scored each of the matches between 0 – 1, with zero representing no matching text between the two terms, and 1 representing a perfect match. This score determined the order in which the candidate matches were presented. Of the 1466 approved matches sourced from the algorithm, 60% of the approved matches were from the highest scoring candidate match, 15% from the second highest scoring match, and 7% from the third highest scoring match, with the remaining 9% sourced from the fourth to seventh highest scoring matches (noting that candidate matches were pruned to display only the top seven matches).

4.1.5 Gaps in the code mappings:

Of the 1880 codes in the UTL, 1248 UTL codes had at least one match approved in the first pass mapping, leaving 632 codes with no matches identified.



Of the 3923 codes in the PBCL, 1476 PBCL codes had at least one match approved in the first pass mapping, leaving 2447 codes with no matches identified.



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4.1.6 Recommended next steps for finalising the mapping (beyond the scope of this project):

17. Review all comments to ensure any concerns have been noted.
18. Ensure that the 632 UTL are legitimate gaps
19. Undertake a quality assurance process on codes. Options:
 - Reassign code batches to a second reviewer and compare the outcomes. Where two reviewers don't agree, flag code match for further considerations.
 - As suggested in the stakeholder consultations, there is the option to prioritise clinically significant codes. An expansion of the frequency tables, used in the UoM analysis, could support the identification of the most frequently used PBCL codes.
20. Prepare a submission for the Pathology Standards Governance Board (PSGB) for the approval of the mappings.

4.1.7 Future improvements to the algorithm:

21. The algorithm utilised was based on matching elements of the text.

22. Future iterations of the algorithm could consider:

- Incorporating lists of known synonyms
- Algorithms that utilise 'semantic' similarity, learnt from analysing large collections of unstructured text.

4.2 Consultation feedback: themes identified with supporting evidence

Feedback from the consultations about the mapping tool was organised into themes and is presented in the following table together with the supporting evidence and recommendations for implementation and use.

Table 2: Consultation feedback themes with supporting evidence

Themes	Findings	Recommendations	Comments
Key themes identified in consultation	Output of all consultation methods summarised	Summary of recommendations	Quotes from consultation participants
The utility of a PBCL to UTL mapping	Stakeholder during the webinar agreed with and supplemented our initial assumptions on the usefulness of a PBCL to UTL Mapping A maintained, version controlled UTL to PBCL mapping would support: Systems to transition their existing coding to the new coding standards	A PBCL to UTL code mapping should be maintained, version controlled, and communicated to a range of users.	<p>“We’ve had lots of issues and we’ve recorded so many times significant events where a drop in renal function was not picked up early enough, so that the trends are not able to be demonstrated easily...not get the right coding in, and when we changed the codes, it just didn’t translate” - Clinical webinar 1</p> <p>“It has happened in the past for examples like PSA (Prostate Specific Antigen) where they changed the coding of the test. And before that coding was changed you can’t see the mapping process in the clinical records, but for other things where the coding hasn’t changed you can see the historical results” – Clinical user’s webinar 2</p> <p>“We develop surveillance systems, so I guess I’m a researcher in this context. We use information from clinical systems to look at trends over time for diseases.... So, by having access to how things change over time, we can explain it when we are looking at trends and surveillance. – Clinical user’s webinar 2</p>

	<p>Systems that have not yet transitioned to interact with systems that have, by providing a translation table</p> <p>A basis for mapping local codes</p> <p>Analysis of patient results over time (e.g. graphing renal function trends between past and present coded results)</p> <p>Researchers working with historical data</p>		<p>“The local LIMS code to Read codes is typically done in middleware. We wouldn’t expect [the middleware suppliers] to keep the Read codes in there, but instead map the LIMS code to the UTL SNOMED code.” –Technical User webinar 2</p> <p>“Obviously not every test when it came out had a Read Code. And I know that they had to sort of manufacture something in the GP system to make it work. Obviously, transitioning to what you are suggesting, a test list with a SNOMED code against it, wouldn’t be necessarily mapped in the GP system. – Clinical Webinar 2</p> <p>“There are certainly many local codes in GP systems and in Scotland / Was... There are certainly local codes in GP systems and in Scotland, Wales and NI many of these have been added to match with new SNOMED CT concepts. Also beware. Local codes still occur in the SNOMED CT domain so there are for example EMIS namespace codes. All adds to the challenge of retrieving data from records. And as Charlie is saying these may be needed while we wait for new concepts to be added / deployed” - Clinical Users Webinar 2</p> <p>“Nearly all lab systems use local codes with still a significant number (?majority) of legacy systems out there which were initially configured 20-30 years ago!” - Clinical Webinar 2</p> <p>[In anticipation of a revised, standardised system] “Ultimately, it will be interesting to see these patterns in pathology tests across the country in the same way the openprescribing.net does for prescribing.” - Clinical webinar2</p> <p>“not all systems pass through LIMS e.g. glucose meters and gas analysers. Sorry- to clarify I mean Point of care devices which operate independently of clinical requesting systems and do not send results through the LIMs” - Clinical user’s webinar 2</p>
<p>The proposed process for mapping the</p>	<p>Users didn’t raise any concerns with the proposed process and</p>	<p>Frequency analysis to identify the most relevant pathology codes could be used</p>	<p>“We want a situation where we can have a smooth transition from where we are now with the EDIFACT system and PBCL with its SNOMED translations, to a situation where whatever we</p>

<p>UTL to PBCL</p>	<p>indicated that they felt it was fit for purpose.</p> <p>They noted the requirement for all codes to be mapped, to ensure past data was not lost in the transition.</p> <p>A reviewer participating in the webinars suggested one improvement that could be made would be to priorities the most clinically significant codes.</p>	<p>to prioritize clinically important tests for mapping review and quality assurance.</p>	<p>are using with UTL can cover everything that we need to have covered, so we don't suddenly find when the switch is flipped that there are a whole lot of tests that were happily coming through without any problems at all and being translated in SNOMED are suddenly no longer coming through because there is not an appropriate representation in UTL.”</p> <p>– Clinical User Webinar 1</p> <p>There may be a small learning process” to being a reviewer. They also noted that there might be some opportunity to priorities the code mapping exercise to the most clinically significant codes (since they found themselves questioning the usefulness of many presented). - (paraphrased), Clinical Webinar 2</p>
<p>Methods for communicating mappings</p>	<p>The assumption was made that end users of clinical systems may not interact directly with the mappings, but rather these would be utilized and incorporated into existing systems.</p> <p>Different users spoke of the utility of the various methods discussed.</p>	<p>Mappings could be communicated in three simultaneous methods:</p> <ul style="list-style-type: none"> A query-able API A downloadable delimited file A searchable, human readable browser <p>All methods should enable the communication of current and past versions of the mappings.</p>	<p>“Although it would be good for systems to be user friendly, I can't imagine the average GP ever having time to look up mapping codes in everyday life.” - Clinical user's webinar 2</p> <p>“My experience with APIs is that an update can be generated for a result or a Unit of Measure that you are expecting back that has been changed. That's fine and dandy if all of the pathology systems are in sync – but they're not. We've got internal systems at the bedside, that are expecting certain Units of Measure and so forth. We've got EPR systems where the doctors are expecting either the same test code, that a result is relevant to a previous result, and that may change if an API has decided to update. So, it could be the case that the updates are available, but we need to define which version we are interested in; and then post-a-validation effort, we can then request the latest version, 1.1, 1.2 etc.” - Technical Webinar 1</p> <p>“You may well want to have some means online where people, clinicians for example, who might just want to browse things, or check things, and this means they can look them up. For example, on the NHS Browser you can find the ref sets that</p>

			<p>relate to the UTL and PBCL, but you then need to have your own tools, or know where to find the tools, to go away and get and the ref sets to see what's in them, as you can't actually browse the ref sets on the NHS browser. So, to have some kind of a portal that allowed people to search for things could be really helpful.” – Clinical User Webinar 1</p> <p>“It would be very useful for us to have access to these mapping to see how things change. We have developed surveillance systems that use APIs, so we tap into systems to gain access to data, so we grab it on an as needs basis, rather than grabbing it locally, to save on server space etc. We use an Azure Cloud type thing, or we are moving towards that anyway” – Clinical Webinar 2</p> <p>“Also, make it open, so you don't have to be within the system, so you don't have to be working for the NHS, as it would definitely be useful for researchers, university colleagues, PhD students, that sort of thing..... I do think a published mapping on the website would be good, like a SNOMED browser kind of thing; that would for us, and certainly for pointing PhD students who are learning.” – Clinical Webinar 2</p> <p>“Batched release preferred, with exceptions for patient safety” - Technical Webinar 1</p>
<p>Methods for reporting, tracking and managing concerns</p>	<p>Users recognized the importance of participating in this feedback loop, for the purposes of improving quality, and ensuring patient safety.</p> <p>Different users require different methods for reporting, tracking and managing</p>	<p>Provide a range of reporting methods for mapping users, including a searchable and interactive forum to drive engagement with the quality improvement process; and an immediate triage service for queries from clinical practitioners utilizing mappings.</p>	<p>“Report to a central portal for rapid cascade. they would have an idea of whether this was a frequently encountered issue across different combination of systems” - Clinical User Webinar 2</p> <p>“Having a log of the problems and being able to comment you've seen it too is a good solution” – PRSB responding to comments in the chat</p> <p>“We need to make reporting as easy as possible. Whilst a portal where existing issues have been logged, and are reviewable would be good, in reality, in the case of primary care, where the GP might not have the time, or not necessarily the inclination to see whether it's already been logged or not. So I think an email address, where they are able to quickly articulate concerns, and</p>

	<p>concerns. For example: busy clinicians might prefer to report concerns or make queries via a service desk function, that can quickly respond (e.g., issue has been noted for future correction – use this code as a workaround, or issue corrected in v1.0.7 etc). Other uses would prefer a searchable forum where they could see what issues had been reported, and indicate their agreement etc.</p>		<p>have someone on the receiving end, checking whether this is an active issue or not would probably work better, and I think you would be much more likely to get flagging and added notification of potential errors if we allow an email address, where the recipient is tasked with finding out whether this is an ongoing issue or a new one. From previous experience, we've had suppliers come in for example for a new template that's been launched, to log things on the website. And actually, the number of problems logged are minimal compared to the number of emails that go to the IT service desk. So, it becomes a parallel process, as opposed to a unified process. So I think just having an email address would work better Clinical Users webinar 2.</p> <p>“How would we differ between recommended changes to the Codes vs this is mandatory change - it must change” - Clinical Webinar 2</p>
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4.3 Risks identified through the consultation

The following risks were noted in relation to the UTL to PBCL Mapping:

1. Stakeholder expressed concerns and previous experiences of systems transitions that resulted in “lost or dead codes”.
 - a. Stakeholders felt a primary cause of this situation was codes that were left unmapped, resulting in these codes being unusable post transition.
 - b. However, some stakeholders noted that SNOMED doesn't record the reasons for retired codes; making it difficult to track retired SNOMED codes and appropriate code maps over time.
 - c. A recommended mitigation for this risk is to ensure all codes (including retired or historic codes) are mapped in the system prior to system transition.

2. Stakeholders emphasized the risk of errors or omissions in pathology information as a result of the translation of the codes through a complex environment of downstream systems utilizing pathology information.

- a. Complex environment of systems includes Laboratory Information Management Systems (LIMS), Middleware, General Practitioner (GP) Systems, and bedside care.
 - b. The sophistication of these system varies. An example of a risk that could arise from their environment would be a filtering system that resulted in results not being presented in downstream systems.
 - c. A recommended mitigation for this risk is to ensure that a local impact and risk assessment, and an extensive testing routine accounting for downstream system environments are undertaken ahead of the change, and future version changes.
3. Stakeholders noted the risk of errors or omissions in pathology information as a result of delays or staggered timeframes in system updates
- a. The complexity overhead of required system changes was noted by participants.
 - b. A recommended mitigation for this risk is to version control the mapping details delivered by the API to ensure that each system specifies which version of the mapping they have implemented and tested.
4. Stakeholders noted that any failure of system users to report concerns would reduce the quality of the mappings.
- a. A recommended mitigation for this risk is to make the reporting process as easy as possible. The suggestions from the consultation were to have multiple reporting options, to accommodate the range of users working with the codes, including:
 - i. An interactive portal where users can log, search and comment on reported issues.
 - ii. A staffed email address to respond to reporters to confirm the status of the issue (for example, whether it had been noted, any version updates which corrected the issues, or whether there was an approved workaround for earlier versions).

5 Findings and discussion: Preferred UoM and options for transmission in FHIR message

This chapter describes the consultation findings from the webinars (section 5.1) which informed the refinement of the methodology proposed to identify and assign a UoM to each test result (Section 5.2) and how this could be communicated in the FHIR message (Section 5.3).

5.1 Preferred UoM for a test result and options or transmission in FHIR message: consultation findings

The draft method developed to identify and assign a preferred Unit of Measure for a test result and how this result should be communicated in the FHIR message was presented to stakeholders during the webinars. Main findings from these consultations are described in the Table 3 below. These were used to inform and iteratively refine the methodology proposed and developed during Phase 1 of the project.

Table 3: Consultation themes for UoM standard and messaging options

Themes	Findings	Recommendations	Supporting comments
Key themes identified in consultation	Output of all consultation methods summarised	Summary of recommendations	Illustrative comments, practical examples and quotes from consultation participants
The proposed process for identifying and assigning a preferred UoM for a test result.	Stakeholders broadly agreed with the proposed methodology for derivation of a preferred UoM. They concurred with the likely benefits, risks and issues arising in relation to using the proposed method at scale and mitigations suggested. The specific requirements of this methodology, as outlined in Table 4 below, are discussed in more detail in section 5.2. And chapter 6.	The use of preferred units is encouraged and accepted. The stakeholders generally agreed to the proposed methods of deriving preferred UoM	
Options for communicating the UoM in the Unified Test List	This was a relatively new concept to some stakeholders and the example diagrams and use case presented during the webinars aided understanding. They agreed with the options appraisal presented. More details are described in section 5.3 below and chapter 6.	The combination of including the preferred unit in the UTL code and the constraint list reference (hybrid, option 3 above) is the preferred option, as it allows for a preferred	

		UoM permanently anchored to the test code, while the constraint list enables other units to be used (good for variable but safe clinical usage, legacy data integration and decision support)	
Conformance with using the preferred UoM: mandatory use vs incentives and drivers to encourage use	<p>Ways of ensuring the preferred UoM was used for a test result was described and acceptable ways to achieve this.</p> <p>The most effective way to drive adoption of preferred UoM is to use existing infrastructure and resources to incentivise laboratory usage.</p> <p>Use PQAD as a mechanism by adding preferred UoM usage to the quality assurance criteria. This will help laboratories gauge how they are doing against the national average and incentivise them to improve conformance.</p> <p>Inclusion of preferred UoM usage in commissioning and systems purchasing specifications are key drivers for adoption.</p>	Provide incentives and drivers which encourage laboratories to use the preferred UoM for a test result rather than mandating use at this stage. Main incentives include inclusion in national laboratory quality criteria and systems purchasing specifications .	<p>Transition is high risk and with moving to a new unit the process of gaining compliance and looking down stream for impact is needed.</p> <p>Not sure it should be absolutely mandatory (use preferred unit); there are softer ways of getting where you should be – natural drivers.</p> <p>Lab networks are a good driver and Model hospital.</p> <p>PQAD – laboratory quality framework with national dashboard showing status of laboratory against national standards. Could have a metric for compliance/ noncompliance with preferred UoM usage for a test result. (Technical webinars)</p>
Risks and issues with the difference in UoM and results for the same test request	<p>In practice there is a choice of commercial analysers available so methods of analysis may differ and order of magnitude of test results may differ.</p> <p>Ways of mitigating risk include: Availability and recording of metadata about how test conducted; publication of</p>	Use of preferred UoM with constraint tables of allowable alternatives. Preferred UoM and allowable alternatives must align with national and international standards (e.g. UCUM, SI	<p>In practice there is a choice of commercial analysers available so methods of analysis may differ and order of magnitude of test results may differ.</p> <p>Ways of doing a test can be different and the metadata (behind the scenes will tell you how the specimen was tested)</p>

	analysers used; precise UTL codes	– like if there is a weight observation, the unit must be a mass unit	Point of care devices also need to be up to date – they don't go through LIMS data collection/assurance and quality control (Technical webinars)
Challenges to ensure changes, pertaining to laboratory tests/test codes are communicated effectively to all relevant stakeholders	At a laboratory level communicating any change to all end users is very challenging due to current infrastructure and processes that impede effective communications. For example, it was noted that it is impossible to gain access to all GPs users to communicate a change in processes.	Explore methods to enhance local laboratory communications with all stakeholders to aid implementation of the pathology programme and its effective adoption.	Getting to GP users, for example, we have a lot of difficulty to tell them of the changes. Need a comms channel to push for standardisation. (Technical webinar)
Challenges are identified with the test result and report outputs being manipulated in end user systems without the laboratories' authorisation	End user result transfer to GP systems and EHR systems may be done without pathology/LIMS consultation or knowledge.	Identify and resolve significant issues and risks related to local end user practices that may impede the effective use of the new pathology standards.	What we see in the lab is what is supposed to be what is seen in the end user system. For example, what we are finding is that test results that have been sent to GPs without, e.g. reference ranges are having a reference range added locally. (Technical webinar)
Methods for identifying and managing mistakes with the introduction of new standards	<p>Concern was raised regarding how quickly a mistake can be identified for example a wrong UTL if an assay changed. This was considered an implementation issue.</p> <p>Introduction of the pathology standard does not negate the need for current safeguarding and failsafe systems.</p> <p>Human oversight, review and authorisation will always be required whatever the level of computerisation and automation.</p>	Implementation: For clinical safety development and introduction of the pathology standard must ensure appropriate level of human expertise , intervention and validation for all significant processes in the development, implementation and use of products and materials pertaining to the standard	<p>Need to have a close look at anything that is new – easy to send out 1000/2000 results that can have an error - clinical risk</p> <p>For example, if the assay changes and the UTL is wrong when will it be noticed? may have sent out 1000s of results before it is noticed.</p> <p>This is an implementation problem, if anything changes then a message is sent out. There are different ways of managing it – safeguarding and failsafe mechanisms. There needs to be human intervention and authorisation in the system, you can't totally rely on computers. (Technical webinars)</p>

<p>There is a role for interesting cases: categorising and agreeing solutions for test results and UoM that are ambiguous and open to misinterpretation</p> <p>The usage and different local practices can create risk for misinterpretation and clinical safety when results are sent out to another potentially slightly different system</p>	<p>There are real and enduring problems with semantics of language between different professional groups and within the same professional group which can lead to problems in transmitting the test result and UoM in FHIR and with interpretation by users of the test results. For example, defining and describing 'value versus interpretation from a clinical and messaging viewpoint.</p> <p>The variation in use of some UoMs is a clinical problem which in turn will cause problems in the messaging. The underlying problems with clinical usage need to be resolved in the first instance. For instance, ratios should be explained in the test UoM, the clinical context and the difference between the result and report is important.</p>	<p>Develop an information model and a reference library, with clinical and technical experts, which includes interesting cases with clear definitions of what goes into the result and interpretation fields.</p> <p>Develop constraint tables for preferred UoM and allowable alternatives</p> <p>Keep interpretation and value fields separate and both will have constraints attached to them</p>	<p>For example, need to know what is being 'ratioed'</p> <p>Interpretation vs value needs clarity as getting them mixed up.</p> <p>Interpretation – there are different ways of viewing this – from a messaging and clinical interpretation senses. For example, a result field that has positive or negative is treated as a 'value' in a messaging sense. Clinical significance of this result is 'interpretation'. For example, 'critically high' is interpretation. ' Maybe using interpretation is maybe not good'</p> <p>What is being ratio'd needs to be known to users for the results'(Technical webinars, Clinical webinars)</p>
<p>Knowing the context is vital to understanding current problems with pathology messaging and results</p>	<p>Some of the problems highlighted were outside the scope of this project. These problems related to such things as using and interpreting test results, decision support requirements, lack of integration of results system with EPR. Highlights how difficult it is to develop a 'bit of a system' without consideration of the wider impact down the line.</p> <p>Messages need to be machine readable to be able to give decision support</p> <p>Important to understand the rationale and background for why 'things are done as they are before you can tinker so you appropriately assess the impact downstream. For example, a test report needs to be issued for charging the customer.</p>	<p>Human oversight, review and authorisation will always be required whatever the level of computerisation and automation.</p> <p>Machine readability is important for decision support, human readability is important for checking and oversight</p>	<p>Antibodies in Rheumatology is an example of GPs not knowing how to interpret the results Suggest put on prompts and information. Also prompts of how often tests should be done.</p> <p>Advise caution of over complicating the system – too many clicks, too much information.</p> <p>Its about clinical content as well.</p> <p>ICE doesn't lift information from the EPR system (EMIS)</p> <p>Decision support - Messages need to be interpretable by the machine to give the support.</p> <p>Remember what is happening to this data downstream. If a report is issued even if there is no data/ test done – then this is chargeable as the report is issued.</p>

			(Clinical and technical webinars)
Problems with non standard comments in result reports	Standardisation of comments in reports	Standardisation of comments in reports	Can we standardise the actual comments going back in the report? For example the following aides would help: link to guidance, constraints, pick list of comments, text strings. (Clinical webinar)
Risk of message ability including: message being disaggregated at the transmission stage and concerns that this won't work for other areas like microbiology and histopathology	HL7 common UCUM expression list viewed as very important, but may not work for the other pathology disciplines, in these circumstances other codes (?SNOMED CT)/value list should be offered	Develop the technology-independent information model for pathology with clear definitions so it's clear what information goes where in the message fields, and for the capture and tracking of new requirements from stakeholders, whether those are expressed as information items, business rules, risks or benefits. The Information should also support a structured Example Authoring and Maintenance Process. Further and continued stakeholder engagement should be used to validate the development and shape the plans for testing and implementation.	Is there a working group for micro , cell path? Concerned that this won't work for the other areas – micro/ hist/ cell path (Technical webinar)

Please also see 6.2 for message related UoM comments.

5.2 Preferred UoM for a test result: proposed method

A summary of the proposed method to identify and assign a preferred Unit of Measure for a test result is shown in Table 4. The table is a high-level description of the main stages and considerations that need to be taken into account when developing this for national roll out.

Table 4: Proposed methodology to standardise the UoM for test result

Collated sample frequency tables of UoM for tests)	Sense check tables with other code systems and experts	UoM development processes and artifacts	Governance and oversight of UoM
<ul style="list-style-type: none"> • Define scope, aims, objectives for using frequency tables (see below) • Use raw anonymised test data from representative samples (NPEX, GP and hospital labs) • Collate and analyse frequency of UoM used for a test (UTL code) 	<ul style="list-style-type: none"> • Compare outputs with standards (UCUM, SNOMED CT expressed with UNICODE/ ASCII) • Categorise and develop solutions for interesting/special cases • Sense check against NPU and LOINC • Validate against expert knowledge base (SMEs, laboratory medicine, clinical guidelines) 	<ul style="list-style-type: none"> • Define preferred UoM and allowable alternatives • Constraint tables/ value sets for allowable UoM • Look-up system, APIs for users • User rapid response feedback tool to answer queries and report problems • Define maintenance system and quality control measures 	<ul style="list-style-type: none"> • Professional Colleges assume responsibility for UoMs • UKTC assumes responsibility for coding • PSGB assumes responsibility for system and reports to NHSD IRES • Existing mechanisms can foster good practices • Implementation roadmap and stakeholder comms (NHSD)

5.2.1 General issues related to the implementation possibilities of UoM

There are different types of results within the different pathology disciplines; the blood sciences currently included mostly rely on value/Unit of Measure pairs in conveying results. The internationally accepted semantically interoperable (machine readable) system to transfer the UoM is UCUM – Unified Codes for Units of Measure. This standard would cover many of the UoMs in the recent iterations of the UTLs and the clinical and technology consensus is that it needs to be used, whenever possible. There are two disadvantages on practical level with using UCUM on

its own, without a standardised human readable representation also included in the result: the UCUM units are not always “user friendly” – and while their syntax facilitates semantic interoperability, all the results need to be checked/validated by providers and users; human readability is a very important part of the clinically safe result communication.

There is a necessity to have a human readable code, where UCUM is difficult to view – but this can be implemented in the value sets/constraint tables. Also, it needs to be considered that the character encoding of the human readable UoM should be done using an appropriate character set, which enables unambiguous representation of the UoM to include, for example, Greek characters– so it is likely that ASCII is not suitable and Unicode should be used for the primary human readable representation. A risk assessment should be done to determine whether there are systems that do not support Unicode, and if so, how this will be addressed.

It is also important to provide some mechanisms to handle legacy data in the laboratory systems – to enable comparing and interpreting pathology data on a timeline; the legacy UoMs should be possible to consolidate with the incoming ones, therefore a mechanism (most likely via value sets/constraint lists) should be explored.

It is important that the best coding system is used for the machine-readable Unit of Measure codes.

The UCUM is currently the best option for this, but a solution using SNOMED CT would overcome the Intellectual Property issues related to using UCUM, and it would provide a more robust governance process. However, it would need to include cooperation and involvement of the SNOMED CT Editorial Committee and the NHSD terminology team. This might require time and resources, but on the other hand the resulting SNOMED CT code representation would offer the advantages of an ontology solution and would allow for international standardisation via SNOMED International. The structure of SNOMED CT, based on description logic, would allow for easy maintenance of synonyms, alternate media renderings, and language translations for the Unit of Measure expressions. The simplest way for SNOMED CT to be used would be for a SNOMED concept to be assigned for each Unit of Measure that is routinely used in healthcare. Ideally this would include a mapping to UCUM, but we understand that the UCUM licencing terms do not allow such mappings.

A more extensive approach would be to extend the SNOMED CT Concept model to allow unit expressions to be constructed from base units. This would allow post coordination to be used to express units that have not been anticipated and already included as SNOMED CT concepts. If SNOMED CT were to be used in place of UCUM as the machine-readable representation of the unit, and if a mapping to UCUM was not possible due to licencing constraints, then the SNOMED CT based solution would need to include conversion tables to support mapping between equivalent units.

An alternative, that could be pursued in parallel, would be to engage with the Regenstrief Institute and explore extending UCUM to allow human readable representations to be maintained, and to address the other intellectual property and governance issues that are of concern.

Using a standardised representation for Units of Measure would enable the work on harmonisation of pathology results and also enable the development and use of standardised reference intervals, where it makes sense. To support this, we believe the de-facto standardisation put

in place to support exchanging data via the NPEX (National Pathology Exchange) is a useful step, and NPEX could form the basis of a validation and monitoring tool.

5.3 Options for constraining the UoM in the Unified Test List

The UoM is a component of the test result which is vital to establish the meaning of the value in the result field.

Table 5 is a high-level description of what this consultation agreed are viable solutions for specifying the UoM that may be used with a specific UTL test result code and the salient features for the UoM format and content. There are three basic options:

1. Embed the UoM in the test UTL,
2. Use a constraint table to define the UoM to be used with each code in the UTL
3. A combination of both (hybrid option): embed the preferred unit in the UTL and provide a link to a constraint table defining the alternatives.

Figures 1,2 and 3, in section 5.3.3. below, are examples of how a UoM for blood test result would be messaged using the options outlined above. The results and considerations expressed here should be used to develop and execute an implementation plan by NHSD.

5.3.1 Interesting/special cases

It is recognised that some tests, result formats and components are potentially confusing for clinicians or developers. During the initial phase of the project, a set of these “interesting/special cases” were looked for and included in the consultation presentations.

As we looked for such interesting cases it became clear that many were cases where the “value” or “unit” field in the result message was being used to carry information that would be more appropriately included in other slots in the result message. For example, “normal” is sometimes found as a value, but in the FHIR message would be sent as an “interpretation”. These interesting cases are less interesting in the context of the FHIR message specification that defines separate slots for value, interpretation, and comment for each observation, as well as a narrative conclusion for the overall test result. There is work to be done to define the “interpretation” values that are expected for each test code in the UTL, so that this field is used consistently. Further examples should be developed and included in the FHIR profile showing how these fields should be populated.

There are cases where the test value is a not a measured quantity, but there is an enumerated list of possible values. The urine ketone test is an example of this, where a dipstick is used, and the value is reported as “+”, “++” and so on. In such cases the valueCodeableConcept should be used to convey the result. The constraint tables should be used to assert the datatype to be used, and the valueset of expected result codes (from SNOMED CT). For some tests there may be either a precise measurable value (conveyed in the FHIR message using valueQuantity), or an enumerated list such as “+”, “++”, etc.

5.3.2 Constraint tables and value sets

The use of constraint tables to define the acceptable valuesets for the Units of Measure and interpretation codes for each Unified Test List code was widely accepted during the consultation, with no alternative approach being proposed. There was a common view that for some, if not all, tests would need to allow more than one Unit of Measure to be used. Indeed, it was anticipated that for some tests there may be a need to allow for quantitative and non-quantitative values. This proposed mechanism for defining constraint tables would support such optionality and would enable inclusion of legacy data. The constraint tables could also be extended to define constraints on other fields in the FHIR profile such as “interpretation” based on the UTL code.

Table 5: Options for including the UoM in the UTL and sending it in HL7 FHIR message

Options for sending UoM with UTL in FHIR message	Preferred Code systems for UoM	Criteria for usability and utility of coding systems	Identification and suggested solutions for interesting cases
<ul style="list-style-type: none"> Option 1: Attach the UoM inside the UTL as a field Option 2: Send the UoM separately with the UTL code in the FHIR message Option 3: Hybrid solution using both (preferred unit contained in UTL, and the actually used unit in the message) 	<ul style="list-style-type: none"> UCUM for quantifiable UoMs (5 g/ L) SNOMED CT codes (for numeric, non- numeric, results that are interpretations (positive; not seen; +++ etc)) string of the UoM expressed using Unicode character set for Human Readable text 	<ul style="list-style-type: none"> Must be machine (MR) and human readable (HR) both needed - UCUM is MR UCUM Requires alternative where codes are not human readable Use SI where possible - exceptions should be explained and agreed UCUM and SNOMED CT are agreed UK code systems 	<ul style="list-style-type: none"> Groups of results (FBC, U&Es) need representation of atomic vs battery/group results Interpretative results (positive, not detected) Non- standard results (*, < or >) expressed in string Non standard units and symbols in UoM field potential role for the comment section of the message to address ambiguity

Options for associating UoM with the UTL code

1. Define exactly one UoM for each code in UTL and publish in the UTL
2. Link one or more UoM to each code in the UTL using a constraint table identifier
3. Include in the UTL both a preferred UoM and a constraint table identifier as a link to a list of possible UoM

Preferred code systems and charactersets for UoM

- UCUM for machine readable UoM in valueQuantity.code
- Unicode for human readable UoM in valueQuantity.unit
- SNOMED for enumerated values in valueCodableConcept (eg “+++++”)

5.3.3 Examples of the options for implementing UoM

The following figures (Figures 1, 2 & 3) show examples for a common blood test, creatinine level in plasma, for each of the three options for how the UoM should be expressed in the UTL.

Figure 1: Example of UoM embedded in UTL (option 1)

SNOMED ID	Fully specified name	Preferred Term	Property	Component	Specimen	Technique	Preferred UoM
1106601000000100	Substance concentration of creatinine in plasma (observable entity)	Creatinine substance concentration in plasma	118556004 Substance concentration(molar concentration)	15373003 Creatinine	119361006 Plasma specimen	272391002 Measurement technique	mmol/L

- Preferred UoM can be expressed in UCUM or SNOMED CT code - (e.g. SNOMED CT code for the above unit is:

Figure 2: Example of UoM added to FHIR message with a constraint table (option 2)

SNOMED ID	Fully specified name	Preferred Term	Property	Component	Specimen	Technique	Constraint Table ID
1106601000000100	Substance concentration of creatinine in plasma (observable entity)	Creatinine substance concentration in plasma	118556004 Substance concentration(molar concentration)	15373003 Creatinine	119361006 Plasma specimen	272391002 Measurement technique	A001

Figure 3: Example of hybrid UoM representation: the preferred unit embedded in the UTL and with a constraint table (option 3)

SNOMED ID	Fully specified name	Preferred Term	Property	Component	Specimen	Technique	Preferred UoM	Constraint Table ID
1106601000000100	Substance concentration of creatinine in plasma (observable entity)	Creatinine substance concentration in plasma	118556004 Substance concentration(molar concentration)	15373003 Creatinine	119361006 Plasma specimen	272391002 Measurement technique	mmol/L	A001

6 Findings and discussion: FHIR message considerations when sending the test result

The consultation topics and findings are summarised under section 6.1. and 6.2

6.1 Consultation topics and findings

This section includes a description of issues and findings encountered during the project. These were shared with the NHS Digital team at the weekly calls that took place throughout the project. Where the issue is known to have been resolved that is noted.

6.1.1 FHIR Profile issues

6.1.1.1 Review of Examples

The examples in the Specification included a number of errors that were detected when submitted to a FHIR server for validation. These included missing references and a space character in a coded item. It is recommended that the publication process for specifications should include a step to check that examples are valid.

Implementers will typically look to the examples as their primary source of information and so ensuring that these are correct is vital.

It may be helpful if the narrative clinical scenarios were extended to include what is done once the test result has been received. This would help to illustrate why national standards are useful. For example, the test result may be used to graph trends for monitoring a long-term condition, or they may be used as input to a decision support tool that alerts the clinician. Providing concrete and credible examples of such uses would help the developers who are working with the specification understand the context in which their work will be used.

As part of building the demonstrator software, we created tables of the clinically interesting data items, the agent-based simulation engine then added timestamps and identifiers, and then the JINJA templates were used to render these as FHIR resources in a bundle. NHS Digital should review its processes for creating examples in the FHIR specifications and look at using an Information Model view that contains just the clinically interesting data items as part of a structured example authoring and maintenance process.

6.1.1.2 Identifier references

The pathology result message is defined as a FHIR bundle that contains a number of resources (MessageHeader, Patient, ProcedureRequest, DiagnosticReport, Specimen, Observation, etc). These resources are linked together using the “reference.value” attribute to hold a pointer to another resource in the bundle. Thus the MessageHeader resource has an attribute “MessageHeader.focus.reference.value” that points to the DiagnosticReport resource.

FHIR resources have an “id” attribute, and also an “identifier” attribute. The “identifier” attribute is used to carry “business” identifiers such as “Order Number” or “Placer Number”, and the “id” attribute is typically expected to be a URL pointing to where the resource can be retrieved from a RESTful FHIR server, or may be a UUID as a temporary identifier within a bundle.

The national pathology specification defines the test result message as a FHIR bundle that includes all the resources with temporary UUID id attributes. These are used to reference the resources within the bundle, but there is no requirement for these identifiers to be preserved when the bundle is received and processed. Furthermore, if a UUID is used as the “id” for a FHIR resource, then the references to it from within other resources need to be prepended with “urn:uuid:” when they are conveyed in a bundle, but not if the identified resource is held in a FHIR server. There is a thread discussing this issue on the HL7 Zulip chat [7]. While the alternate representation of references is not hard once the implementer is aware that it needs to be done, this was a source of some confusion while developing the simulation and may be a confusion to other FHIR implementers in future.

Alternative approaches include:

- using logical references to point to the “identifier” attribute in the target resource, where a “business level identifier” could be held. This has the advantage of using existing identifiers that are used in the business process for identifying the Patient, Specimen, etc, but loses the robustness of a globally unique identifier, and the automatic integrity checking that FHIR servers perform for references to the “id” attribute. This is the approach that has been used in the Manchester Pathology FHIR specification.
- Using a UUID, but requiring that the “fullURL” attribute includes the base URL or the originating system. This would give every resource a “home” server, which in principle could be queried to retrieve the resource in future. The current practice of including all of the resources in the test result bundle would still be supported. This would allow the UUID to be preserved in the “id”, and allow the routine integrity checking, but would come at the price of a longer identifier, and having a URL as the identifier that will not be dereferenceable unless there is a substantial architectural change to support RESTful access to FHIR resources. This is an approach suggested by contributions on the HL7.org Zulip chat [8]

This is a topic that is not specific to Pathology, and further work on this is beyond the scope of this report. It is recommended that further work be done within the UK FHIR community to maintain guidelines on the identification and referencing of resources in bundles and FHIR servers.

6.1.1.3 Values other than ValueQuantity should be allowed

The FHIR profile for the Observation.value in the pathology message specification is limited to valueQuantity. This is suitable for results that have a quantifiable result, but there are many tests where the result is a codable concept, and some situations where the test result may be expressed as a string. It is recommended that the profile allow for values of any of the datatypes permitted in the base resource definition [9], and that any further constraints on the expected value datatype be determined in the constraint tables associated with the Unified Test List Code, and any local test catalogues.

6.1.2 Reference Implementation

To test the demonstrator it was useful to have publicly available FHIR servers that could be used to test and demonstrate the generated messages. The Care Connect Reference Implementation was used to validate the FHIR bundle, and the Smart-on-FHIR FHIR server based on HAPI was used as a generic FHIR server to demonstrate the storage of the FHIR resources separately. To support implementers, it would be useful to have FHIR servers and demo user interfaces available that can be used during initial prototyping and development. Such reference implementations would ideally be available with and without example data, and it should be possible for users to easily reset the reference implementation to a known state.

Such reference implementations could be distributed as docker containers (as is done for the CCRI), or be made available as cloud services. The Care Connect [Reference Implementation](#) was configured to automatically load an FHIR profiles posted into the server. This was a helpful capability and made it easy to use the implementation for new data flows that were not included in the original Care Connect specification. Unfortunately, it was configured to only accept a limited number of resource types, and these did not include the pathology-specific resources such as “Specimen” and “DiagnosticReport”. It would be helpful if future reference implementations were created with as few restrictions as possible, so that they could remain of value as requirements evolve.

6.1.3 OpenTest connectivity

The connection to OpenTest required two levels of security to be configured: a VPN and an exchange of credentials to establish the MESH connection. As an entry-level sandbox environment this was more complicated than needed or expected. Setting up the VPN was complicated by the fact that the recommended client software is no longer supported on the OSX platform, so work had to be done in a Windows simulator. Creating and verifying the MESH client also required some support from the NHSD experts.

Once the connection to MESH was established, there was a prolonged outage, due to hardware issues in the provisioning of OpenTest. This was exceptional and unfortunate but did restrict our ability to do extensive validation using the MESH services.

The ability to access a test environment as early as possible in the development process is very valuable for developers, and it is recommended that effort be put into establishing a robust test environment that is easy to access. Simple access controls should be put in place to prevent denial of service attacks, minimising the barriers for developers getting connected, and also reducing the amount of support that NHSD need to provide.

6.1.4 FHIR Versioning

There is ongoing discussion about whether the existing National Pathology Messaging Specification which has been created against FHIR DSTU3 should be up-versioned to FHIR R4 to be consistent with the FHIR UK Core specification. When considering this in the context of the simulation development, the differences were not substantial, especially if the prospect needed to support alternative versions was planned for. The ability to support new requirements coming from AI and Genetics is part of the business case for moving to FHIR for Pathology messaging, so it is important that implementations are created with this in mind. Support for multiple versions of the pathology messaging specifications may be provided by the receiving applications themselves, or by middleware. It is recommended that the FHIR Pathology

messaging implementation plans include the capability to support multiple versions. Detailed recommendations on the frequency and management of such changes is beyond the scope of this document.

6.1.5 HL7v2 to FHIR Pathology Mapping

During the engagement with HL7.org and HL7UK it became clear that there is work being done in Manchester on FHIR profiles for pathology based on the existing HL7v2 flows, taking into account the work that is being done in HL7 International on FHIR-HL7v2 mappings for orders and results.

Given the extensive use of HL7v2 in pathology messaging within hospitals, it would be helpful to build on the work done in Manchester and for there to be documentation and mapping tables developed between the HL7UK V2 Profile and the National Pathology FHIR profile.

This does not need to be a fully executable mapping that provides semantic equivalence – there would be substantial value in the mapping tables and documentation to help organisations and suppliers that currently support HL7v2 pathology messaging to evaluate the impact of moving to the FHIR/UTL/UCUM specification suite. Given the variety in existing HL7v2 implementations, it is not realistic to expect a centrally maintained mapping to be sufficient to provide safe, automated translations, but it would substantially reduce the risk and cost of locally maintained transformations or migrations.

Such a centrally maintained mapping resource could be extended to include tooling and advice on the testing and clinical validation of locally maintained transformations and migrations. This could be done specifically for Pathology, but there is a wider opportunity to establish a set of good practices for the transformation and migration of clinical information. This is something that the PRSB have been discussing with NHSX, and is a suitable topic for the organisations to collaborate on.

6.1.6 Implementation Planning

While implementation planning is beyond the scope of this document, this section captures ideas that came up during the project that may help to deliver value using the Pathology FHIR messaging and Unified Test List.

6.1.6.1 Track adoption and conformance using the Pathology Quality Assurance Dashboard

The dashboard could be used to communicate the levels of adoption of the specifications across the pathology services provider community. Establishing exactly what the metrics should be is beyond the scope of this project, but these could include establishing whether the local catalogue of tests has been fully mapped to the Unified Test List, whether the Units of Measure used are as defined in the constraint tables, and whether the provider is able to send test results in the format defined in the National Pathology FHIR messaging specifications. Note that these are decoupled criteria, as there is value in mapping the local catalogue to the Unified Test List, even if these cannot be communicated in the FHIR message.

6.1.6.2 Validate Historic Data Against the UTL and associated constraints

There is a large amount of existing pathology result data that could be tested against the UTL and associated constraint tables where mappings make this possible. This would help prepare for using this data alongside test results that are reported using the UTL and FHIR messaging. It would also provide an immediate patient safety benefit as tests with inappropriate units could be identified and reviewed. This mapping of existing data to the UTL would also allow errors or omissions in the UTL to be identified before it is used for the live reporting of test results, when the resolving of issues would be time critical.

6.1.6.3 Validate local Test Catalogues against the UTL and associated constraint tables

In addition to testing existing patient data against the UTL using mapping tables, it would be possible to check existing test catalogues. This would allow any tests that are in local catalogues but not in the UTL to be identified and assessed for addition. It would allow any tests that are being performed and reported with a Unit of Measure other than the preferred unit in the UTL to be identified and local arrangements made to change to using the preferred unit. A local risk and impact assessment could be made, and changes could either be made before the transition to supporting the UTL and FHIR messaging, or the changes could be rolled into one. In either case, establishing early whether non-preferred units are being used would allow potential patient safety issues to be identified and addressed.

6.1.6.4 Sender and receiver responsibilities associated with constraint tables

The constraint tables can be used to detect when a Unit of Measure has been used that is not the preferred unit for the test result code. A decision needs to be made during the implementation planning what should be done when this is detected, and whether the sender and/or receiver are required to check.

It is recommended that this decision be made once there is more frequency data available and the costs and risks associated with changing local test catalogues is known. It may be that initially reporting the level of conformance in the Pathology Quality Dashboard would be appropriate, allowing local communities to manage the migration to using the nationally agreed units over time.

6.1.6.5 Logical Information View for Clinical and Stakeholder Engagement

The FHIR profile and associated valuesets are not very easy for non-technical stakeholders to review and comment on, and within the specification package there is not a clear linkage to the key clinical risks and benefits that are a concern to clinicians and other stakeholders.

This has been addressed in presentations by providing example fragments, and by providing a “Bundle Diagram” in the overview section of the specification.

The FHIR message includes many identifiers and codes that are needed for processing the message, but that are not relevant for clinical users. Having an option to see the specification and examples that only include the clinically interesting items would simplify clinical engagement and the gathering of feedback on the specification.

The ability to see just the clinically relevant items would also make it easier to use the specifications in contexts where FHIR is not (yet) being used. This includes the HL7v2 message flows, as well as in the internal data models and form designs in clinical applications, and to provide a standard glossary for the discussion of pathology test results more generally.

It would be helpful to have a view of the specification that only included the information items that are of interest to users, and to establish a methodology that allows for the capture and tracking of new requirements from stakeholders, whether those are expressed as information items, business rules, risks or benefits. This could build on the previous work by the PRSB on a technology-independent information model for pathology, as well as the work in the HL7 community on the FHIR Logical Model, and the tooling that is available to support that.

Such a Logical Information View would also be helpful in a structured Example Authoring and Maintenance Process.

6.1.7 Constraint Tables

6.1.7.1 Standardisation

The tactical approach to use constraint tables as discussed above will meet the immediate needs of this project, but there is an opportunity to develop national and/or international guidance or standards defining how such co-occurrence constraints should be expressed. Such standards would add value for all health information profiles and implementation guides that followed them by:

- a. Making it easier to test conformance to the profile or implementation guide (as validation tooling would be able to take account of the machine processable co-occurrence rules)
- b. Making it easier to validate that the profile or implementation guide is a consistent implementation of the underlying specification. For example, local test catalogues may be defined that are a subset of the national Unified Test List. If the same constraint table formalism is used for both, then it will be easy to detect any inconsistency, and act upon it (either by modifying the local or national specification).
- c. Exposing relationships between profiles and implementation guides. This would allow, for example, different local pathology test catalogues to be compared, and any inconsistencies identified and assessed for clinical risk.
- d. Making it easier to edit and maintain the profiles and implementation guides. Co-occurrence constraints are commonly used and having to define how this is done for each guide wastes time and introduces risk if the definition is not sufficiently rigorous.

There are a number of potential standardisation routes that could be explored, and these are not mutually exclusive:

- A. Develop UK guidance that can be used across NHS Digital FHIR profiles, the NHS Metadata repository, the NHS Data Dictionary, the Professional Record Standards Body (PRSB) specifications, and other organizations in the UK who are creating specifications that combine information models and terminology. The project should take account of how this problem is addressed across government in the UK, and in other industries. This could build upon the tactical solution proposed in this project, and relatively quickly establish a national specification.
- B. Initiate work within HL7 to define how terminology-driven co-occurrence constraints should be expressed for FHIR specifications. This

would be helpful for suppliers as such a standard if built into the core FHIR methodology could then be taken into account by the wider FHIR community, and so be built into the tools and applications that are available for use in the UK.

- C. Initiate work within ISO and CEN on how terminology driven co-occurrence constraints should be expressed in logical model specifications that define information models and link them to terminology, but to not specify a particular implementation formalism. There are a number of important international specifications of this sort, including those that define the International Patient Summary (IPS), and others that define the Identification of Medicinal Products (IDMP). Having a standard formalism for such logical models that includes a standard way of expressing terminology-dependent constraints (co-occurrence constraints) would provide all the benefits described above, and enable model-driven tooling to support maintenance and implementation of the specifications. Any such work in ISO and CEN should be undertaken in collaboration with other health informatics standards development organisations, possibly coordinated through the Joint Initiative Council.

6.1.7.2 Constraining the datatype of observation.value

We have recommended above that different datatypes for observation.value be supported to allow for result values that are not expressed as quantities. Currently only valueQuantity is permitted in the profiles, and this should be extended to include valueCodeableConcept and the other value datatypes. While the content model for “value” should be relaxed in the message profile, the constraint tables should be used to specify which datatypes may be used for any specific test result code in the UTL.

6.1.7.3 Constraining other fields

There are a number of fields within the observation resource that could be constrained based on the specific test being reported. In particular “interpretation”, “valueQuantity.comparator”, and “dataAbsentReason” were identified, as these are fields that can be used to carry information that is sometimes conveyed in the “unit” field for existing pathology message flows. This matter was explored in depth during the consultations, and it is proposed that “interpretation” should be constrained based on the test result code from the UTL, but that the other fields should not be included in the constraint tables.

It is recommended that the “interpretation” is constrained independently from the Unit of Measure for each UTL code, thus the same set of interpretations would be available whatever datatype or Unit of Measure is used for the observation value.

6.1.8 Representation of Units in the Message

There are two slots in the valueQuantity attribute for the Unit of Measure. One can be used to hold a human readable representation of the unit, and the other a machine-readable representation (UCUM). It is recommended that both slots be populated in each test result observation, so that receivers can always use one for displaying the unit, and the other for analysis or conversion to alternate units if there is a local need for that.

The UCUM syntax for units allows for “annotations” to be included in the unit. These are typically used to name the property that is being counted or measured. This often duplicates information that is available in the test result code, and it is recommended that the use of UCUM annotations be kept to a minimum in the preferred units for tests in the Unified Test List.

6.1.9 Unit Identifier for associating other metadata

The FHIR message will carry the human readable Unit of Measure, and a UCUM representation of the unit. However, there may be requirements to map these units to:

- the Units of Measure in SNOMED,
- longer descriptions of the Unit of Measure
- Translations of the Unit of Measure into other languages
- Audio renderings of the Unit of Measure, or alternative graphical representations.

In order to facilitate this it is recommended that a list of all the Units of Measure used in the constraint tables be maintained, and that an identifier be assigned for each line in this unified table. The list would be a set of tuples (identifier, human readable representation and UCUM representation). It is anticipated that the human readable representation of the unit will in fact be unique (i.e. that a given literal string used to express a Unit of Measure will always represent the same Unit of Measure concept, whichever UTL code it is used with).

Maintaining a separate identifier for the tuples in the complete list may be helpful for those maintaining the list. Care should be taken to avoid creating yet another identifier scheme for Units of Measure, and these identifiers should only be used within the specification and should not be used in patient records or test result messages.

6.2 Consultation feedback

Table 6: Consultation feedback themes with supporting evidence

Themes	Evidence	Findings	Recommendations	Comments
Key themes identified in consultation	Literature review and discovery phase evidence	Output of all consultation methods summarised	Summary of recommendations	Quotes from consultation participants (from technical and clinical webinars)
Should there be a single Unit of Measure for each test result code in the Unified Test List?		Some test result codes are used to cover tests done on different platforms, and so may need different Units of Measure.	The precision of the test result codes in the UTL should be addressed in the editorial guidelines for maintaining the UTL and associated constraint tables.	“Some tests are analysed on different platforms; each analyser "could" use a different UoM” - in this case it is not clear whether different Units of Measure should be used, or there should be a different test code in the UTL for the different platforms. This needs t be addressed in the editorial guidelines for the UTL”.

<p>In addition to the preferred unit, should there be other units that can be used with a test result quantity?</p>	<p>Frequency analysis showed that multiple Units of Measure are currently used with individual test codes. It was not clear whether any of this variation was useful.</p>	<p>There was substantial resistance to the idea of requiring that a single Unit of Measure always be used with a specific test code.</p>	<p>Define a preferred Unit of Measure for every test that has a quantity as a result – but where there are other units that may be used these should also be listed, to avoid forcing change where it may be difficult to achieve and of limited value. Better to support incremental adoption and understand what the barriers are to more rapid adoption.</p>	<p>“I think a preferred UoM is ok- a mandatory UoM is a different thing”.</p> <p>“labs encouraged to use preferred. where not using preferred there needs to be a conversation.... example of occupational monitoring for lead lab networks are a driver”</p>
<p>Need clarity on what should be sent as a “value”, “interpretation”, “dataAbsentReason” or “note” against the observation, and what should be sent in the diagnostic report text fields.</p>	<p>Issue identified during the simulation exercise, and in preparing the constraint table recommendation</p>	<p>Constraints needed for individual test result codes, and examples to show how reasons for missing data should be conveyed.</p>	<p>Develop the information model for pathology with clear definitions so it's clear what information goes where in the message fields. These definitions should be combined where necessary with appropriate constraints associated with individual items in the UTL using constraint tables. For example the "value" field should be constrained so that it does not include information that is included in the valueset for "interpretation", which in turn will be determined by the constraint tables. The risks associated with such definitions and constraints not being followed should be documented and managed. Maintaining such an information model</p>	<p>“The value could be numerical most of the time but result would be text depending on sample quality. Potassium is a good example 4.5mmol/L or haemolysed.” When the sample is haemolysed it may be better to report this as “reasonDataAbsent”, rather than as a textual result.</p> <p>“The lims I use can send out a free text comment on a numeric result should the BMS want to send an explanation out rather than a result, e.g. sample haemolysed unable to report a K result. If the format was fixed at the receiving end based on the code we may find results being rejected.”</p> <p>“eg dna abs 12.3 ru/ml, interpretation: weak Positive? i.e. interpretation allows for internal interpretation on a numeric result. i.e. some tests have two results!”</p> <p>“Interpretation vs value - not just an issue for clinical receivers but also an issue for end systems and their ability to process results”</p> <p>“missing values: NA= not available- reasons added in 'comments'. Also SC= see comment- result cannot be entered but there is a relevant commentary. 'sas= see original report when the lims cannot cope with a complex report and result going back on paper”</p>

			and set of constraints alongside the suite of other PRSB information specifications would contribute to consistency across the health system.	<p>Webinar chat poll: Should the possible Interpretation values be constrained for each test result code in the UTL?</p> <p>Yes 58% (7)</p> <p>No 25% (3)</p> <p>Not sure 16% (2)</p> <p>12 responses</p>
Should there be a rule for each test result code saying whether the value and/or interpretation are required?	This was identified as a possibility during the development of the constraint tables.	There was no consensus on this question during the consultation, and so this is seen as an issue that should be addressed once further work has been done to define the interpretation codes that are used.	If instances are identified where either the result or the interpretation would normally be populated, then the constraint should be that the appropriate attribute is populated, or "dataAbsentReason" is populated.	<p>"No - because internal audits/clinical correlations can lead to introduction of differing categories/ cut-offs"</p> <p>Webinar chat poll: Should there be a rule for each test result code saying whether the value and/or interpretation are required</p> <p>yes - this would be helpful 33% (3)</p> <p>No - there will be too many exceptions for this to be useful 22% (2)</p> <p>Not sure 44% (4)</p>
What happens if a Unit of Measure is used with a UTL code that is not in the constraint table?	The automated validation allows for the detection of when the business rules are not being followed, and it will be for the implementation project to determine what happens when the test result message does	There was a strong consensus that incremental adoption would need to be supported, with the move to standardised Units of Measure being supported by the adoption of the FHIR messaging, but not being a prerequisite for it.		<p>"We don't have much control over specialised labs and what UoM they use. We have to replicate it when we send it out. The only way round this if it was rejected would be to remove the UTL code from the item."</p> <p>"there is an ongoing harmonisation project for the professional bodies here. Quick wins already done but tools for automated audit would allow for a longer-term approach which does not require audit participation. You just get a report saying that you are an outlier"</p> <p>"I think a preferred UoM is ok- a mandatory UoM is a different thing"</p> <p>"labs encouraged to use preferred. where not using</p>

	not conform to all the rules in the constraint table.			preferred there needs to be a conversation. see example of occupational monitoring for lead above. lab networks are a driver”
Is there a need for additional metadata about Units of Measure including long descriptions, language translations, audio and other modalities, and mappings to other Unit of Measure terminologies such as SNOMED CT.	This was identified as a potential requirement during the development of the constraint tables	During the consultation there was no objection to this, and some interest.	This is not an immediate requirement for the reporting of test results, but is likely to become more useful as the Unified Test List gets adopted across the system.	Webinar chat poll: Is there a need to support other metadata associated with each Unit of Measure beyond a human readable string and a UCUM expression (such as valid date range, alternate human readable representations?...) yes - more metadata is needed 50% (4) no - nothing more needed 0% (0) not sure 50% (4) both 0% (0)
Should the things that are counted or measured as percentages be named in the human readable unit or UCUM expression?	There is significant variation in the frequency tables and the existing “frequently used unit” lists, where these are sometimes included and sometimes not	While there was extensive discussion on this topic, there was consensus towards the end of the consultation that the unit should not include text that is expressed in the test result code, and so in general “%” should be left unqualified in the unit.	The frequency tables should be used to establish current practice, but in general the use of UCUM annotations should be kept to a minimum, and the human readable unit should not include the names of the things counted / measured, this should be included in the test name.	“re countable issue I think yes - e.g. FBC and % of white cell types e.g. eosinophil, neutrophil etc being reported as number and % of total” “INR has no UoM” “perhaps it should have!” “vote for a similar list of units mmol/mmol, umol/mol” “Agree - no reason not to have units for ratios as you would for a single analyte”

7 Findings and discussion: Patients' consultation

7.1 Consultation feedback: themes identified with supporting evidence

Feedback from the citizen consultation was organised into themes and is presented in the following table together with the supporting evidence and recommendations for implementation and use.

It should be noted that some of the recommendations in this section are out of scope of the standards feasibility work but should be considered in any subsequent implementation strategy.

Table 7: Consultation feedback themes with supporting evidence

Themes	Evidence	Findings	Recommendations	Comments
Key themes identified in <i>consultation</i>	Literature review and discovery phase evidence	Output of all consultation methods summarized	Summary of recommendations	Quotes from consultation participants
Experience of receiving test results currently	All patients had experience of receiving test results on multiple occasions via a wide variety of methods, face to face or over the phone in primary care, online via GP Websites, in secondary care (as an in-patient) and in private care.	<p>There was a single consistent view that lab test results were not generally well understood (in detail) by health care staff or they were generally poorly communicated by health care professionals (HCPs) to patients including the implication of such results for the patient.</p> <p>There is a strong desire from patients, particularly those with long term conditions, to understand test results in greater detail beyond being simply advised whether or not the results were 'normal' or otherwise.</p> <p>Two out of the six patients consulted told of experiences of errors including communication of another patients test results or used for planning of their future treatment.</p>	Communication to HCPs - many patients have an expectation of greater levels of detail of test results being provided to them.	

Themes	Evidence	Findings	Recommendations	Comments
Key themes identified in <i>consultation</i>	Literature review and discovery phase evidence	Output of all consultation methods summarized	Summary of recommendations	Quotes from consultation participants
		Patients having access to these reports would (and have from these given experiences) help to identify such errors and mitigate the associated risks.		
Whether the results were straight-forward to access and understand	All citizens agreed (with one exception who had greater level of access to their GP records) that access to Pathology test results tended to be difficult to obtain regardless of format	<p>It is not general knowledge to patients (or clinical staff) that patients have the right to access this information and provision of access is not timely. Many stated that this placed patients at significant disadvantage when accessing treatment away from their normal place of treatment. (due to lack of interoperability)</p> <p>A majority attending the webinar had longer term health conditions and made the point that without access to and understanding of these reports, self-management of their condition(s) was made more difficult.</p>	HCPs need to be reminded of: a) citizen's rights and expectations of access to test results. b) Such access also supports self-management of longer-term conditions	<p><i>"How can I go to my local MP to pressurise on a topic if I am unable to get access to such basic information."</i></p> <p><i>"... but for those (patients) that do (want access), it should be made 'barrierless'."</i></p> <p><i>"If patients are to take responsibility for management their health conditions, they need access to their own health information."</i></p>
How they would like to access test results in future	All participants felt that the development of common standards for pathology reports would ultimately be beneficial to patient's ability to access test results.	<p>The vast majority preferred this to be in electronic format via phone or laptop whether via an app or email/text.</p> <p>However, one patient's preference was of it being in paper format reflecting that not everyone has access to or is able to operate electronic devices or has the</p>	<p>Any proposed solution adopted must facilitate the onward electronic transmission of test results to the patient.</p> <p>Equality of access must be considered for those who do not have access to electronic records</p>	

Themes	Evidence	Findings	Recommendations	Comments
Key themes identified in <i>consultation</i>	Literature review and discovery phase evidence	Output of all consultation methods summarized	Summary of recommendations	Quotes from consultation participants
		necessary level of IT literacy. This is an important consideration in terms of equality of access to test results.		
Whether supplementary explanation is necessary	To facilitate understanding of accessed test results (and to avoid misinterpretation through internet search results), supplementary information explaining both the test and the result (but not the relevance to the individual) is necessary	<p>A majority of patients attending stated that they needed supplementary information to be available somewhere so that they could understand the information contained within the test result.</p> <p>Two patients felt that they had sufficient understanding because of their research and frequency of pathology testing that they just wanted the raw information. (i.e. no supplementary information was necessary for them).</p> <p>Many patients commented that not only was the importance of supplementary information necessary for its own sake but also because it affects equality of access to information and hence treatment.</p>	<p>Plain language supplementary information explaining the test and the test result does not need to sit within any result output or FHIR messaging.</p> <p>However, such supplementary information does need to be accessible to patients e.g. through NHS or GP websites (or their supporting software suppliers) or handouts hand-outs, other authorised websites (such as Labtest Online UK or via Apps.</p>	<p><i>“access without comprehension is pointless”</i></p> <p><i>“we need to make sure it is understandable to an average 12-year old”</i></p> <p><i>“it helps ensure equality...”</i></p>
Format of information presented to patients	There was some divergence of opinion on the style in which test result information should be presented which probably reflects differences in levels of	<p>Opinions ranged from just wanting the raw information, those wanting to know only about results which were outside the normal ranges.</p> <p>Many patients commented that for them, a representation ‘normal’ at a</p>	Any solution adopted should facilitate a layered approach with a summary of only those tests outside of normal (population) ranges and the test value and with the ability to then drill down into all test	<i>“I want to know everything (about my health condition) but other members of my family prefer to know nothing about their conditions”</i>

Themes	Evidence	Findings	Recommendations	Comments
Key themes identified in <i>consultation</i>	Literature review and discovery phase evidence	Output of all consultation methods summarized	Summary of recommendations	Quotes from consultation participants
	detail required by individual patients and the use to which such information would be put.	<p>population level may not be normal for them.</p> <p>Some patients wanted to be able to compare their test results with previous results for comparison purposes.</p> <p>There was overall a broad consensus that a majority of patients might like to see a layered approach with a summary of only those tests outside of normal (population) ranges and the test value and with the ability to then drill down into all test results (i.e. two layers comprising summary and detail)</p>	results (i.e. two layers comprising summary and detail)	
Patient Concerns	Units of Measure	Concerns were raised over the approach of having more than one 'Unit of Measure' for each test as confusing for all and the further risks that this posed to patients and HCPs in incorrect conversions.	Patients may be accepting of multiple units for a given test as a transitional approach during implementation but clear communication is suggested to all stakeholders regarding patient concerns and expectations of the longer term move to a single Unit of Measure for any given test.	
	Timing of result notification to patients	There was an overall desire to receive access to test results as quickly as possible, especially for those self-managing longer term conditions.	All 'up-front' test results should be considered to be potentially 'life changing' and patient access to the test result delayed until the requesting HCP sanctions release to the patient.	<p><i>"I want thought to be given before the test result is sent to me if the results are life changing."</i></p> <p><i>"(Any) new conditions need to be included (as being</i></p>

Themes	Evidence	Findings	Recommendations	Comments
Key themes identified in <i>consultation</i>	Literature review and discovery phase evidence	Output of all consultation methods summarized	Summary of recommendations	Quotes from consultation participants
		<p>Patients recognised that there could be circumstances where the patient should receive the information at the same time as HCPs and other times when it might be inappropriate for this to happen and that HCPs should receive this for a period prior to the patient receiving the results. When asked under what circumstances the latter should apply, patients started to use the phrase “life changing” – I would want this to be a ‘face to face’ communication”.</p> <p>An advisor suggested that It might be easier to consider all ‘up-front’ test results to be potentially ‘life changing’ and any ‘routine’ test result less likely to be ‘life changing’. This was generally accepted as a high-level approach.</p>	Any ‘routine’ test result less likely to be ‘life changing’ and therefore access should be provided without HCP sanction.	<i>potentially life changing”</i>
	To ensure that any changes improve the ability for patients to self-manage their health condition(s)	To do this wherever possible was in the patient’s best interests and by doing so to reduce pressure on the NHS was in everyone’s best interests. Implementation of such a significant change without taking advantage of this opportunity would not be in anyone’s interest	Any solution adopted must facilitate patient’s ability to self-manage their condition and reduce the burden on the NHS	

Themes	Evidence	Findings	Recommendations	Comments
Key themes identified in <i>consultation</i>	Literature review and discovery phase evidence	Output of all consultation methods summarized	Summary of recommendations	Quotes from consultation participants
	Maintaining confidence in the NHS esp. during COVID	There were a number of questions raised around understanding the approach to national implementation given historic challenges that the NHS has faced with IT implementations. Most patients expressed the view that it was important for the NHS to reassure patients and clearly demonstrate to them that such a significant change was a proven success (for all stakeholders incl. patients) via a phased approach rather than a 'big bang' approach.	Communications to Patients (and primary care) is key prior to, during and after implementation to reassure patients about the need and benefits of change and clearly demonstrate to them that such a significant change was a proven success (for all stakeholders incl. patients)	

8 Conclusions and recommendations

8.1 PBCL to UTL mapping

8.1.1 Conclusions from the consultation

The conclusions gathered from the stakeholder engagement webinar in relation to the UTL to PBCL Mapping are summarized below:

1. A UTL to PBCL code mapping is useful for a number of groups and purposes, and should be made available to support:
 - a) System Transition: both as a basis to change and test systems transitioning to the new coding standards, and as support/translation tool for systems who are still using older coding.
 - b) Inform local mappings:
 - c) Analysis of Trends over time: by mapping newer coded results, to past results coded with previous coding systems.
 - d) Research on historical data

Additionally, stakeholders suggested that the mappings be accompanied by examples of how the mappings would be utilized between systems (e.g., Order comms to Lab system, Lab system to GP System etc.) to support understanding.

2. The proposed method of mapping raised no concerns with stakeholders when presented. The following additional points were noted:
 - a) A reviewer recommended that future mapping reviews could focus on the most clinically significant tests
 - b) A stakeholder stressed that the mapping should cover all tests to ensure that past test results are not lost in the system.
3. Stakeholders told us that they expected batched updates of additions and corrections to the mapping table and extended UTL tables (with some exceptions for changes which may impact clinical safety). They suggested that multiple communication methods are utilized to communicate mappings and tables, acknowledging the range of uses and audiences. The methods suggested were:
 - a) An application processing interface (API) for use with data systems
 - b) A delimited file for bulk systems changes
 - c) A searchable browser (similar to the SNOMED CT Browser) for users without data tooling.
4. Stakeholders acknowledged that utilizing the mappings and reporting problems or concerns with the table would support the quality of the mapping. The methods suggested for how this could occur were:
 - a. A searchable, interactive portal where users could log concerns, search guidance and previously noted concerns and comment on these.
 - b. A support/ "triage" email address/help desk function for people to raise concerns and receive a response (acknowledging the need to supplement the portal with a quick and easy reporting mechanism to encourage reports of concerns). The response should communicate to the user the status of the concern, and any noted advice associated with this (e.g., this has been corrected in v1.0.7 - please contact your system support, this is a newly noted concern and will be investigated etc.).

- c. A general question was raised on how to indicate/classify severity of these reports. For example, determining between a correction that “must change”, versus a “recommended change”. No suggestions from participants were offered on the webinar at the time. Further investigation of this topic is required.

8.1.2 Recommendations and next steps

1. Complete the UTL to PBCL mapping table using the process proposed by the project, and agreed to by the stakeholders to ensure all current and past PBCL codes are mapped to a UTL code.
 - a. Next steps in the process are to cross validate the findings from the first pass review by conducting a second review of the codes. Where specialists agree on matches, stakeholders agreed this would-be good basis for an approved mapping, with any inconsistencies referred for further review.
 - b. Frequently used codes (see UoM frequency analysis tables) could be prioritized for a second review.
2. Mappings should be communicated early to stakeholders to enable review, comment and testing. Preferred methods of communication have been outlined in the findings above.
3. A system for reporting, logging and responding to mapping concerns should be established. Suggestions for the system have been noted in the findings section.
4. The following projects and contacts were noted during the stakeholder workshops as potential sources of lessons learned, and happy to be contacted for further comment. Its recommended that their experiences be utilised and incorporated in the next stage of the programme.
 - a. GP to GP: contact John Williams
 - b. NHS Wales GP Care Records: contact Brett Foley

8.2 Units of Measure

8.2.1 Conclusions

1. The use of preferred units is encouraged and accepted.
2. The stakeholders generally agreed to the proposed methods of deriving preferred UoM
3. The combination of including the preferred unit in the UTL code and the constraint list reference (hybrid, option 3 above) is the preferred option, as it allows for a preferred UoM permanently anchored to the test code, while the constraint list enables other units to be used (good for variable but safe clinical usage, legacy data integration and decision support)
4. The most effective way to drive adoption of preferred UoM is to use existing infrastructure and resources to incentivise laboratory usage.
5. Use Pathology Quality Assurance Dashboard (PQAD) as a mechanism by adding preferred UoM usage to the quality assurance criteria.
6. Human oversight, review and authorisation will always be required whatever the level of computerisation and automation.

7. Machine readability is important for decision support, human readability is important for checking and oversight.

8.2.2 Recommendations and next steps

1. Develop the technology-independent information model for pathology with clear definitions so it's clear what information goes where in the message fields, and for the capture and tracking of new requirements from stakeholders, whether those are expressed as information items, business rules, risks or benefits. The Information should also support a structured Example Authoring and Maintenance Process. The information model would also be standard for handling investigation results in users systems and for transferring information between systems or for shared care records, ensuring alignment and consistency across systems beyond just the user and laboratory interface.
2. Define a preferred Unit of Measure for every test that has a quantity as a result. Define a value datatype for any test that does not have a quantity as a result.
3. Use the preferred UoM with constraint tables of allowable alternatives to cover all the potential units for any tests and can be used for safety and conversion if necessary, constraint tables are useful for local code system mappings and checks.
4. Further work should be carried out with the standards development organisations to address the lack of a human readable representation of the UoM in UCUM and its proprietary governance and restrictive license arrangements. Options are detailed in section 5.2.1
5. Provide incentives and drivers which encourage laboratories to use the preferred UoM for a test result rather than mandating use at this stage.
6. Identify and resolve significant issues and risks related to local end user practices that may impede the effective use of the new pathology standards.
7. Frequency tables should be used to track units used in the real-world practice and used to inform the maintenance of constraint tables.

8.3 FHIR messaging

8.3.1 Conclusions

1. The National Pathology FHIR Messaging Specification can be used with the Unified Test List and UCUM Units of Measure to convey pathology results.
2. A set of additional constraints are required to define the Units of Measure to be used with each test result code in the Unified Test List that has a measurement as a value. For test results that have values that come from an enumerated list, or that are strings, the datatype of the value needs to be specified as part of these additional constraints.
3. The examples in the FHIR profile are critically important.

8.3.2 Recommendations

8.3.2.1 Implementation support

1. The release process for FHIR Implementation Guides should include a check that examples are valid against the profile defined in the guide.
2. Test Harnesses (such as OpenTest) should be made available on the open internet

with automated registration and minimal, simple security to protect against excessive load or denial of service attacks.

3. Reference implementations should be maintained alongside the test harnesses.
4. Obtain value from the UTL and constraint tables by using them to find unexpected Units of Measure in existing test results. This may deliver early patient safety benefits prior to full roll-out of the FHIR messaging. Use the UTL and constraint tables to check the Units of Measure used in existing local test catalogues. This may deliver early patient safety benefits before the full rollout of FHIR messaging.
5. Use Pathology Quality Audit to encourage and track adoption. This could use the frequency table information to identify where results are using Units of Measure that are not in the preferred list, as well as establishing where the tests mapped to UTL SNOMED CT concept identifiers, and are using the appropriate unit for the UTL SNOMED CT concept identifier.
6. Technology-independent test scenarios:
 - Suitable for testing APIs, UI Browser testing tools, and network infrastructure testing
 - Developed alongside risk analysis to ensure that technical risks and mitigations are tested
7. V2-FHIR mapping. In order to support wider roll-out and replacement of existing HL7v2 information flows, or interoperability with them in a mixed economy, it is recommended that a Pathology FHIR to HL7v2 mapping toolkit be developed. This would be used to support local transformation and migration projects, as well as help to inform implementation plans for the FHIR specifications Adaptors project – mapping to EDIFACT
 - Publish mappings to enable them to be used and reviewed by organisations that currently maintain EDIFACT solutions.
8. Issue Resolution Process:
 - Questions and response should include examples that can be used to illustrate the issue and resolution / mitigation, and that can be added to the technology independent test scenarios

8.3.2.2 Recommendations – Constraint tables

9. Constraints
 - Value datatype and datatype-specific constraints
 - Interpretation should be independently constrained for each UTL result code

8.3.2.3 Recommendations - FHIR implementation guide

10. A structured Example Authoring and Maintenance Process should be established across all FHIR specifications. This should include capturing examples using a logical Information Model that only includes data items that are clinically interesting and validating the examples against the FHIR profile and UTL constraint tables. In addition to the current narrative scenario and the FHIR bundle, a “clinical review” view should be provided that displays the clinically interesting data items as specified in the logical Information Model view.
11. Guidance on the use of text fields in the FHIR messages
 - Supporting validation tooling to check for possible mistakes (e.g. is an “interpretation” keyword included in another text field)
12. Guidance on the use of dataAbsentReason
 - Taking examples from the frequency analysis for where reasons such as “test not done” or “sample damaged” are found in existing result messaging flows

- Note that this only applies to “value”, not interpretation which may also be missing

8.3.2.4 Recommendation – Standards Engagement

13. Constraint tables

- Develop UK guidance for how terminology driven constraints should be expressed for NHS Digital FHIR profiles, NHS Metadata Repository, NHS Data Dictionary, PRSB Information Specifications, and other national healthcare information standards that include information models and valuesets.
- Initiate work in HL7 International to establish how such co-occurrence constraints should be expressed in FHIR profiles, extending the work to address information models maintained by ISO, CEN and other international standards groups. In particular the IDMP work on medicines may also include significant terminology driven constraints.

14. SNOMED and Regenstrief collaboration

- Units of Measure. Ideally there would be interoperability between Unit of Measure concepts in SNOMED CT and UCUM, with the former used to maintain a valueset of regularly used units with human readable renderings and translations, and with the UCUM expression as a machine readable representation to manage conversions. The NHS should engage with both organisations to attempt to achieve this, or other options discussed in this paper.
- Test Codes and mappings to Units of Measure. The current licencing agreements do not permit a mapping from LOINC to SNOMED to be used to establish consistent Units of Measure. The NHS should work with both organisations to promote interoperability between systems that use SNOMED and those that use LOINC. This is needed not just to enable consistent use of Units of Measure, but also to ensure that both healthcare data, and the systems that process it, can be used across borders, and in environments where both LOINC and SNOMED are used.

15. Logical Information Models

- There is a growing recognition of the value of Information Models that are maintained in a technology neutral way, and so can be used across FHIR, HL7v2, EDIFACT, CDA, HL7v3, 13606, OpenEHR and other technology platforms. The PRSB Information Standards fall into this category, as do the Logical Model for the International Patient Summary, and the proposed logical model for the ISO IDMP medicines standards. Such a logical Information model should be defined for Pathology. The HL7 FHIR community have defined a FHIR Logical Model, and this may be the appropriate way to express a logical model that is linked to the FHIR Pathology profile.
- At a more general level, it would be useful to have a consistent definition of how such logical models should be expressed, and the NHS should initiate work in the international level to bring together the HL7, CEN and ISO work on this sort of information model.

8.4 Patient engagement

8.4.1 Recommendations from patient engagement

1. Healthcare professionals need to be aware of a citizen’s rights to access test results, which

also helps to support self-management, and expectations of seeing more than just a result value or 1 one word outcome. A layered approach to a summary and then more detail was recommended.

2. Any solution for pathology results transmission should facilitate onward electronic transmission of test results to patient, and consider equity of access for those without electronic access to their records.
3. Supplementary information should be available to patients in accessible forms through authoritative websites. Note this does not need to be transmitted with the result.
4. Patients can accept the use of multiple units for a test result as a transitional approach to support implementation, but with a long-term move to a single Unit of Measure for a test result.
5. The idea put forward that all 'up-front' test results should be considered to be potentially 'life changing' and patient access to the test result delayed until the requesting HCP sanctions release to the patient, and any 'routine' test results (less likely to be 'life changing') should be provided without HCP sanction, was considered a good starting point for further consideration.
6. Comms to patients is key prior to, during and after implementation to reassure patients about the need and benefits of change and clearly demonstrate success.

8.5 Overall

8.5.1 Conclusions

1. The consultation included representation from Scotland and Wales (Northern Ireland representation was invited) and the outputs of this work can be considered to apply UK wide, certainly for Wales and Scotland.

8.5.2 Recommendations

1. The stakeholders were very keen to engage and support the programme and use their front-line knowledge and lived experience to help shape the standards and guide the implementation so that it can deliver new standards resulting in safe and effective implementation which will make a real difference to pathology testing and care. It is strongly recommended that further and continued stakeholder engagement is used to validate the development and shape the plans for testing and implementation.

9 Appendices

9.1 Project Team

The project team was assembled with partners, clinical leads and a patient lead to ensure suitable knowledge and skills, led by clinicians and a patient. The team comprised:

Patient Lead	Pete Wheatstone
Clinical Lead (GP)	Dr Geoff Schrecker
Clinical Lead (Pathology) & UoM lead	Laszlo Igali
Analyst & clinical researcher	Annette Gilmore (PRSB)
Code mapping analyst	Courtney Irwin (MetadataWorks)
FHIR architect	Charlie McCay (Ramsey Systems)
Project Manager	Martin Orton (PRSB)

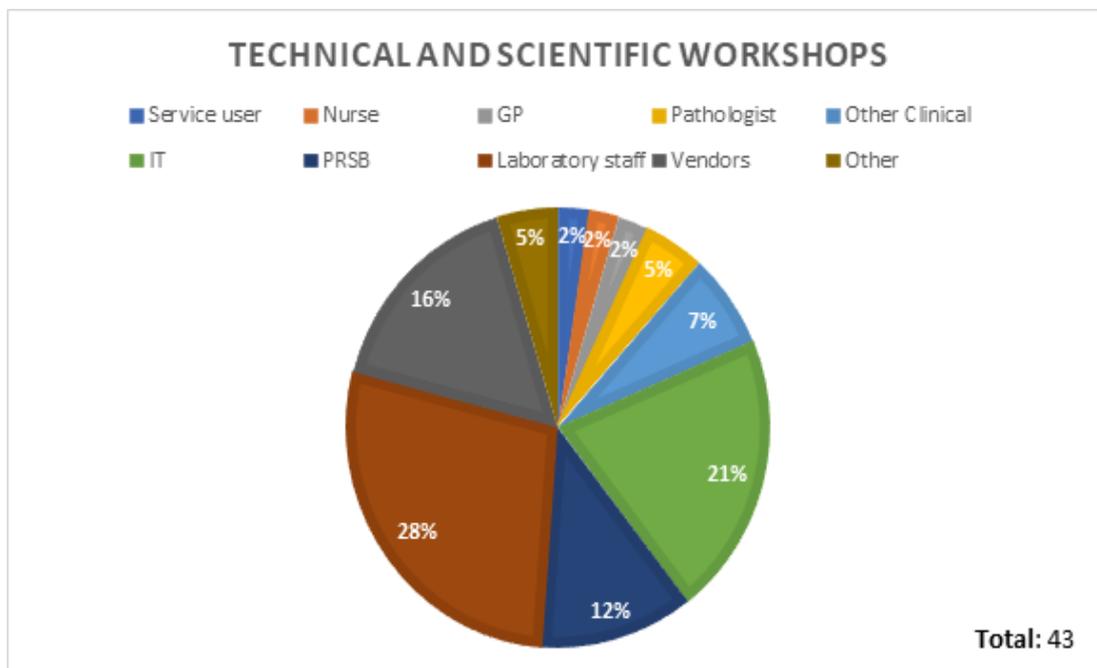
9.2 Webinar Details

3 streams of consultation were held.

9.2.1 Technical and scientific

Three webinars were held at one-week intervals for those with technical and scientific understanding including system suppliers and IT staff in provider organisations who will need to implement the standards. The discussion continued across all three workshops, including a short recap of previous ones, with attendees encouraged to attend all three sessions if possible.

The chart below shows the proportions of different groups who attended at least one of the webinars with many attending two or all three.



9.2.2 Clinical users, including researchers

Two webinars were held at a two-week interval for clinical users of pathology test results both for direct care and for research. The two webinars followed a very similar agenda with some attendees only attending one session, but others attending both.

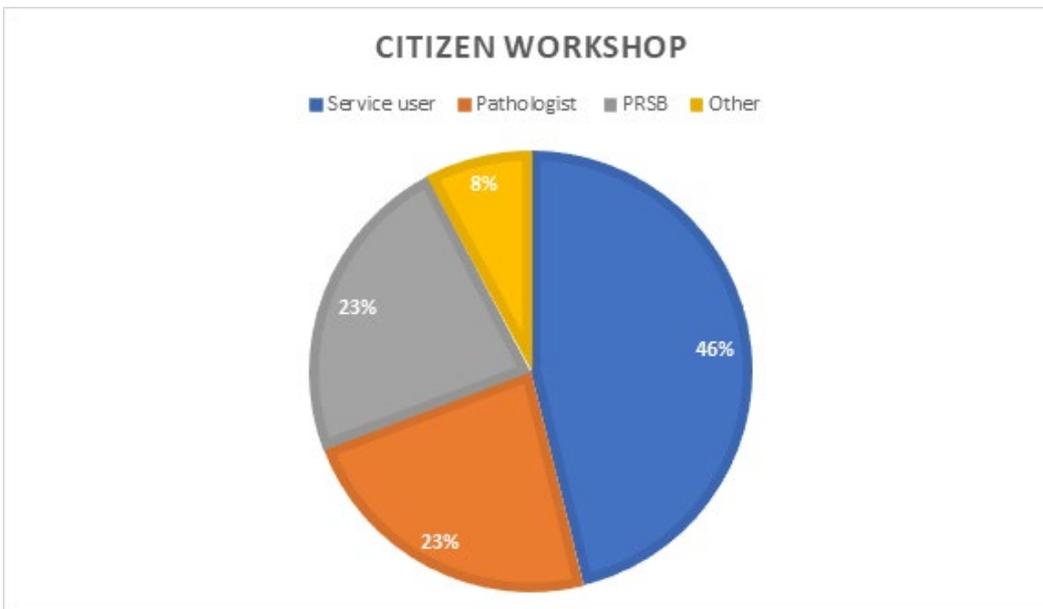
The chart below shows the proportions of different groups who attended one of the two webinars.



9.2.3 Patients

A single webinar was held for patients, led by the project patient lead.

There were twelve participants; five other patients attended along with PRSB team members, two NHS Digital staff and a pathologist, as shown in the chart below.



10 References

- [1] <https://github.com/charliemccay/cade-path8>
- [2] <https://github.com/charliemccay/cade-path8/tree/main/resources/outputs/exhaust>
- [3] <https://github.com/charliemccay/cade-path8/blob/main/resources/files/pathway/BPMN/Path1.bpmn>
- [4] <https://github.com/charliemccay/cade-path8/blob/main/resources/files/pathway/Observation.csv>
- [5] <https://camunda.com/download/modeler/>
- [6] <https://github.com/charliemccay/cade-path8/blob/main/resources/files/pathway/values.json>
- [7] <https://www.hl7.org/fhir/references.html>
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- [9] https://www.hl7.org/fhir/observation-definitions.html#Observation.value_x_