Pathology Standards:

Implementation Roadmap

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Document History

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Change history

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1. Introduction

This document is one of three related reports and should be read in conjunction with its two predecessors: ‘Pathology Messaging - the Past 30 Years’ and ‘Pathology Standards - Implementation Principles’. These documents identify, and progressively build upon, the elements of early pathology standards work which are considered to have been fundamental to their success.

The ‘Implementation Principles’ document begins with an assessment of the IT systems that generate and consume pathology orders and results data and their capability to adopt the new standards that are being adopted elsewhere in the NHS such as SNOMED CT and FHIR. It then takes the ‘success’ themes from the first document and proposes a generic delivery programme structure that could be used to implement new standards in the Pathology ‘Order-Comms’ domain.

An analysis of these two related, but quite separate, subjects was undertaken which identified 14 key standards implementation principles which were subsequently grouped into 5 value streams. The document concluded with 3 important recommendations concerning validation of the principles, an assessment of the ongoing development of a new Unified Test List and a more detailed assessment of systems and suppliers in order to establish the readiness of systems to adopt new standards and the willingness and capacity of suppliers to do so.

This final document proposes a series of activities, a ‘Pathology and Other Diagnostic Services Standards Roadmap’, grouped into five discrete workstreams:

- (a) three to implement each of the three recommendations from the ‘Principles’ document and
- (b) two additional workstreams which will
  (i) determine the requirements of ‘secondary use’ services of pathology data (e.g. national returns) and
  (ii) determine the priorities for the implementation of standards into each of the 19 pathology disciplines and the wider diagnostics services such as Imaging, Genomics and Screening

1.1 Vision

NHS Digital’s ‘Vision for NHS Clinical Information Standards’ states:

- clinicians can record, share and access patient information that retains the semantic fidelity (meaning) of clinical encounters
- commissioners, researchers and public health planners can access clinical information for ‘secondary uses’ with the rich detail of the clinical encounters

In order to share and aggregate such data it is necessary to encode this information with an appropriate clinical coding standard which the NHS has previously selected as SNOMED CT\(^1\) and this is one of a number of fundamental clinical information standards of NHS Digital’s along with the ‘Unified Test List’ currently being developed as a replacement for the PMIP PBCL test list which is no longer supported. The UTL uses SNOMED CT codes held with HL7 FHIR Resource profiles. This work also aims to continue the standardisation of the PBCL UOM (Units of Measure) standard with the potential to use UCUM as the UOM standard.

\(^{1}\) For Pathology some clinicians and informaticians have suggested the standard commonly used in N America - LOINC. A formal assessment of LOINC against SNOMED CT resulted in SNOMED CT offering clear advantages over LOINC and so SNOMED CT remains the preferred coding scheme for both general clinical terms and Pathology.
The use of FHIR is also seen as an enabler for SNOMEDCT with the FHIR standard having gained significant interest amongst suppliers as the next generation healthcare information exchange standard using SNOMED CT as the coding scheme of choice².

NHS England have also stated that their system-wide move towards interoperability focuses upon the following areas:

- Working with services to identify their strategic business needs in relation to interoperability to inform development of required solutions
- Development of priority use cases for interoperability to provide business justification for local investment and development of supporting systems and products nationally

Seven top priorities have been identified by the Chief Clinical Information Officer for Health and Care in England as part of their interoperability vision and are referred to as the ‘CCIO 7’. Two of which relate to diagnostic services:

‘**Basic Pathology** - A consistent set of interoperability standards for the sharing of a core set of pathology tests’ and

‘**Diagnostic coding** – implementation of SNOMED CT across the wider service. SNOMED CT must be utilised in place of Read codes before 1 April 2018 across Primary care settings. For Secondary Care, Acute Care, Mental Health, Community systems, Dentistry and other systems used in the direct management of care of an individual must use SNOMED CT as the clinical terminology before 1 April 2020.’

There is therefore a clearly articulated requirement to implement SNOMED CT standards across Pathology and also the wider Diagnostic services and that the status quo (i.e. the legacy READ2 and EDIFACT ‘PMIP’ standards) need urgent replacement.

The NHS England ‘Interoperability’ section goes on to say

‘**The NHS Standard Contract has required organisations to align their inpatient, emergency care, mental health discharges and outpatient letters to nationally published specifications. Provider must ensure that its major clinical information technology systems enable clinical data to be accessible to other providers of services to Service Users as structured information through open interfaces in accordance with Open API Policy and Guidance and, with effect from 1 April 2020, Care Connect APIs**’

and

‘**CareConnect Open APIs have been developed by NHS Digital and INTEROpen to support the delivery of care by opening up information and data held across different clinical care settings. The CareConnect Open APIs use nationally defined FHIR resources and are a method of transferring records from a source to a recipient.**’

and

‘**When combined with other capabilities (such as National Record Locator Service (NRLS) CareConnect Open API will enable clinicians in one care setting to view records from across other care settings (i.e. a clinician in A&E accessing a patient’s medical record from an out of area service)**’

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² FHIR Resources allow any clinical coding scheme to be used. Most HL7 countries are electing to use SNOMED CT not all have decided to use SNOMED CT for all their coding, e.g. LOINC is use in the USA for Pathology coding.
Note: The CareConnect APIs are based on the use of FHIR standards which themselves mostly contain SNOMED CT codes. The adoption of these standards (FHIR and SNOMED) will begin to standardise the clinical ‘language’ between clinicians across care settings which should help persuade the diagnostic community in particular that standardisation is also required in their ‘back yard’.

1.2 Audience
The primary audience for this Roadmap are organisations considering introducing new information standards into the IT systems used by Pathology Laboratory Services which share their information with other systems. These organisations could include various NHS ALBs such as NHS X, NHS Digital, NHS Improvement as well as organisations such as the Professional Records Standards Board (PRSB), Public Health England’s Screening Programmes and recipients of mandatory data collections.

2 Background
This document, and its two predecessors, comprise a set of Pathology Standards documents commissioned by NHS Digital. This specific document has been produced in response to the request below (in italics). The sub-bullets beneath each indicate where the response to each explicit requirement is located - the Value Streams are documented in the ‘Principles’ document and the ‘Workstreams’ are documented within this document.

‘The production of a documented high level Implementation Roadmap fit for presentation to Standards Commissioners and Approvers including:

- **Contribution to achieving the vision for NHS Clinical Information Standards**
  - This will be achieved by undertaking the activities included in this document as detailed under each of the five workstreams

- **How the Principles would evolve iteratively**
  - Workstream 1 requires the initial set of Principles to be validated which may result in some refinement. They will evolve further through continued use in future standards development projects

- **How and When Existing and New National Standards will be impacted including Information Standard changes**
  - Standards should never be static and should undergo continuous (update and revision) as healthcare practices evolve.

- **Stakeholders engaged and impacted**
  - The Principles under Value Stream 3 ensure continued stakeholder engagement and the nature of their involvement is depicted in Figure 1

- **Options for levels of integration, functionality and associated costs for different stakeholders**
  - This information will form the output from Workstream 3 (IT readiness) and Workstream 5 (Future Standards)

- **Implementation Processes, (DN VS 4 and VS5) Products (VS2 & WS2), Resources (VS1-P3) recommended and why**
  - Implementation processes are documented under the principles within Value Streams 4 and 5 (See ‘Implementation Principles’ document); Implementation Products are documented under Value Stream 2 and Workstream 2 and Resources and documented under Value Stream 3 - Principle 3.
3 Implementation Roadmap

The rationale behind the development of this Roadmap is in recognition of the breadth and depth of standards development and implementation activities required across the Pathology and wider Diagnostic services domains in order to replace the current ‘PMIP’ standards and to continue the work which PMIP started and introduce the new standards across the entire estate.

In this context it is worth repeating the fact that across Pathology alone, of the 1.2 billion results reported each year, only 7% (70% of the 1.1 million sent to GP systems) of those reports include a national clinical code (READ 2) which is now more than 2 years past its retirement date.

It is not unreasonable to state that there is a huge amount of work required by a large a diverse group of clinicians, suppliers, clinical business managers, IT managers across an equally diverse range of organisations in order to effect this change.

This roadmap proposes a number of discreet, but related, sets of activities grouped into ‘workstreams’ in order to provide some focus to the work required. This document does not attempt to place any specific timescales around these activities but does occasionally provide indicative durations.

3.1 Delivering the Vision

In order to deliver the vision of NHS Digital and NHS England in respect of Pathology and other Diagnostic services this Roadmap:

- recognises the work that is currently underway by NHS Digital to develop the Unified Test List (UTL) - a replacement for the current, but retired, Pathology Bounded Code List (PBCL),
- acknowledges SNOMED CT as the clinical standard for use across UK healthcare noting that it may need further development (by NHS Digital) if it does not currently have sufficient scope and content to support
  - the replacement of PBCL by the UTL including the additional attributes within the UTL model and
  - the coverage for additional disciplines beyond those covered by the original PBCL
- acknowledges the current position of FHIR (see Note) as a favoured technical standard by most NHS IT suppliers for
  - Exchanging healthcare information between IT systems and
  - using FHIR Resources as a canonical data model for the storage of Pathology Request and Result data and data associated with other diagnostic disciplines
- Reflects on the need for existing systems generating, receiving and processing diagnostic services data to support the standards expected to be used including systems used to collect data for secondary uses.

Note: NHS Digital are currently working on a submission to the Data Coordination Board (DCB) for FHIR to become a DCB standard. This is currently forecast for DCB consideration in the early summer of 2020.
3.2 The Roadmap Workstreams

The Pathology Standards: Implementation Principles document included three key recommendations (listed below) which form the basis of the first three sets of activities - henceforth named ‘workstreams’.

**Recommendation 1**: Each of the Principles, P1 to P14, under the 5 value streams should be validated by suitable peers who have been involved in similar standards delivery programmes, and particularly those in the Pathology Services domain.

**Recommendation 2**: The Unified Test List (UTL), developed by NHS Digital since 2018 is intended to be a like-for-like replacement for PMIP Pathology Bounded Code List (PBCL) covering Clinical Biochemistry, Haematology and some Microbiology. However, as noted in the Observations section above, it lacks any support for profiles/panels/batteries, screens or dynamic function tests as such is not yet suitable to replace the PBCL. However, there is value in reviewing what has been developed so far. This review should focus on:

a. whether its structure (i.e. not content) can support the wider Pathology domains such as Histopathology, Microbiology, Virology, Immunology, Molecular Genetics, Cytopathology, Cytogenetics and others so that it can be used to support the full roll-out of electronic pathology Orders and Reports,

b. the content of those disciplines that have been developed so far,

c. a review of the currently proposed FHIR resources and FHIR Profiles to establish whether they are capable of supporting the existing UTL structure and any amendments that the review of it (a) above recommends.

Note that any organisation implementing such a standard would be more supportive of a UTL data model that has wider utility beyond that covered by PMIP/PBCL.

**Recommendation 3**: Suppliers of LIMS, Lab Order Comms Systems and Trust Integration Engines (TIE) should be invited to a series of open meeting to discuss their system’s capabilities in terms of FHIR and SNOMED CT support for Pathology Test Requests and Test Reports. Additionally the TIE suppliers should be asked whether they could transform an HL7 v2.x ORU message into a FHIR bundle for those recipients who can support it.

In addition to these three workstreams, two further workstreams are also proposed:

- Investigate secondary uses of Pathology/Diagnostic Service data and
- Determine the prioritisation of further diagnostic disciplines beyond those covered by the PMIP PBCL and the evolving UTL.
The five proposed Workstreams are thus:

**Workstream 1.** Validation of the Implementation Principles and their associated value streams

**Workstream 2.** Evaluation of the current standards in development in order to establish their operational readiness, including:

a. the structure and data model of the UTL and its extensibility to accommodate further disciplines

b. assessment and enhancement of the current content of the UTL with the aim to address any gaps or impediments to restrict adoption

c. the currently curated draft FHIR profiles and resources

d. the scope of the Laboratory Standardised Representation for UOM (units of measure) standard and the plan to consider a migration to UCUM for units.

**Workstream 3.** Assessment of Supplier Capability to support the adoption of the new standards including SNOMED CT and FHIR. This needs to include all suppliers currently processing Pathology Orders and Results and any whose systems may have the ability to transform HL7 v2.x Pathology messages into SNOMED CT/FHIR.

**Workstream 4.** Secondary Use Recipients and addressing the need to support pathology national data returns by utilising SNOMED CT with particular focus on Microbiology and Histopathology

**Workstream 5.** Future Standards Development and establishing the priorities for the remaining Pathology disciplines as well as looking to provide the wider diagnostic services community an appropriate adoption Roadmap
3.3 Initial Stakeholder Engagement

Perhaps the most important value stream (VS3) within the Implementation Principles is that of Stakeholder Engagement. All of the activities within this Roadmap will by necessity require the input and support from a diverse range of stakeholders in order to be progressed and delivered. It is therefore crucial that an exercise is undertaken at a very early stage to recruit sufficient stakeholders across the various stakeholder groups in order to gain their support and establish their required contribution, involvement, and specifically their participation in the activities detailed within the Workstreams described below.

The stakeholder segmentation diagram below has been included as an illustration of the complex and diverse nature of the stakeholders involved. Note that there are a significant number of stakeholders who are fundamental to the development and delivery of new standards and a not insignificant number who will need to be actively involved.

It is suggested that the diagram itself is used when establishing the initial communications strategy and that it is also validated during the initial the stakeholder recruitment exercise.

Figure 1: Stakeholder Segmentation
3.4 Governance

One of the key implementation principles within the Planning value stream (VS4) was to establish both the Clinical and Technical governance arrangements (P9). Within this roadmap we have identified a number of workstreams of activity that when commenced will require significant coordination and oversight to ensure that they deliver the required outputs and to the expected timescales. Whilst we accept that the Principles themselves require validation it is our recommendation that as part of the initial stakeholder engagement exercise described consideration is given to the early establishment of effective governance arrangements, underpinned by appropriate terms of reference and clearly defined roles and responsibilities. At the outset this should include and encompass the following:

a) **Operational Governance** - An operational governance board should be established in order to own the vision, set the aims and objectives and be accountable for the delivery of the required workstream outcomes. This could be through the formation of an Oversight Board underpinned by a number of focused Steering Group as created in Scotland for their National Laboratories Programme\(^3\). It is however recommended for workstreams 1, 2c and 3 proposed herein, that greater supplier representation is included owing to the focus on supplier participation in these workstreams and the delivery of new products and services.

b) **Clinical Governance** - To provide a more specific clinical leadership, ownership and accountability specifically for Workstreams 2a (Unified Test List Model/Structure), 2b (Unified Test List content) and Workstream 5 (prioritise additional disciplines beyond those covered by PMIP/PBCL).

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\(^3\) [https://www.labs.scot.nhs.uk/governance](https://www.labs.scot.nhs.uk/governance)
4 Workstream Descriptions

Each of the Workstreams is described in this sections follow a standardised structure which includes:

- Description and Rationale
- Output - the expected output, e.g. product, achievement
- Inputs - To reflect any intrinsic link between the outputs of one workstream with the input from another.
- Activities - the activities required to deliver the outputs and any recommendations on how these activities may be undertaken
- Stakeholders - the stakeholders who need to be involved (see Figure 1 for their engagement role)
- Importance - Indicates the relative importance of the workstream outputs, either Necessary, Important or Critical
- Indicative Duration - an indication on expected timescales
- Dependencies - any external or internal (i.e. other workstream outputs)

4.1 Workstream 1: Validation of the Implementation Principles

Figure 3: Workstream 1 Activities
Description and Rationale

Validation of the 14 Implementation Principles, grouped into 5 value streams, contained in the Pathology Standards - Implementation Principles document as illustrated in the following diagram:

It is anticipated that the principles will be non-contentious and be broadly accepted given they are based predominantly on proven good practice, for example VS3 - Stakeholder Engagement - states the need for a comprehensive Communications Strategy (P7). This is likely to require minimal validation; others however, may require a broader review in order to establish consensus agreement.

Note that validation of the principles does not require commencing any activities associated with each principle - it is purely a validation exercise that each principle is well founded and justified in the context of undertaking an exercise in introducing new standards into the Pathology Services domain, and particularly where those standards and required to be supported by IT systems sharing information with Pathology systems.

It is also important to note that these principles could be utilised to support the introduction of standards across the wider diagnostics sector. As such, it might be beneficial to undertake an additional validation exercise of the principles within this context.

As an outcome from the validation exercise it will be necessary to ensure that a process is established that allows the principles to evolve and develop over time. As part of this process it is important that the principles can be regularly challenged and that they remain valid. This will be especially important once any implementation activity has commenced.

<table>
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<tr>
<th>Inputs</th>
<th>Recruitment of suitable stakeholders to review each value stream (see “Stakeholders; below)</th>
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<tr>
<td>Activities</td>
<td>● Each of the 5 value streams and their associated principles should be validated by peer review by a selected a relevant subset of stakeholders for each value stream.</td>
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- It is recommended that the principles are circulated to each stakeholder group together with the ‘Principles’ report to provide background context and ‘The Past 30 Years’ report to provide anecdotal evidence.
- Given the nature of the review exercise it should not be necessary to convene the reviewers together - a WebEx or similar remote meeting should suffice for the final review.
- Following validation, the principles should be formally released via the appropriately agreed channels (e.g. published by NHSD).
- As part of the peer review process it will be necessary to establish a process whereby the value streams and principles can be regularly reviewed in order to ensure that they remain valid.

<table>
<thead>
<tr>
<th>Outputs</th>
<th>An agreed set of Implementation Principles for the introduction of the new Pathology Standards shared with standards development and implementation bodies and made widely available.</th>
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<tr>
<td>Stakeholders</td>
<td>Peer review of each of the value streams and supporting principles will require the input from a diverse range of stakeholders across the Pathology Services domain. This should include representation from all the stakeholders identified in the ‘Keep Involved’ section within Figure 1.</td>
</tr>
<tr>
<td>NB. Given the wide and diverse nature of the stakeholders that could be involved (e.g. the clinical and supplier communities), the use of representative bodies (e.g. trade associations for suppliers) may offer a more manageable approach.</td>
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<tr>
<td>Importance</td>
<td>Necessary</td>
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<tr>
<td>Indicative Duration</td>
<td>Once appropriate stakeholders have been recruited, which could take several months, it is expected that the validation exercise should take no longer than 2 months.</td>
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4.2 Workstream 2: Evaluation of Current Standards

Description and Rationale

Note that NHS Digital and others have already identified that PMIP/EDIFACT and the associated PBCL are in urgent need of replacement.

This is a critical and necessary Workstream. Apart from SNOMED CT which is reasonably mature and has well-founded maintenance and development arrangements across a number of countries, other standards identified as candidates for conveying Pathology data such as FHIR and the UTL are in their infancy and are still subject to significant change.

If new Pathology standards are to be introduced to support the flow of Orders and Result Reports around the Pathology IT landscape it will be important to (a) define a suitable baseline of agreed standards to support specific information flows and (b) to determine the priorities for further development in order for them to be operationally deployable as (i) a viable replacement for PMIP, i.e. no loss of current functionality, and (ii) a suitable standard to support the bulk of the remaining 93% of Pathology information exchange which is not covered by PMIP.

This workstream should look to ensure that at the very least the UTL, including the associated FHIR Resources and Profiles, can deliver in accordance with the stated scope of the UTL including:

- clinical need - the ability to share basic pathology results across health and care
- accounting and commissioning - the ability to unambiguously identify tests and associated
results to support commissioning and accounting

- patient safety - the ability to interpret and analyse aggregated lab results where the same test can be returned to different clinicians in more than one unit of measure.

This Workstream should include:

a) A review of the UTL in order to determine whether its structure (i.e. the data model) is extensible and can support the wider Pathology domains such as Histopathology, Microbiology, Virology, Immunology, Molecular Genetics, Cytopathology, Cytogenetics and others so that it can ultimately be used to support the full roll-out of electronic pathology Orders and Results (i.e. not just PMIP (GP Reporting)).

b) A review of the UTL content in order to determine if it is a capable replacement for the PBCL. Initial observations would indicate that the current release of the UTL (v0.3 October 2019) is limited to single tests and does not include support for test batteries, panels, profiles or dynamic function tests. This is a significant omission and would prevent roll-out to GPs beyond a Proof of Concept (or similar exercise) as this would not deliver a like for like PMIP replacement. (Note: this specific review task is helped by the existence of the last PBCL and the PMIP documentation and a large number of existing users to consult.)

c) A review of the draft FHIR resources and profiles to support the electronic exchange of pathology Orders and Result Reports (Procedure Request, Specimen, Observation and Diagnostic Report) to obtain confirmation that they are capable of supporting the required use cases associated with the replacement for PMIP/EDIFACT and extension into the other Pathology disciplines.

d) The introduction on an agreed set of units (UOMs) as an extension to the ongoing maintenance of the PBCL was regarded as a highly beneficial piece of work by the clinical community; however, it is an exercise of great clinical risk. The change of a unit of measure (e.g. from g/dL to g/L, of viral loads reported as Log Values to actual values) for a given test can have large ramifications for both clinicians used to viewing results within a familiar numeric range and systems that display result graphically or have built in rules, algorithms, alerts etc that react to values outside their expected range. It is an exercise that requires very careful planning and consultation and can only realistically be undertaken at local level. However, the benefits or standardising UOMs are also potentially large as it allows for the exchange of data between systems more easily and reduces clinical risk as clinicians move between clinical environments where UOMs are the same. It is therefore essential that the Royal College of Pathologists owns and governs this work and that any proposed changes are supported by an effective communications strategy. A review of the current Units of Measure (UOM) work being undertaken by NHS Digital to document (i) the existing scope of agreement on standard UOMs and uptake, (ii) the issues/obstacles preventing further standardisation and (iii) the scope for further standardisation using UCUM as the standard will be a extremely useful continuation of the work undertaken by Rick Jones ten or so years ago.

e) Consult a number of suitably experienced Suppliers and Trusts to evaluate the possibility of conducting a Proof of Concept exercise in order to validate the current UTL data model, its associated content and the use of the FHIR STU3 and R4 Resources and Profiles. Note that although the UTL has not yet been developed to support Orders it will be important that any PoC exercise covers the complete Order-to-Report lifecycle.

Inputs

- Current NHS Digital UTL artefacts and associated material on
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<th>‘Kahootz’ website.</th>
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<tr>
<td>Current NHS Digital UOM artefacts and associated material on ‘Kahootz’ website. Any extant material produced during the last UOM standardisation work undertaken by the late Rick Jones for NHS Digital.</td>
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<tr>
<td>Output from Workstream 5, specifically the future discipline priorities and any discipline specific requirements in order to ensure that the UTL data model is extensible across all required pathology disciplines.</td>
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<th>Activities</th>
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<tr>
<td>Undertake an exercise to review the current data model and UTL structure to confirm its extensibility and ability to support all pathology disciplines.</td>
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<td>Conduct appropriate clinically led specialist review in order to establish and enhance the current baseline content with regards to the UTL and its ability to replace the PBCL. (Important Note: The PBCL covered two disciplines well - Haematology and Biochemistry - and only partially covered other disciplines such as Virology). It is recommended that this is addressed as part of this review, i.e. for each discipline a decision needs to be made on whether the UTL should cover a discipline in its entirety or whether partial coverage is acceptable) Priority activities here need to include:</td>
</tr>
<tr>
<td>Inclusion of support for test batteries/profiles such as Urea &amp; Electrolytes, Liver Function Tests, Full Blood Count, etc</td>
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<td>Inclusion of support for Dynamic Function Tests.</td>
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<tr>
<td>Liaise with RCPath over the proposals to (a) build on the original UOM standardisation work to extend its scope and (b) to look at further standardisation of the initial UOM work to move towards the use of UCUM as the default standard for UOMs. Perform a ‘stock take’ on UOM and UCUM work that NHS Digital have undertaken to date and to establish a baseline of what has already been agreed and by whom and any ongoing work to further develop UOMs.</td>
</tr>
<tr>
<td>Work with the RCPath to establish appropriate clinical governance and eventual ownership and maintenance of both the UTL and associated UOM.</td>
</tr>
<tr>
<td>Seek confirmation from InterOpen, HL7UK and other specialists on the status and curation process that has led to the development of the draft FHIR STU3 and R4 Resources and Profiles for Procedure Request, Specimen, Observation and Diagnostic Report. (Note: FHIR standard development is usually undertaken by volunteers and may not have had the level of clinical input and oversight that is necessary for developments of this nature.).</td>
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<tr>
<td>If the results of the above activities indicate the potential to</td>
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undertake a Proof of Concept (POC) exercise then try and identify a suitable laboratory with which to undertake this exercise in order to gain some real-world feedback on (a) UTL content and structure and (b) the extent of IT support for FHIR etc.

Note: The POC should be undertaken in the usual manner, i.e. as a parallel activity alongside a live information flow but using IT components that have been built for testing rather than production. It is also likely that given the expected development of Pathology standards as part of the other workstreams, any standards used for the POC will have changed significantly during the POC period.

### Outputs

A detailed report that describes the outcome of the review, as described in the workstream ‘Activities’ section above and details the further activities are needed in order to:

- Ensure that the current content of the UTL is suitable for use across the two disciplines currently developed (i.e. Haematology and Biochemistry).
- Ensure that the structure of the UTL supports Orders and Reports and specifically batteries, panels, profiles and dynamic function tests.
- Ensure that the FHIR Resources and Profiles are sufficiently mature that they are capable of supporting the transfer of pathology test data within the 2 disciplines above - meaning that they have been clinically validated by appropriate clinicians from those domains (i.e. the senders) and the receivers of the information (e.g. GPs).
- Ensure that the UTL content is sufficiently comprehensive in order that it can be utilised as an effective replacement for the PBCL for specified disciplines. (Note: see ‘Important Note’ above).
- Further develop the UTL data model and structure so that it is able to support the wider pathology domains and will ultimately be able to support both Orders and Results.
- Confirm that the current draft FHIR profiles and resources can be utilised as a direct replacement for EDIFACT.
- A short report on the potential scope and timeline for a Proof of Concept exercise.

### Stakeholders

This will require input from a very wide range of stakeholders include representation from all the stakeholders identified in the ‘Keep Involved’ section within Figure 1 i.e.

- Healthcare Professionals
- System Suppliers
- Business Managers
- IT Managers
and also
- NHS Digital (as the developer of the UTL)
- PRSB/Academy of Medical Royal Colleges and specifically RCPath and RCGP.
- Supplier Trade Bodies and collaboratives (e.g., Care Connect, InterOpen)

<table>
<thead>
<tr>
<th>Importance</th>
<th>Critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicative Duration</td>
<td>There are a number of different activities to be undertaken by a number of different stakeholder groups in this Workstream, some of which are not insignificant and some are independent on others. It is not possible to estimate the likely duration as this will require the input and contribution from a diverse range of experienced stakeholder resources in order to deliver in an acceptable time frame. Given its high importance it is therefore recommended that this Workstream be seen as a priority.</td>
</tr>
</tbody>
</table>
4. Workstream 3: Assessment of Supplier Capability

**Description and Rationale**

This workstream is focused on undertaking an assessment of the capability of suppliers to discover the ‘Art of the Possible’. This needs to cover the systems that currently process Pathology orders and results. It needs to cover their ability and willingness to adopt both SNOMED CT and FHIR. Critically, the ability of the middleware systems and Trust Integration Engines to transform HL7 v2.x Pathology messages (the most common format currently in use) into FHIR Resources containing SNOMED CT codes could be a ‘game changer’ in the Pathology messaging world.

Note that although guidance has been published indicating that newly procured systems for the NHS have to support these new standards, associated use cases have not. It is therefore essential to engage the supplier community in order to ensure support for these standards is forthcoming. This must, as a minimum, cover the replacement of PMIP/EDIFACT but could also include the use case for wider adoption of SNOMED CT into histopathology and microbiology to underpin an improvement in data quality of national data returns (Workstream 4).

**Inputs**

- Output from Workstream 2 - a report on the operational readiness of new and developing standards and expected timescales.
- **NEEDED**: A clear statement by NHSD/NHSX/NHSI (as appropriate) that NHS Pathology Services and their suppliers must work together to replace the PMIP/EDIFACT standards with FHIR/SNOMED CT based standards as soon as is practical.

**Activities**

- Identify the leading suppliers of LIMS, Lab Order Comms Systems, Trust Integration Engines (TIE), GP systems, Trust EPR and Departmental systems who receive Lab Result data (i.e.
HL7 v2.x ORU messages) and a representative number of customers of these systems who have an interest in clinical standards which is likely to be a mix of clinicians, business manages and IT managers.

- Approach each of the suppliers individually initially (as they tend to keep their cards close to their chest in public) to establish their motivation and capability to adopt FHIR and SNOMEDCT standards. For the TIE suppliers, discuss the possibility of using their products to translate local Test codes into SNOMEDCT for onward distribution around Trusts and to GPs and others.

- Analyse and document the findings and decide on the next course of action. If a pan-supplier meeting is one future action then consider using Tech UK as the supplier trade association to convene such meetings.

- Note that the possible outcomes of the engagement exercises could be wide and varied and it is therefore not possible or sensible to predict what these might be here.

### Outputs

- Documented understanding of the capability of all suppliers within the pathology information exchange space to adopt FHIR/SNOMED CT based messaging standards for Orders and Reports. This should reflect:
  - Existing system limitations and any future development requirements.
  - Anticipated development timescales and associated costs to fully enable systems.
  - The ability for Trust Integration Engine (whose products route 90 to 100% of all Pathology LIMS messages) to transform legacy HL7 v2 messages into FHIR/SNOMED CT messages.
  - The ability of Laboratory ‘Order’ systems to accept FHIR/SNOMED CT orders.

### Stakeholders

This will require input from:
- System Suppliers - very wide range
- Business Managers - main Pathology related systems
- IT Managers - Trust IT Departments and Pathology IT
- Supplier Bodies

### Importance

| Critical |

### Indicative Duration

It is expected that this exercise could take as little as 2-3 months for the main Pathology related systems but up to 6 months to establish a much wider picture across the entire Laboratory landscape.
4.4 Workstream 4: Determine Secondary Use Requirements

**Figure 6: Workstream 4 Activities**

**Description and Rationale**

This Workstream covers the activities associated with gathering details of the flow of data from Laboratory systems for secondary use and for each feed whether they are capable of receiving SNOMED CT encoded data and if not, when they will be able to do so. This is set in the context of a variety of existing data feeds, mainly to Public Health England (PHE) using a variety of coding standards including retired versions of SNOMED.

The primary focus of this workstream is the production of national returns by laboratories including:

**Disease Surveillance**
- Communicable Disease Report (CDR)
- Antimicrobial Resistance Report (AMR)
- Chlamydia Testing Activity Dataset (CTAD)

**Cancer and Screening**
- Cancer Outcomes and Services Dataset (COSD)
- Cervical Cancer Screening

It would also be beneficial to establish the full extent of secondary use data provision (result sharing) by laboratories where the wider use of SNOMED CT, the UTL and possibly FHIR may deliver added benefits to both the laboratories and to their data recipients.

**Disease Surveillance**

NHS Laboratories are obligated to routinely provide PHE with microbiological surveillance (CDR), antibiotic resistance (AMR) and Chlamydia testing data however it is known that the information provided is locally coded leading to significant variation in reporting and the requirement for extensive mapping prior to being uploaded into the PHE database and analysed. PHE has already indicated an intention to move to SNOMED CT and, as part of this transition it
would be opportune to enable laboratories to adopt SNOMED CT at source in order to standardise microbiology reporting and therefore improve data quality.

Cancer and Screening
NHS Histopathology and some Haematology laboratories are required to submit the Cancer Outcomes and Services Dataset (COSD) to The National Cancer Registration and Analysis Service (NCRAS) on a monthly basis. Legacy versions of SNOMED ceased to be licensed for use by the International Health Terminology Standards Development Organisation (IHTSDO) from April 2017, however, evidence would indicate that old versions are still in extensive use in many laboratories. At least 2 Laboratories are known to have sent SNOMED CT coded data only to have it rejected despite COSD saying it supports SNOMED CT. Whilst the current COSD specification accommodates the use of these legacy versions as well as SNOMED CT there is obviously a need for understanding (on the part of the COSD service at least) with clear communications and a co-ordinated implementation approach required.

With the introduction of HPV primary screening and the reconfiguration of the screening laboratories the Cervical Cancer screening programme has recently undergone significant change. Historically screening laboratories produced the annual KC61 return however given the changes to the programme it has been noted by PHE that

Data collection and the standards used to assess the quality and performance of the programme need to be updated to reflect the new pathway.\(^4\)

An opportunity therefore exists to work with PHE, the screening programme and the laboratories to determine if SNOMED CT could be utilised to support future data collection requirements.

<table>
<thead>
<tr>
<th>Inputs</th>
<th>The outputs from Workstream 3, for suppliers in common with those of this workstream, will expedite the activities in this workstream.</th>
</tr>
</thead>
</table>
| Activities                                                            | • Gather a baseline of secondary use data provision, whether national or otherwise, by contacting a representative number of Laboratories. For each identified flow establish the nature of the data feed (content, format, frequency, transport method) and the current and future clinical coding requirements.  
  • Contact the recipients of the data (e.g. PHE) and establish whether they have any plans to migrate any of their data feeds to support SNOMED CT and in what way (e.g. format, frequency, transport) and whether any such updates are likely to also support the use of FHIR and specifically:
    a) Liaise with providers of microbiology surveillance (CDR) and antibiotic resistance (AMR) data (i.e. Microbiology laboratories) and their LIMS suppliers to investigate their readiness to adapt their outputs (e.g. to incorporate SNOMED CT) to meet the needs of the recipients.
    b) Liaise with providers of Histopathology data and their LIMS suppliers to investigate their readiness to adapt their outputs (e.g. to incorporate SNOMED CT) to meet the needs of the recipients. |

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\(^4\) [https://phescreening.blog.gov.uk/2020/01/14/cervical-screening-standards-report/](https://phescreening.blog.gov.uk/2020/01/14/cervical-screening-standards-report/)
the needs of the recipients. And specifically in relation to the provision of data to COSD, establish a migration pathway from the use of legacy SNOMED to SNOMED CT to support histopathology reporting.

c) In conjunction with PHE and the national screening programme establish the requirements for the use of SNOMED CT to support the future data reporting requirements for the Cervical Cancer Screening Programme.

| Outputs                                                                 | A report detailing the various information flows supporting secondary uses of Pathology data, specifically those related to mandatory notifications of pathological findings. This needs to include for each information flow:
|                                                                         | ● Confirmation of the Use Case for the provision of pathology data.
|                                                                         | ● An assessment of the capability of the receivers of such data to adopt SNOMED CT, and, if applicable, in FHIR format.
|                                                                         | ● An assessment of the capability of the providers of the data (i.e. NHS laboratories and their various systems), and specifically Microbiology and Histopathology, to supply data using SNOMED CT coding and, if applicable, in FHIR format.
|                                                                         | ● Where feasible, to propose a migration pathway for the adoption of SNOMED CT to support both infection surveillance and cancer reporting by NHS laboratories.

| Stakeholders                                                                 | This will require input from:
|                                                                         | ● System Suppliers - LIMS, PHE NCRAS, and any other recipient systems of ‘secondary use’ data
|                                                                         | ● Business Managers - main Pathology related systems
|                                                                         | ● IT Managers - Trust IT Departments and Pathology IT
|                                                                         | ● Pathology Healthcare Professionals

| Priority | Important |
| Indicative Duration | Given the relatively discrete nature of secondary use data flows it is estimated that this exercise could complete within 3-4 months, particularly if this subject is included in Workstream 3 for those suppliers in common. |
4.5 Workstream 5: Determine Priorities for Future Standards

![Diagram of Workstream 5 Activities]

**Description and Rationale**

This workstream covers the activities needed to identify the priorities for the introduction of standards into pathology disciplines other than the initial PMIP disciplines including Microbiology, Histopathology, Genomics and others; the national Screening programmes and other diagnostic services such as Radiology and other imaging disciplines.

It will look at the capacity of the UTL to support these other diagnostic disciplines in its current form or whether new artefacts will need to be developed to support other diagnostic services.

It is anticipated that this may ultimately lead to establishing a standards adoption Roadmap for the diagnostics community as a whole rather than just pathology.

**Inputs**

- Royal College of Pathologists authoritative list of Pathology disciplines\(^5\)
- Royal College of Radiologists (for their list of disciplines)
- Screening Programmes (PHE) that use Pathology and other Diagnostic Services
- Current UTL and associated material

**Activities**

Liaise with appropriate clinical and business stakeholders to determine the priorities for the remaining pathology disciplines for inclusion.

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\(^5\) [https://www.rcpath.org/specialist-area.html](https://www.rcpath.org/specialist-area.html)
within the UTL.

For Pathology, it is recommended that the Royal College of Pathologists list of 17 pathology specialities are used as the definitive list and therefore the full set of disciplines should be:

- Blood Sciences including Clinical Biochemistry, Haematology, Immunology and Toxicology
- Medical Microbiology and Virology
- Histopathology including Cytopathology, Neuropathology, Dermatopathology and Paediatric and Perinatal pathology
- Clinical Cytogenetics and Molecular Genetics
- Transfusion Medicine

For Radiology the UTL needs to support the various diagnostic imaging disciplines such as:

- Radiography
- MRI
- CT
- Ultrasound
- Nuclear Medicine
- Echocardiography

For Screening, the UTL needs to support the needs of the various Screening programmes, in particular:

- Cervical Cancer Screening,
- Bowel Cancer Screening,
- Blood Spot Screening
- Breast Screening
- AAA
- Ante-natal
- New-born Hearing Screening
- Etc

and potentially others including AAA, Ante-natal, Breast, etc. (Note that a number of the screening programmes involve imaging related studies.)

Given the scope of the exercise, specifically the breadth of users of diagnostic services, the activities proposed could, at face value, take a significant length of time. It is therefore proposed that priority should be determined initially by volumes of tests per discipline and diagnostic service and then by importance and benefit. Importance could be aspects such as whether it affects a mandatory data return and benefit could be rated by the level of benefit gained (e.g. reduction in clinical risk, reduced workload, greater analytical capability). An overall score could be calculated by combining volume, importance and benefit to create an indicative priority ‘score’ to determine the final priority.

The output from this workstream will feed into Workstream 2 and will ensure that any specific requirements that may impact the currently proposed data model of the UTL are suitably captured and addressed as necessary.

The inclusion, and relative priority of additional disciplines and
domains, may also require alignment with any future adoption proposition in order to ensure any dependencies and priorities are taken account of.

Once the additional Pathology disciplines and other diagnostic domains are identified it will be necessary to conduct an evaluation of the UTL to establish whether it can accommodate the extensions required to cover additional disciplines and domains and/or whether other similar artefacts need to be developed for other domains. It is not proposed that this be undertaken as part of this workstream but this may well be a recommendation that results from it.

<table>
<thead>
<tr>
<th>Output</th>
<th>A published list of priorities and development Roadmap for the UTL that facilitates coverage across all aspects of pathology services (including genomics and screening) and other diagnostic disciplines.</th>
</tr>
</thead>
</table>
| Stakeholders | This will require input from:  
  - Healthcare Professionals  
  - Business Managers  
  - IT Managers  
across all parts of the health service who use Pathology and other diagnostic services. |
| Priority | Important |
| Indicative Duration | Given the scope of the exercise, specifically the breadth of users of diagnostic services to be prioritised, the activities proposed could take a significant length of time. Given the other workstreams are expected to take up to 6 months to deliver it is suggested that an initial draft set of priorities from this workstream is produced within 6 months with a final set within 9 months. |
5 Recommendations

During the production of this document the authors considered that a small number of observations
require immediate attention. It is therefore recommended that the following are undertaken as quickly
as possible, and ideally before any of the workstreams commence their proposed activity:

1. Initiate an exercise to add support for battery/profile level structure into the UTL for both
requesting and reporting

2. Initiate a communications strategy to:
   a. establish communications channels with the various stakeholder groups (see Figure 1),
   b. commence broad stakeholder engagement and
   c. identify potential clinical champions, board/steering groups members

3. Establish governance arrangements (See 3.4 Governance), terms of reference and
   membership structure for an operational board/steering group to provide leadership and
   facilitate decision making and direction for the work recommended in this ‘Roadmap’.