Pathology Standards:

Implementation Principles
Document History

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1. Executive Summary

This document is the second of three documents examining Pathology information standards in the UK. The first document explored events over the past 30 years and identified a number of themes which either contributed to the success of previous work or prevented success due to their absence. This second document explores the current digital landscape of systems involved in the generation and consumption of pathology messages between systems and, using the success themes from the first document, develops a set of principles which should be used to help guide any future Pathology standards adoption to a successful conclusion. The third document will propose a roadmap for the development and implementation of new Pathology standards including activities associated with the recommendations within this document.

The document set in general recognises huge benefits that the PMIP (Pathology Messaging Implementation Programme) brought to the flow of results to GPs in the early 2000s but which is now based on redundant standards and technologies and urgently requires a standards uplift. The work required should not be a like for like replacement as GP test results represents less than 10% of the results sent and any new standards work needs to develop artefacts such as the new UTL (Unified Test List) which has greater utility across the 19 Pathology disciplines and should ideally encompass the further Diagnostics Services such as Radiology.

The Pathology Landscape section describes the various IT systems that a typical Pathology Laboratory has and with which it communicates and is illustrated in Figure 2. Figure 1 illustrates the relative proportions of the 1.2 billion pathology results messages that are sent each year in England. Of these, only 70% of the 1.1 million sent to GPs (i.e. 7%) contain a clinical code to identify the test meaning approximately 93% of the 1.2 billion results being sent from Pathology systems do not contain a nationally recognised clinical code. This probably represents the largest set of clinical data flowing across NHS systems without a national clinical code to identify it.

The messages being sent to GPs are using READ2, a coding system that was retired from NHS use in Oct 2017, and Laboratories are now unable to code new tests or new units of measure as a result. Additionally these codes only ever covered approximately 70% of pathology tests – the remaining 30% are still sent uncoded.

The Current Digital Maturity section describes the relative maturity of the systems managing and generating pathology data (Laboratory Information Management Systems or LIMS), receiving pathology results (Hospital EPR and departmental, GP and Secondary Use systems) and moving it between systems (Trust Integration Engines). Most of these systems are of a reasonable digital maturity with many supporting modern day clinical standards such as FHIR and SNOMED CT. Whilst the situation is improving many LIMS have been in place for well over 25 years and are functionally unable to support modern standards such as SNOMED CT or FHIR without resorting to significant development expense and associated risk to service.

The Implementation of Pathology Standards section describes in further detail, the key elements of a pathology standards delivery programme outlined in Report 1. This covers the early stages of identifying a clear business need for a standard and establishing outline costs to see whether it is a viable proposition. Further sections cover clinical and supplier engagement, both key to gaining the required support from those most actively involved in using standards, the need for a widespread communications strategy and the need to decide what level of central control and funding might be required. Report 1 clearly highlighted the need for some central programme to coordinate standards implementation and just publishing a standard and mandating its use has very rarely worked or achieved the desired implementation timescales.

1 https://www.rcpath.org/asset/85F80BB8-CC8D-4822-8F6120B46188048D/
The Adoption Principles for Pathology Standards section builds upon the key success themes and proposes a number of key principles under five Value Streams – Business Justification, Standards Development, Stakeholder Engagement, Planning and Delivery – the latter containing no surprises. However, the first 4 sets of principles promote:

(a) a more collaborative approach working in partnership which has seen recent success in the GP Connect and Care Connect Programmes under NHS Digital,
(b) a more extensive set of activities to determine the readiness of the users, their systems and their suppliers to be able to develop, deliver and use new pathology standards and
(c) an early implementation planning exercise to establish how the transition of a new standard into a complex network of systems currently exchanging coded and uncoded can be achieved.

Figure 4 illustrates how the Value Streams can be used as a series of ‘Gates’ for a delivery programme. For example, if a clear business need cannot be established or support from clinicians and suppliers cannot be obtained or no funding secured then you should not proceed to the Standards Development phase.

Finally, the Recommendations section proposes some further activities for consideration such as validating the principles, talking to suppliers and validating any new standard under development.
2. Introduction

This report draws upon the wealth of knowledge and experience gained from the numerous projects and programmes that have both succeeded and failed in their attempts to introduce clinical information and messaging standards into the Pathology Order Communications environment over the past 30 years.

The predecessor report to this, ‘Pathology Messaging Standards - the Past 30 Years’, reflects upon a number of local and national initiatives in the Pathology Order Communications environment and identified a number of themes which were considered important, if not critical, to the successful adoption of clinical and technical standards to support the safe exchange of laboratory test requests and reports between clinicians across the laboratory services domain.

This report builds upon those ‘themes’ and develops a number of Implementation Principles that should be followed, if not adhered to, for any project or programme intending to implement new, or change existing, Pathology Order Communications related clinical information or technical standards. These principles apply equally to the various systems within the Pathology environment (e.g. LIMS, Middleware, Order Comms) and the various external systems with which they communicate (e.g. Hospital Departmental systems, GP systems, National Return systems).

These principles support:

- Delivery of ‘Basic Pathology - a consistent set of interoperability standards for the sharing of a core set of pathology tests’ one of the seven priority areas (‘the CCIO7’) for [interoperability](https://www.england.nhs.uk/digitaltechnology/connecteddigitalsystems/interoperability/) by the Chief Clinical Information Officer for Health and Care in England.

2.1 Audience

The primary audience for this report 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.

2.2 Scope

The scope of previous pathology messaging standards work has been predominantly around the sending of results to GPs. The LIMS Information Exchange domain (see Figure 1) clearly illustrates that this is only a small part of the information sharing landscape and although there have been other projects that have looked into the development of standards for other parts of this community, none to date have taken a holistic view.

It is a widely held view by many professionals working in this field that, apart from the flow of data to the secondary use services, the nature of the information flows and their purpose is the same i.e. a clinician requests a test to be performed on a sample and requires the results to be reported back to them in a clear and concise manner and in a format that allows it to be added to the patient’s electronic record. The nature of these information flows necessarily contains both business/clinical and technical content and this is reflected in the Principles contained in this report.

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[3](https://www.england.nhs.uk/digitaltechnology/connecteddigitalsystems/interoperability/)
Observers of the various projects and programmes of work over the past 30 years have commented that the only real success story (so far) is PMIP which was heavily business focussed as a programme with significant clinical representation whilst most of the technology driven projects (e.g. HL7 v3 Path messages, NLMC) had either failed or achieved limited success.

Given the wider information sharing agenda and the increased uptake of common clinical standards such as SNOMED CT, it would be a serious oversight if any future standards development work in the Pathology domain did not support the entire community. The scope of this document is therefore aimed firmly at the entire community as illustrated in Figure 1.

**Important Note.**

Although the scope of this report is focused primarily around standards within the Pathology services domain, the principles contained herein are arguably transferable to other diagnostic service domains with minimal adjustment. The references within are to previous Pathology standards work because there have been few, if any, attempts to implement clinical coding standards within other similar services such as Radiology. It is perhaps worth mentioning that several Radiology Departments have used the PMIP predecessor EDIFACT messages (‘NHS002’) to send Radiology reports to their GPs using clinical codes of their own choosing. Whilst undertaking the review of Pathology standards (see ‘Pathology Messaging Standards - the Past 30 Years’) a number of GPs, when asked about what they’d like to receive next electronically, requested the receipt of Radiology Reports as these are the next largest volume of diagnostic reports received in General Practice.

### 3. Pathology Landscape

The business of Pathology Services in simplistic terms is the process of receiving a request for a test to be performed on a sample and reporting the results back to the requesting clinician. This has changed little over the past 30+ years, however, the analysers and instrumentation, methods used, range of tests undertaken and automation of sample processing has continually evolved as technology, diagnostic testing techniques and methodologies have developed significantly as diagnostic medicine has evolved.

From an IT perspective Pathology Services continues to be underpinned by a LIMS and associated support systems. Whilst it is true that some modern LIMS are now natively designed to support electronic order management, many legacy systems are still sample driven and based around sample management and the concept of a sample identifier rather than a request/order identifier. The information sharing model for Pathology is predominantly rooted in serving the local Secondary Care systems across a typical Trust with little consideration for national standards when local coding works perfectly well in this closed environment. Sending coded results to GP systems and sending mandatory returns are usually the only use of a national standard in a LIMS system and constitute less than 10% of all messaging.

The formation of regionalised networks for Pathology Services across England is currently driving a level of unprecedented change in laboratories service delivery. Demands for standardisation of working practice and information exchanges is in turn leading to a consolidation of LIMS and related IT systems.

**Figure 1** provides a high level illustration of the main healthcare sectors served by Pathology Services in England, the different types and volumes of data exchange between them and the level of information standards used within them. It is interesting to note how little of the 1.2 billion order requests and reports flowing around the service incorporate any national data standards. The largest volume of coded data comprises the PMIP EDIFACT Pathology Reports sent to GPs using the now obsolete READ codes, whose roll-out completed in 2004.
Figure 1: LIMS Information Exchanges

It is worth exploring this diagram further to add some background and context:
There are currently 105 Hospital Trusts in England providing pathology services from 122 individual Pathology Laboratories. In addition to these, there are a number of large private sector organisations who provide pathology services to both the NHS and the private healthcare sector.

In accordance with NHS Improvement’s transformation agenda\(^4\) and the NHS Long Term Plan, all NHS laboratories in England are currently being consolidated into one of 29 regional Pathology networks with a target completion date of 2021.

Laboratories conduct in the region of 1.2 billion tests per year (according to recent figures from NHS Improvement). If these figures are compared with those published in the Digital First report in 2014 it would indicate that there has been an increase in overall volume by nearly 40% in around 5 years.

Approximately 100 million pathology test results are sent electronically by laboratories to GP’s using the PMIP standards developed at the end of the 90s.

Approximately 1.5 million laboratory to laboratory requests annually are exchanged electronically between LIMS using NPEx with a projected annual increase of nearly 40%.

Provision of secondary use result data, both locally and nationally, from pathology laboratories is extensive and examples include:

- Communicable Disease Report (CDR) and Antimicrobial Resistance Reports (AMR) to Public Health England (PHE)
- Chlamydia Testing Activity Dataset (CTAD) to Public Health England (PHE)
- Pathology cancer data as part of the Cancer Outcomes and Services Dataset (COSD) to the National Cancer Registration and Analysis Service (NCRAS)
- Cervical Cancer screening Recall and Management data to NHAIS
- Copy results to national data repositories such as the Renal Registry
- Copy results to local secondary systems including Infection Control, Colposcopy, Oncology, MDT, etc
- Copy results data for use in research, etc

The Pathology integration environment, and specifically the message flows between a LIMS and associated systems, is now highly complex and is dependent on a variety of legacy and proprietary messaging standards. Various systems have also been introduced over time at a local level to address the variations in the local business and clinical needs of individual laboratories and their networks. This has included clinical order communications systems to support both external and internal requesting as well as links to systems such as the National Pathology Exchange (NPEx) to support Lab to Lab requests and referrals. Secondary use data is exchanged with recipient third party systems using various HL7v2 standards, proprietary messaging formats, repurposed PMIP messages and file transfers.

Figure 2 below shows a typical laboratory’s data flows and illustrates the interoperability challenges and system complexity associated with the interactions between these systems and each other. Use of national standards is limited to the transmission of results to GP systems using the PMIP/EDIFACT standard. Most other systems are integrated using local approaches and codes with limited or no support for national standards or coding.

\(^4\) [https://improvement.nhs.uk/resources/pathology-networks/](https://improvement.nhs.uk/resources/pathology-networks/)
Figure 2: LIMS Integration landscape
4. Current Digital Maturity

4.1 Standards Development

The use of national/international clinical coding standards to identify tests across the Pathology landscape (see Figure 1: LIMS Information Exchanges and Figure 2: LIMS Integration landscape) is very minimal with only result messages sent to GPs and data sent to Secondary Use systems containing clinical coding. All other data is mostly only contains local codes from the LIMS Test Catalogue and is therefore only ‘understood’ in that local environment.

In terms of messaging standards, internal messages within a Trust use a flavour of HL7 v2.x OBR (request) and ORU (report) messages across a Trust network whilst GP systems receive EDIFACT messages over MESH.

Elsewhere in Healthcare IT, the move from Read 2 and CTV3 to SNOMED CT is progressing at pace with many Hospital systems and GP systems supporting SNOMED CT in part or in full, with GP systems expecting to complete their rollout in autumn 2020.

The use of FHIR, the next generation HL7 standard, is widely supported across many supplier communities with many suppliers heavily involved with NHS Digital FHIR-based projects such as GP Connect and Care Connect. Many suppliers are also involved in InterOpen - an international supplier forum for the development of FHIR Resources. Although FHIR is agnostic to the clinical coding scheme, the majority of the FHIR resources being developed through InterOpen, and all the FHIR Resources used in the UK have SNOMED CT as their clinical coding scheme.

The current PMIP originated Pathology results messaging service to GPs still uses READ2 codes (formally retired as a clinical terminology standard in Oct 2017) and EDIFACT as the message syntax which carries the information. EDIFACT is a UN standard developed in 1987 and surprisingly is still in use in the UK although it has not been used to define any new healthcare messages since the mid-1990s and is effectively another retired standard as far as suppliers are concerned with little or no extant knowledge remaining in the suppliers that support it!

Of particular relevance to Pathology is the Pathology Bounded Code List (PBCL) - the set of READ2 codes that are used in the EDIFACT messages to convey test results to GPs. Its last release was Oct 2017 and as such it is becoming progressively out of date as it cannot be extended to include new tests or new Units of Measure for tests and is therefore potentially a risk to clinical safety.

There is thus a fairly urgent need to replace the PMIP standards not only across England but also in Scotland, Wales and Northern Ireland where it is also used to send results to GPs.

As a consequence, supplier support for new pathology standards including SNOMED CT and FHIR is already being encouraged via a number of channels. Examples include NHS Scotland's National Laboratories Programme output based specification guidance that stipulates that all new LIMS should support SNOMED CT and FHIR as well as the similar IT procurement instruction from NHS England to the formative pathology networks in England.

Whilst this approach is useful and welcomed, it is apparent that these mandates do not necessarily reflect the ability or willingness to implement these standards as they are not supported by clearly articulated use cases for the specific use of the standards. Whilst support for the standards may be confirmed by individual suppliers as part of a tender response the context and extent of compliance and associated readiness is likely to be unclear.
4.2 Laboratory IT Systems

Assessing the digital maturity of pathology services is a complex exercise owing to:

a. the complex nature of the various components such as analytical instrumentation, tracking, IT systems
b. the absence of any apparent coherent attempt to measure it.

Although there are many aspects of a Pathology Service where digitisation is well advanced and without which the laboratory would be unable to function, there are other areas where the IT has remained mostly unchanged since the 1990s and is unable to be modified or adapted to support new information standards such as SNOMED CT. Many laboratories have, however, successfully introduced electronic requesting and results reporting and in so doing have moved away from the dependency of paper requests and hard copy reports. There are, however, still some Trusts reliant on paper requests and paper reporting for up to 30% of their activity. Whilst not necessarily related to the scope of this report an increasing number of laboratories are also now moving forward with the digitisation of Histopathology which is leading to additional informatics challenges similar to those faced by Radiology during the introduction of PACS systems.

The LIMS is undoubtedly the mainstay of every laboratory’s IT environment, however, many of these systems are based on aging technologies and in some cases haven’t been replaced for well over 25 years. The longevity of these deployments clearly demonstrates however that the systems are in most cases extremely stable and the functionality wise the software is able to handle the core functions very well.

Laboratories rarely use any standardised form of test coding or test catalogue with each Laboratory developing its own local test catalogue containing their own codes and test descriptions and also their own test attributes. LIMS are configured around this local test catalogue with little or no standardisation other than perhaps commencing their original system build with one provided by their LIMS supplier. Test catalogues can vary widely in purpose with some Laboratories including ‘orderable’ items as distinct from ‘reportable items. From a standards perspective, the dependence on these local home-grown test catalogues remains a significant challenge to standards adoption and even with more recent LIMS deployments this dependency continues due in part to the lack of a suitable standard being available.

From an instrument integration perspective, LIMS are still, in most cases, able to support the connectivity of new and modern instrumentation. The availability of technologically advanced analyser platforms has however driven the demand for increasingly complex IT integration. As a consequence, Blood Sciences laboratories are now increasingly dependent on proprietary IT systems such as instrumentation middleware that are specifically designed to operate in addition to the LIMS and support the complex tasks associated with the management and handling of samples by the diagnostic analysers and their associated pre analytic systems, post analytic archives and sample track systems.

Laboratories have increasingly adopted Order Communications systems to handle test requesting and results reporting. Again, most of these have been locally deployed, either across primary care, secondary care, or jointly across both. Whilst deploying systems like this obviously delivers operational and clinical benefits, most of those within secondary care, as previously noted, rely on the use of various HL7v2.x messaging formats and non standard approaches such as the variable use of comment fields or note segments to convey additional information and results carried in comment fields rather than the actual result value fields.

In order to support the efficient management and handling of laboratory to laboratory requests a significant number of laboratories are now connected to the X-Lab National Pathology Exchange.

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5 NHS Improvement have in fact noted from their annual data collections that digital maturity is very variable across pathology although their measurement criteria are not known.

With an NPEx connection, laboratory end users can securely request tests and get results to and from another laboratory on the NPEx network. NPEx consists of a messaging engine that translates local datasets and codes from senders to a standard messaging format, mapped against SNOMED-CT coding standards, within the central hub. These messages are then translated once more into the local format of the receiver meaning that users can send and receive requests and results regardless of their LIMS. Connection of individual LIMS to NPEx is not standardised and varies (e.g. HL7v2.x or PMIP for instance) depending on system supplier and local requirements. (Note: only a small subset of specialised tests are ‘sent away’ to other Laboratories via NPEx and thus the coverage of SNOMED CT mappings is very small (circa 5%))

The use of the PMIP messaging standards from 2001 to support the provision of results to GP systems is still the only demonstrable use of a national standard (ISB 15578). There have been a number of subsequent national initiatives aimed at promoting additional standards including the development of the National Laboratory Medicine Catalogue (NLMC) and a move to encourage a wider adoption of improved standardised Units of Measure, however, both of these have seen limited adoption for a variety of technical and clinical reasons.

Use of coding systems is still currently limited to the use of Read Codes within the PMIP PBCL product and the use of legacy versions of SNOMED for coding of Histopathology reports in COSD for submission to Cancer registries. Evidence would seem to indicate that so far SNOMED CT has seen limited adoption by some histopathology laboratories but its wider adoption is constrained by the apparent lack of technical capability within the legacy LIMS estate and with SNOMED CT being perceived as too complex and with limited benefit to undertake such a migration.

Even with the introduction of pathology networks there appears to be little evidence to date of local laboratories utilising standards (either old or new) to support information exchange beyond PMIP. The reasons for this are unknown but are likely to be for a number of reasons not least of which will be the effort involved by each Laboratory and recipient systems, the inbuilt limitations of the LIMS software and the attitude and appetite of their suppliers to support such change. This is resulting in significant variance in areas such as interoperability and data exchange between laboratory IT systems and clinical systems. Most have been configured to address a local data sharing and interoperability needs and rely on proprietary and basic messaging formats such as HL7 v2.x which itself has not been used in a consistent way by Labs.

As a consequence, and based on the figures detailed in this report, only 10% of transmitted pathology results are currently associated with a data standard with approximately 90% of pathology data being exchanged between a variety systems without using any national data standards to identify what it is. This probably represents the largest volume of data flowing around the NHS without being associated with any data standard.

4.3 GP Systems

GP Systems are arguably the most digitally mature of all healthcare systems in the UK. This is due to a number of key programmes such as ‘Requirements for Accreditation (RFA)’, ‘GP systems of Choice (GPSoC)’ and ‘GP IT Futures (GPITF)’ all of which have linked funding for these systems to the functionality provided by them. This worked very well in the early years when there were upwards of 100 different systems which rapidly reduced to around 30 once the lure of a ‘free’ system under RFA had been widely accepted as a good thing.

RFA and GPSoC operated from the early 90s until the present time with GPITF becoming operational as the new funding vehicle for GP systems from early 2020. RFA introduced the PMIP standards that

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7 https://www.npex.nhs.uk/
enabled all the GP systems in England to receive Pathology messages from Labs and similar schemes in Wales, Scotland and N Ireland did the same for the rest of the UK. (Note: The PMIP EDIFACT message is currently the only common message used by all 4 home countries which is a tribute to its utility in its day.)

More recently GPsOC has ensured GP systems can exchange complete patient records, including attachments, between them using the ‘GP2GP Record Transfer’ standard, has driven the adoption of FHIR standards into GP systems under the ‘GP Connect’ Programme and will see GP systems finish implementing SNOMED CT in 2020.

Whilst RFA and GPsOC were responsible for fairly quick adoption of these, and other, key interoperability standards, there have been a large number of GP systems that have fallen by the wayside with only 4 suppliers and 4 systems currently operational in England and with 2 having 90%+ of the market between them.

4.4 Hospital EPR/Departmental Systems

A typical NHS Acute Trust, of which there are currently 135 (July 2017), often comprises a collection (often 50+) of disparate departmental IT systems clustered around a PAS (Patient Administration System) and a Trust Integration Engine (TIE). However, a significant number of Trusts have procured a single Hospital EPR system to replace many of the departmental systems, some with a PAS and some without, but still utilising a TIE to orchestrate the various messages between the remaining systems and the NHS systems outside of the Trust.

The implementation of Hospital EPR systems has not been without its problems and whilst the end result can greatly simplify a Trust’s IT system environment, the cost, pain and anguish which is associated with the upheaval that such procurements bring with them, has led many Trusts to re-visit their business cases before committing their staff to such change. Acute Trust IT environments consequently comprise a very varied mix of standards and architectures which don’t necessarily support the new standards (e.g. SNOMED CT) which the NHS is wishing to implement.

4.5 Trust Integration Engines

The key system at the heart of a typical Acute Trust ecosystem is arguably the Trust Integration Engine (TIE) and its constituent parts which orchestrates all the messages both between systems within a Trust and also with those systems external to it.

TIEs have been around in Hospital environments for many years and there are a number of suppliers of TIE software across the world supporting the integration of large numbers of healthcare systems. Whilst the UK may not have progressed very far with the adoption of modern healthcare standards such as SNOMED CT and FHIR, arguably due to the NHS being non-commercial and the market being non-competitive, these TIEs have adopted many different standards including SNOMED and FHIR for their non-UK customers.

Here in the UK, the recent formation of Local HealthCare Record (LHCR) communities has brought many of these standards into these communities in order to achieve the interoperability required between various systems. A TIE will typically be at the heart of a LHCR implementation and the TIE suppliers now also provide Clinical Data Repositories (CDRs), Clinical Portals and integrated Electronic Healthcare Records (iEHRs) as the central ‘patient record’ system used to share information across them. This has enabled them to communicate with a range of systems across a community such as GP systems, Social Care, Community, Mental Health and others, all of whose suppliers are keen to participate in these high profile developments. The consequence of this has been the rapid adoption of FHIR and SNOMED CT as the fundamental fabric of a LHCR community.
The TIE suppliers have also worked closely with GP suppliers under the ‘GP Connect’ programme and some Hospital system suppliers under the ‘Care Connect’ programme. They are also heavily involved with standards settings bodies such as HL7 and IHE and participate in supplier led standards development collaboratives such as InterOpen.

Whilst the TIEs in Acute Trusts may not be configured in the same way as those at the heart of a LHCR, the capability exists within them to use these standards both within a typical Trust environment and also with external systems such as those participating in LHCRs (e.g. GP systems). And thus the TIE suppliers should be able to provide these capabilities to their Trust customers.

This ability, whether enabled or not, to ‘communicate’ with various systems using FHIR and SNOMED CT, translating codes and message formats between systems, offers a significant opportunity to translate existing Laboratory Result data in HL7 v2.x format into FHIR and SNOMED CT format. Given the growing number of systems able to receive these standards it is astonishing that although many TIEs are FHIR and SCT enabled, all the laboratory results flowing through their systems still use local LIMS codes and are moved around using HL7 v2.x messages developed in the last century. It ought to be a relatively straightforward take an HL7 v2.x ORU (Pathology Result message) with a LIMS code and transform it into a FHIR message with a SNOMED CT codes FHIR Resource in it. (See Recommendations section).

### 4.6 Secondary Use Systems

As previously noted in the supporting commentary and illustrated in Figure 1 the requirement for pathology laboratories to supply secondary use information is extensive. The type and quantity of information produced varies from laboratory to laboratory but in most cases includes copy result information supplied to local or regional clinical systems as well as providing bespoke structured data outputs in support of disease surveillance, cancer diagnosis and screening programmes to organisations such as PHE.

The transfer modalities for this information are extremely varied with examples including variations of HL7v2, file transfer of various types of delimited flat files, XML based outputs, as well as bespoke mechanisms requiring intermediate (usually proprietary) messaging software applications. Whilst several of the national data returns such as the Chlamydia Testing Activity Dataset (CTAD) and Cancer Outcomes and Services Dataset (COSD) have incorporated the use of SNOMED CT into their latest specifications, it is currently unclear how many laboratories, if any, are supplying natively coded information.

There is at least one example of SNOMED CT being stipulated within the data specification of the receiving secondary use organisation who then rejected that information from one of its Labs as it itself hadn’t been updated to SNOMED CT and was still operating a legacy version of SNOMED. The laboratory concerned, which had spent over 3 months upgrading its systems to be fully SNOMED CT enabled, then had to use a backwards map to the legacy version in order to submit their returns. This is a good example of the need to (a) coordinate upgrades from one standard to another and (b) to support a mixed environment whilst systems transition from one standard to another.
5. Implementation of Pathology Standards

5.1 Vision, Mandate or Proposition

It is fairly common, although not always the case, that projects or programmes of work to implement standards in one or more systems across the NHS are accompanied by, or make reference to, a simple ‘vision’ statement or in some cases just a ‘mandate’. The top-down ‘mandate’ approach has been tried many times and often fails more times than it succeeds (e.g. HL7 V3 CDA, SNOMED CT, Hospital ‘EPR 6’) and is not an approach that is recommended. It shouldn’t be assumed that a Vision Statement is a necessary prerequisite for such work as there have been many examples of standards adoption achieved by other mechanisms.

The GP IT Futures programme, and its predecessors GPSOC and RFA, are examples of contractual arrangements with suppliers which obliged them to implement a range of standards in order to sell their systems into the NHS - without the accreditation of that system with its standard(s) central funding would not be made available to purchase it.

More recently programmes such as ITK, GP Connect and Care Connect are examples of ‘Propositions’ put to a business/clinical community with an initial set of aims. These have adopted a ‘collaborative’ approach to solving a problem with users, suppliers and the NHS working collaboratively together to achieve a set of agreed objectives. These examples are also ones that are firmly supported by a clear business need and not driven by technology for technology's sake.

When a clear need for a new data standard has been identified (see ‘Business Justification’ below) it is not sufficient to create a vision statement alone as this is unlikely to attract the required support from the associated business and clinical communities affected. However, a clearly articulated and relevant business/clinical investment proposition comprising a set of aims and objectives and proposing a collaborative approach between the affected organisations and suppliers is more likely to gain the required support and traction.

PMIP PBCL Example

Using the need to replace the redundant PMIP PBCL (Pathology Bounded Code List) as an example, the investment proposition needs to reflect the urgent need to replace the PBCL (and its associated legacy EDIFACT messaging standard) as it is no longer being maintained and as such its usefulness and integrity is gradually in decline with gradual slippage into uncoded or inappropriately coded results.

GP suppliers, Middleware suppliers and the GP Community are likely to support this in its simplest of forms, especially following recent developments around FHIR and SNOMED CT. However, whilst replacing PBCL (and PMIP EDIFACT messages) is obviously crucial for the identified reasons it is also important to ensure that the standards adoption proposition does not lose sight of the fact that this only encompasses 10% of the total of pathology Orders and Results traffic. To be of value and to help deliver the associated benefits of pathology consolidation, notably to increase the standardisation of clinical pathology services across the UK as well as promote standardisation of IT systems and results delivery, standards adoption needs to be encouraged across the entirety of the pathology messaging and information exchange domain. This should include across secondary care, screening programmes and secondary data uses.

Given the PMIP standards set is in use in the other 3 home countries and there is some cross-border laboratory work, it would also be sensible to enter into close dialogue with these countries as there may be value in sharing ideas and plans. Given many of the suppliers operating in these countries are the same as England there may also be economies of scale that could be achieved by closer collaboration around the development of any new standards.
5.2 Delivery Programme

It is important to note that PMEP, the pathology standards ‘enabling’ programme, failed to be followed by customer orders and supplier delivery and thus roll-out was glacial in pace until PMIP was established. The roll-out of Choose and Book, GP2GP and EPS are other examples where a national programme was required to ‘encourage’ roll-out - perhaps taking their lesson from PMIP. There are few examples of national standards which ‘just happened’ following publication and it is therefore recommended that in order to effect the roll-out and use of a national data or information standard that a delivery focussed programme is setup to ensure that the standards are adopted and the anticipated benefits realised.

Such a programme will require a suitably representative board to be established in order to provide the necessary governance and leadership. Membership of such a board needs to be broad and potentially have representation not only from the clinical, supplier and standards communities, but also from organisations and representative bodies such as NHSD and possibly NHSX. Given the current priorities around laboratory consolidation, such a board will need to be strategically aligned with the National Pathology Optimisation Delivery Board to reflect delivery of common objectives and associated benefits.

Report 1 in this series - ‘Pathology Messaging Standards - the Past 30 years’ - identified a number of key ‘themes’ which led to the successful implementation of (already developed) Pathology standards and it is suggested that these are included in any future delivery focused programme within the Pathology messaging domain. It is important to note that these ‘themes’ assume that the standards to be implemented have been developed and are regarded as ‘fit for purpose’ by the organisations and clinical communities adopting them.

Using a ‘PMIP replacement standards suite’ as an example: this will require the replacement of the underlying clinical codes (e.g. to identify the property/thing/specimen triad and associated UoM) and also the ‘message’ specification (e.g. FHIR resource profile and message bundle) to carry orders and results between clinicians and their organisations. The development of such standards in itself requires two stages - (a) the creation of the clinical terms and (b) the creation of the message structures and transport methods and rules.

Given the relatively successful approach that GP Connect and Care Connect have taken where a combination of suppliers and clinicians have worked together to develop solutions, and in the absence of any alternative proven approach to ‘solutioneering’, it is recommended that a similar approach is taken to developing the standards which will be used to ‘enable’ the pathology IT systems landscape (see Figure 1 and Figure 2).

5.2.1 Programme Themes

The key themes for successful Pathology Standards implementation identified in Report 1 are represented in Figure 3 below. These common themes run through those delivery programmes which were successful or conversely, were either missing or poorly considered, by the unsuccessful programmes.
This section will explore these themes in more detail and develop a number of key principles which any future Pathology ‘Standards’ work needs to consider if it is expecting those standards to be adopted by pathology services in order to provide an ‘orders and reporting’ service to their customers.

Prior to doing so it is worth reflecting on the number of previous standards often seen as ‘good causes’ that litter the healthcare IT roadside having failed to be adopted in any significant number. Within the Pathology domain both the ASTM 1238 and PMEP EDIFACT messages failed to be adopted and implemented in any significant number as neither the GP or LIMS suppliers or GP Practice or Laboratory Managers were left to decide for themselves whether these were standards worth developing. Similarly, the HL7 v3 CDA message specifications for the exchange of Discharge Notifications (and other document types) from Hospitals to GP Practices, even with the national target for NHS Trusts to send all Discharges electronically to GPs, failed to achieve any live messaging. Again GP suppliers failed to enable their systems and Trust IT Managers ignored the mandate - and none were financially penalised or threatened.

Although the RFA mechanism (i.e. funding compliant GP systems for Practices) was fortunately delivering support for EDIFACT Pathology, Trust Laboratories had no such mechanism to enable their LIMS. It was the emergence of a small number of ‘middleware’ suppliers who spotted an opportunity in the market to provide a translation component for Labs that enabled messages flowing. Around the same time a few key individuals, mainly clinicians, made representations to the NHS Information Authority asking for a national implementation programme to roll out ‘PMIP’ across the whole of England to all
Labs and all GP Practices which luckily fell upon listening ears; as the PMIP Programme Manager at the time said “the right people just happened to be in the right positions at the right time.”

NPfIT/NHS CFH/HSCIC failed to deliver much of its agenda with only those programmes involving GP systems (e.g. CAB (now ERS), EPS, SCR, GP2GP) having achieved anything like the expected delivery and this was because GPSoC mandated those standards and suppliers couldn’t sell their systems to PCTs (and latterly CCGs) without the capabilities being present.

The above examples clearly illustrate that developing standards, fit for purpose or otherwise, will have little effect on their own - they need to be accompanied by some degree of central coordination and enablement to ensure they are implemented safely and efficiently and that the individual organisations involved can see a clear benefit to those involved.

5.2.2 Business Justification

IT systems are not free and are rarely cheap; and thus any organisation paying for an IT system expects something in return and healthcare is no different. Most IT systems pay for themselves by making businesses more efficient through the automation of processes that were often historically labour intensive. Modern day IT systems are also able to perform tasks that have no human equivalence and therefore difficult to quantify. Examples of these include risk reduction and safety improvement through greater accuracy and improved consistency which in turn can lead to improved outcomes, whether through more reliable and efficient care or by patients receiving faster and more accurate diagnosis and treatment and a quicker return to health.

Although being funded by the state, the NHS does not operate in the same way as commercial businesses and thus the organisations operating within it do not have the same levels of autonomy and freedom as commercial organisations. However, NHS organisations have budgets and have to spend them wisely and make similar purchasing decisions to commercial organisations, i.e. reduce costs and improve productivity where opportunities arise.

It is therefore important to recognise that any change to a healthcare organisation’s IT system will usually have an associated cost and that cost has to be both justified and the monies obtained, or savings made, to fund it. This becomes more difficult when two or more organisations are involved (i.e. multiple IT systems need investment to effect a change) and neither organisation is in receipt of all the benefits. Each organisation will typically evaluate their own proposed change and neither will see the overall benefit which may often be greater than the sum of two halves. Adding the IT suppliers into this equation often results in 4 or more parties needing to be convinced individually that a return on their investment can be achieved. From a supplier perspective the main issue is being confident of a return on their investment which requires roll-out of their solutions to their customers in reasonable time. This has been a perennial issue facing numerous NHS interoperability and standards adoption initiatives for many years and remains a complex problem to solve.

As mentioned earlier, there have been examples where this problem has been solved but these successes are few in number compared to the failures. A common theme across the successful initiatives is a significant element of central control and funding, either directly to the suppliers or to the NHS organisations using their systems. As an example, the PMIP Programme only paid GP suppliers once they had delivered training and switched Pathology messaging on, i.e. payment upon delivery. GPSoC paid suppliers for their up-front development which wasn’t always followed by delivery to customers and where it was, not at the pace required. Such central funding was, and still is, only possible where a clear business justification has been determined as this is usually a condition for the use of public funds.

There are more recent examples of local initiatives such as the various LHCR projects across England, where local communities of interest have worked collaboratively together to develop a local business case in order to release local, and sometimes central, funding for these initiatives. The most successful of these are where the right balance between national and local funding is achieved. LHCRs are good
present day examples of this and PMIP was itself a very good example of this. PMIP required Pathology Labs to produce their own business case (aided by a PMIP provided template) in order to procure the middleware systems they needed and GP suppliers were paid from a central fund (with an associated Business Case) per Practice for each successful implementation.

In order to implement any new Pathology messaging standards it will be necessary to devise an approach that will need to engage numerous types of organisation, numerous clinical communities and numerous suppliers. Publishing standards alone will not cause them to be adopted. It will be necessary to provide the required funding to the various parties involved in order to deliver new IT systems in an acceptable timeframe and this may require a mix of upfront costs and payments upon delivery. This may in turn require a number of business cases for each organisation type in order to secure the funding available which will necessitate a degree of central coordination.

Creating a business justification around the introduction of new standards or information flows, or changes to existing flows, needs to be underpinned by evidence of a demonstrable business need for their introduction. As mentioned above, any attempt to introduce a standard without such evidence is unlikely to result in a successful outcome. Business change, in whatever guise, has to be advantageous for each business involved, whether an NHS organisation or a commercial IT supplier, with a clear net gain for each.

It is important to note that improvements in individual patient or population health should also be regarded as a benefit, and thus benefits could include improved clinical safety, reduced risk, better informed clinicians and administrators as well as reduced direct and indirect costs.

Obtaining the support of key business stakeholders who are prepared to ‘champion the cause’ is crucial and this needs to be supported by widespread and effective engagement across the whole business including Pathology Senior Management, Technical and IT Management, Hospital Trust CCIO and CIO’s as well as GP’s, Practice Managers and others including suppliers and appropriate professional bodies.

5.2.3 Clinical Engagement

Assuming a clear business need for the adoption of new information standards has been established, there is a need to establish strong and effective clinical support and clinical involvement. One of the key reasons for the success of PMIP and many other healthcare IT transformation projects, is the direct involvement of key business users, particularly where the nature of the change has a direct impact on a clinical community.

This is not an easy task as clinicians are often extremely busy people and securing their input and support at the level required is rarely achieved. One of the key success factors of PMIP was the appointment of clinical ‘champions’ who worked closely with the Programme and their professional bodies. They also worked closely together, e.g. Pathologists with GPs and Hospital Consultants, and also with the business managers to ensure that the proposed ‘solutions’ were both clinically and operationally pragmatic. Effective clinical engagement will ensure that projects are focussed not just on addressing technical outcomes but on ensuring changes deliver the key clinical and/or business benefits expected.

5.2.4 Supplier Engagement

There are a large number of IT systems involved in the processing of Pathology test orders and results (see Figures 1 and 2). It is essential that all those suppliers whose systems will generate, consume or transform any of the messages associated with an order or a result are involved in any programme of work to change these messages in anyway. Many of these suppliers will have a 2-3 year development programme and it is therefore critical to engage with them at a very early stage if any substantial change to their systems is expected. They are also highly likely to have been involved in similar exercises and can bring a wealth of experience to any future standards related programme and, sometimes unwanted, a large dose of realism around expected timescales and costs.
Many of the suppliers (e.g. of GP, Integration Engine, EPR/EHR, Order Comms systems) operating in this sector are also heavily involved in existing standards developments and programmes such as SNOMED CT adoption, FHIR profiling and resource development, GP Connect, Care Connect, Transfer of Care and others. There are likely to be useful lessons that have been learnt from these programmes that can help shape any future pathology standards programme.

5.2.5 Clinical Governance

Projects that deliver significant transformational change to a clinical community need to be seen to have appropriate clinical governance by their peers. This will provide them with the confidence that their clinical and administrative processes are understood, that their needs are represented and that improvements in patient care are foremost in their minds.

Given the implementation of clinical information standards usually requires the use of and/or change to clinical IT systems it is important to have appropriate technical representation from the supplier community to ensure that appropriate advice and guidance is provided and that an effective partnership exists between the clinical and technical domains. This will help to ensure practical solutions are always at the forefront of decision making. It is not therefore recommended that the clinical governance boards of the past, comprising clinical representatives only, are part of any future standards programmes.

The modern day approach to systems development uses Agile methodologies which are heavily focused on suppliers and users working closely together to develop changes to systems - an approach used in NHS Digital’s GP Connect and Care Connect Programmes which are seen as being far more successful than previous projects with similar aims.

The importance of such representation and collaborative approaches cannot be underestimated; one of the key reasons for the success of the PMIP programme was the existence of the Issues Resolution Forum (IRF). The IRF, perhaps uniquely across similar projects in recent years, comprised clinical and technical people who (a) still worked day-to-day amongst their peers in the communities where the solutions were being deployed and (b) passionately believed in the benefits that the project would bring. This may not be an easy arrangement to repeat and there is no guarantee that the right people could be found again, but finding the right blend of clinical and technical personnel from users and suppliers with the appropriate knowledge and experience is essential to the success of projects of this nature.

5.2.6 Communications Strategy

When planning business change it is important to ensure that all of the various stakeholders are engaged. Identifying the stakeholders is often left until too late and identifying the correct roles (i.e. the way in which they are involved) if often misunderstood or misrepresented. It is important to differentiate the stakeholders using a RACI (Responsible, Accountable, Consulted or Informed) matrix (or similar segmentation method) and validate it at the initiation stage as this will identify the communities with whom the project or programme will need to communicate with.

It is essential that communications strategy is built around and appropriately targeted at the stakeholder communities and that communication begins immediately. Several high profile NHS standards development/adoption projects have failed to come to fruition due to failure to engage with key stakeholders either not at all or too late in the process to secure their required involvement.

Communications and engagement with stakeholders can never start too early and has to be open and transparent. It has to be relevant to each stakeholder group and understand the needs of each stakeholder group whilst maintaining a commonality of message across them. It has to be appropriate to each group, i.e. include technical information to IT suppliers, clinical benefits to clinicians, etc. Consideration should also be given to the channels-mode(s) of communication using various forms of media as necessary.
An effective early communications strategy can also be used to recruit clinicians and others into the ‘programme’ both to help the programme and also as a conduit to their colleagues in their representative organisations/bodies.

5.2.7 Planning

The approach to implementation of a new pathology standard will need careful consideration and detailed planning. It will be dictated to by a number of factors in both the Pathology/Trust and Supplier domains including existing priorities, resource availability, expectations around timescales and availability of funding. A central delivery programme can help deliver implementation in a more controlled and predictable manner as clearly demonstrated by the success of PMIP, however, programmes such as this are inherently costly in terms of central overheads and may not necessarily gain the level of local buy-in and ownership required without significant central project input.

A key success factor for PMIP was the regional implementation facilitator team who could speak with authority to the laboratories and clinicians they were working with at a local level. At the other end of the spectrum setting a standard and then expecting the supplier and pathology community to deliver it on its own is extremely unlikely to succeed. Striking a balance somewhere between these two extremes is probably a more successful approach to follow.

Establishing a local delivery focus using local stakeholders who are able to champion the adoption of new standards under a framework of a light touch centralised programme may offer the best chance of success. As noted in the previous section, such an approach will need to be underpinned by appropriate governance arrangements in order to provide the required clinical, technical and managerial oversight required by a programme of this magnitude.

Another key success factor of previous projects has been the use of ‘early adopters’ or ‘pilots’. Such an approach will allow for the identification of any deficiencies or limitations in the solutions or implementation approach that can then be addressed prior to commencing full rollout. It will also allow for both good and bad practice to be identified.

The complexity and risks associated with migrating from one pathology standard (e.g. PMIP EDIFACT and PBCL) to a new standard should not be underestimated. There will need to be significant planning and preparation by all parties in order to ensure that during the migration any disruption to the current service is avoided. The criticality of messages to GPs alone will require detailed planning to transition in the new standards to minimise risks. There will inevitably be a period of concurrency in the use of old and new standards until the whole pathology order communications landscape has completed the transition to the new standards.

It is almost certainly worthwhile being able to track the roll-out of a new standard and may, depending on the requirements of any central funding organisation, require a formal tracking mechanism. Whilst it may not be necessary to go to lengths that PMIP did with the Tracking Database, it was a good example of recording and monitoring many disparate elements of a complex programme. As a minimum, the implementation of a new standard by individual Laboratories and by each recipient system, whether GP or internal Trust system, would not be difficult to achieve and during the initial roll-out will instil confidence in later organisations due to receive upgrades.

If, as suggested earlier, payments are based heavily on delivery rather than development, an implementation tracking system will be required to trigger such payments. Consideration should also be given to the automated collection of systems going live with a new standard in the way that the NMAS (National Message Assurance Service) did as each Lab and GP System sent messages to NMAS to prove successful implementation and live use. If required, such systems could also generate KPIs.

Delivering a light touch centralised programme will necessitate the availability of appropriate support and reference materials, probably via a centralised website or information portal. Such a documentation library could be quite extensive and as well as the requisite technical guidance, specifications and
implementation documentation associated with such an exercise, it could also include templates for local business cases, implementation plans, system specific guidance, lessons learnt and progress reports.

5.2.8 Assurance

The successful delivery of any standards implementation programme requires assurance at a number of levels. This might begin with assuring the standards being implemented have been appropriately assured themselves through various stages of the programme through to assuring that the final implementations of the IT systems using the standards have themselves been clinically and technically assured.

Assurance has historically either been recognised as very important and over-engineered to be inherently onerous or undervalued, under resourced and poorly undertaken with inherent risks. In the latter case, its importance may only be recognised when things go wrong which is often far too late.

The modern day approach to assurance is usually undertaken using a risk-based approach rather than the more onerous ‘assure everything’ approach of recent times. This allows the work to be focussed on those areas of greatest clinical risk and is an approach widely accepted in healthcare IT organisations such as NHS Digital and many IT suppliers.

The advent of Clinical Safety standards has, through the use of Hazard Logs, highlighted areas of greatest risk and hence directed the attention of assurance teams to those specific areas. There can be some contention in following this approach as user organisations and suppliers may take different views and there is therefore an exercise to gain agreement amongst the various parties on where assurance effort should be directed and to what extent.

Modern day testing tools allowing significant automation and repeatability can be employed at various stages which can (a) increase quality through repeatable testing, (b) reduce the time taken to undertake assurance activities and (c) extend the scope, increase the quality and reduce the time taken to release patches, upgrades and new versions of products into the environment.

5.2.9 Benefits Realisation

If central funding is used to support the introduction of a new pathology standard it may be necessary to undertake a formal benefits realisation exercise during or upon completion of the project. In such circumstances it is essential that the expected benefits are identified and agreed by all relevant parties before the project or programme of work commences as these should be clearly identified in the business need justification established at the outset. It should be noted that whilst PMIP was ultimately a success, there was never a formal benefits realisation exercise undertaken and although all involved will testify to its success, the benefits derived from it have never been formally measured.

Given the potential number and complexity of stakeholders involved in future standards adoption, it is recommended that a structured approach is taken to identifying expected benefits and in undertaking the benefits realisation exercise. This should include:

- Defining a benefits management plan in order to identify how benefits are measured, the roles and responsibilities of people or systems involved, priorities and any associated key performance indicators (KPIs).
- Identify and define benefits in order to ensure that each benefit (or disbenefit) is documented in terms of its priority, interdependencies, value, timescales and ownership.
- Establishing a benefits relation plan that encompasses the timeline and milestones for realising benefits, including any dependencies or interactions between benefits.
- Agreement of when the realisation exercise should be undertaken as although some benefits will be apparent at an early stage, it may be that others are only realised after the transition has been completed. As such it may be necessary to ensure longer term monitoring is included as part of a delivery plan.
If a benefits realisation exercise is planned it should regularly reviewed as circumstances may arise that either impact upon the expected benefit of the say in which it is measured and it could also be that an expected benefit may not be realised at all. Additional benefits or dis-benefits may also become apparent that were not identified at the outset and it is important to ensure that these are assessed against the initial aims and objectives that underpin the project to ensure they remain achievable.
6. Adoption Principles for Pathology Standards

This report has described the pathology landscape, the current digital maturity of systems across that landscape and the various implementation themes that have contributed to previous successful pathology standards work. Further analysis of this material has resulted in a number of key principles emerging which can be used to help determine whether a future pathology standards proposition is likely to succeed and if so how best to ensure that it is successfully implemented.

These have been grouped into four value streams and their use is summarised below and illustrated in the supporting relationship diagram (Figure 4). Each value stream is summarised below and then further elaborated in the tables that follow.

<table>
<thead>
<tr>
<th>Value Stream 1: Business Justification</th>
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<tr>
<td>1. Establish a Clear Business Need</td>
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<tr>
<td>2. Obtain Clinical and Supplier Support</td>
</tr>
<tr>
<td>3. Obtain Baseline Costs and Secure Funding</td>
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VS1: Business Justification - this is critical to any standards adoption programme. If a clear business need cannot be identified or either the support of the clinical or supplier communities cannot be obtained or central funding cannot be obtained then it is unlikely that the programme will succeed. The three principles in VS1 can in this regard be considered a gateway test (Gate 1) to decide whether to proceed or re-evaluate the proposition.

<table>
<thead>
<tr>
<th>Value Stream 2: Standards Development</th>
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<tbody>
<tr>
<td>4. Adopt a Re-Use/Adapt/Create Standards approach</td>
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<tr>
<td>5. Validate Proposed Standards</td>
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<td>6. Establish IT Estate Standards Readiness</td>
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VS2: Standards Development - This set of principles can be considered as Gate 2: If standards do not exist, need to be developed, have not received the necessary clinical or technical validation (i.e. are fit for purpose) or the IT systems expecting to adopt them aren’t ready then the start of the programme needs to be delayed. It can only commence once P5 and P6 are true.

<table>
<thead>
<tr>
<th>Value Stream 3: Stakeholder Engagement</th>
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<tbody>
<tr>
<td>7. Establish Communication Strategy</td>
</tr>
<tr>
<td>○ Pathology Networks</td>
</tr>
<tr>
<td>○ Clinical Customer Community</td>
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<tr>
<td>○ Supplier Community</td>
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<tr>
<td>○ Standards Bodies</td>
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VS3: Stakeholder Engagement - In order to implement business change effective stakeholder engagement and a targeted communications strategy that looks to engage and involve all impacted stakeholder groups is essential. Communication and engagement can be envisaged as commencing at Gate 0 and this value stream and principle will be relevant across the entire programme lifecycle.
**Value Stream 4: Planning**

- 8. Establish Implementation Approach
- 9. Establish Clinical and Technical Governance
- 10. Agree Assurance Approach
- 11. Agree Project/Programme Management Approach

**Value Stream 5: Delivery, Lessons Learnt and Benefits Realisation**

- 12. Monitor Delivery
- 13. Capture Lessons Learnt
- 14. Undertake Benefits Realisation Activity

**VS4: Planning** - The set of principles within this value stream can be considered as Gate 3 and can only really commence if the criteria to exit Gate 2 have been successfully met. Principles P8 through to P11 focus on the required planning, unpin the delivery and incorporate the implementation approach, governance arrangements, assurance and establishing effective project or programme management to support delivery.

**VS5: Delivery, Lessons Learnt and Benefits Realisation** On the assumption that a project/programme has been established to deliver a new standard into the Pathology systems landscape, it is important to ensure that any lessons learnt are captured and documented as the project progresses and any expected benefits are measured during, if necessary, and after the delivery has been completed. Note that formality of these exercises will be dependent on the way in which a new standard is introduced and the expectations of any funding authority.

Figure 4: Value Streams and Principles
### 6.1.1 Value Stream 1: Business Justification

#### Principle P1: Establish a Clear Business Need

**Purpose**
- To ensure that there is a clear business need for the standard(s) to be implemented in the domains impacted, i.e. any organisation sending or receiving information containing the standard(s).

**Justification**
- Without a clear benefit or business need there is unlikely to be sufficient justification for adopting a new information standard,
- The business need, whether the pathology service itself or its customer communities, should demonstrate a net gain for the service as a whole,
- Potential benefits include:
  - improved productivity / reduced effort (e.g. greater automation or more efficient processes)
  - reduced direct cost (e.g. staff, materials, systems)
  - improved clinical safety / reduced risk (e.g. better informed clinicians, improved data quality, faster flow of information)
  - improved patient care / population health (e.g. better quality data, improved analytical capability) through better informed clinicians and administrators

#### Principle P2: Obtain Clinical and Supplier Support

**Purpose**
- To gain the backing of the customers and system suppliers that the proposed change is needed, achievable, and affordable and has a realistic set of objectives and expectations. Recruiting clinical champions to ‘sell’ the proposals to their peers will greatly improve the chance of gaining widespread support.

**Justification**
- If the pathology service or its customers do not agree with the business need and support the expense of effort required by them to achieve it there is little realistic chance of it succeeding
- Likewise, if the suppliers who will need to invest in changes to their systems cannot see the opportunity to get a return on their investment they will be reluctant to implement the changes required. They will look to their customers to see if they support the proposals to the extent that they will invest in system upgrades. The Establish widespread support across clinical and supplier community
- Gaining such support will provide a degree of credibility often absent in such initiatives

#### Principle P3: Obtain Baseline Costs and Secure Funding

**Purpose**
- To obtain a good understanding of the expected direct and indirect costs and the anticipated direct and in direct savings for each organisation impacted and also for the programme as a whole.
- To determine how much central funding will be required to ensure implementation occurs in a reasonable timeframe.
| Justification | ● Without a good idea of the expected costs (direct and indirect, one-offs and ongoing) it will not be possible to decide whether the benefits achieved are worth the investment. |

### 6.1.2 Value Stream 2: Standards Development

**Principle P4: Adopt a Re-Use/Adapt/Create Standards approach**

| Purpose | ● There are many healthcare standards in use and every new standards implementation exercise should look to:  
  ○ re-use an existing standard first and if no suitable standard can be found  
  ○ to adapt a suitable ‘closest fit’ standard and only if both these are unsuitable  
  ○ create a new standard |
| Justification | ● The more standards IT systems have to support the more complex they become and the more costly they are to maintain.  
● The more complex a system is the greater the chance of errors and thus the greater the clinical risk of using such systems becomes. Conversely the fewer standards in use the lower the associated clinical risk.  
● Existing standards cover clinical terms, clinical information models/data collections/data archetypes, messages / containers to hold sets of data and transport mechanisms to exchange them between systems, and various syntaxes to encode everything.  
● If a new standard is required its utility or extensibility outside the immediate domain should be considered, e.g. if developing a standard for haematology consideration should be given to microbiology, histology, etc. and if developing a standard for pathology consideration should be given to the other diagnostic domains such as radiology. |

**Principle 5: Validate Proposed Standards**

| Purpose | ● To formally validate any new proposed pathology standard to ensure it is fit for purpose both clinically, from a user perspective, and technically, from an IT systems perspective. An appropriate mechanism that involves all relevant stakeholders including all suppliers whose systems are expected to process information containing or using the standard. |
| Justification | ● Standards are sometimes developed in relative isolation and even when the work is published during the development phase the intended readership may not have undertaken a diligent review.  
● It is often not until a mandate, target implementation date or a proposed programme is announced that the communities expected to implement them conduct a thorough assessment of its impact - by which time it is often too late.  
● Any information standard relating to orders or results reporting introduced into the pathology domain will impact a vast number of external systems, maybe far more than initially expected, and if the users and suppliers of those systems are not consulted and involved in plans for their implementation. |
implementation there is a significant chance of those plans failing to succeed.

**Principle P6: Establish IT Estate Standards Readiness**

**Purpose**
- To formally assess the capabilities of all systems that will need to use the information standard in some way and to create a baseline of technical readiness together with timescales for completion.

**Justification**
- The implementation of any new information standard into any healthcare domain will very often, if not always, require the systems operating in that domain being ready to support the new standard.
- It is unlikely that all systems will be ready without having to undertake some development or configuration work.
- The inability of systems to support a new standard doesn’t necessarily mean that the standard cannot be implemented as long as some systems can support it and as long as the rollout of the standard can be undertaken on an system/organisation by system/organisation basis and any information flows using a previous standard can continue to operate, i.e. as long as it is possible to operate in a mixed environment.
- For Pathology, the number of Pathology disciplines and LIMS, Order Comms, TIEs, GP, Hospital and, Secondary Use systems is quite large and there will be complex many-to-many system relationships to manage.
- Adding system readiness into the mix will likely create a complex but manageable implementation schedule.

**6.1.3 Value Stream 3: Stakeholder Engagement**

**Principle P7: Establish Communications Strategy**

**Purpose**
- To create a communications strategy that will:
  a. inform all stakeholders of the intention to introduce a new standard with appropriate reasoning and justifications and
  b. give stakeholders the opportunity to participate in various aspects of the delivery programme including the appointment of clinical champions
  c. span the whole programme lifecycle from identification of business need through to benefits realisation.

**Justification**
- Pathology is a discipline that underpins every branch of medicine and thus Pathology information is shared with every type of clinician and thus every type of healthcare IT system. Implementing a new Pathology standard arguably has the potential to impact a very large number of stakeholders and it will be important to the success of a standards project to adequately engage with each.
- Furthermore, the involvement of stakeholders is a theme running from the very beginning to the very end of a standards implementation programme and thus stakeholder engagement is an extremely important exercise. A comprehensive communications strategy will be required to ensure they are kept informed at every stage.
• Stakeholder groups include:
  ○ Pathology Networks
  ○ Clinical Customer Communities
  ○ Supplier Community
  ○ Standards Bodies

6.1.4 Value Stream 4: Planning and Delivery

Principle P8: Establish Implementation Approach

| Purpose | ● Establish a realistic and practical outline implementation approach (i.e. how it will be delivered on the ground as distinct from the delivery programme structure) that takes into account
  ○ User readiness and uptake capacity,
  ○ IT systems readiness and supplier delivery capacity,
  ○ Standards readiness,
  ○ Funding availability (where agreed),
  ○ Enabling activities (e.g. early adopter),
  ○ Dependencies (e.g. assurance, training)
  ○ Competing priorities

  ● and builds in suitable checkpoints such as
    ○ go/no go, pause, stop decisions
    ○ early assessments of early adopter implementations, benefits, disbenefits, issues, etc

  ● in order to obtain outline commitment from suppliers and the affected clinical communities.

| Justification | ● The implementation of a new pathology standard is likely to impact a large community of disparate users and systems and could require extensive and complex planning. Undertaking an exercise to work through those complexities and to produce an outline plan for delivery will be essential in order to obtain the widespread required for the programme to go ahead.

  ● The supplier community will be pivotal in this as the majority of the delivery will be incumbent upon them to deliver something (e.g. systems, training, and data migration) and these and not trivial exercises.

  ● Likewise, the user community may, depending on the nature of the change associated with the standard, also be pivotal in accepting change and making best use of it.

Principle P9: Establish Clinical and Technical Governance

| Purpose | ● If a project/programme is to be created to manage the delivery of a new standard it is important to establish appropriate clinical and technical governance, ideally working in unison, to provide the necessary steering and oversight required as representatives of the users and suppliers.

| Justification | ● The introduction of a new pathology standard should be underpinned by a business need and it is essential that those businesses are represented and, when IT systems have to change to deliver that need, that their suppliers
are also represented.
● The role these representatives play (e.g. Steering Group, Governance Board) is immaterial as long as the representatives have delegated authority to represent their colleagues and an appropriate leading role within the project/programme.

Principle P10: Agree Assurance Approach

| Purpose | To agree an assurance approach across the various elements of a standards delivery project/programme to ensure that business continuity and clinical safety are maintained. |
| Justification | The successful delivery of any standards implementation programme requires assurance at a number of levels. This might begin with assuring the standards being implemented have been appropriately assured themselves through to the final implementations of the IT systems utilising these standards have themselves been clinically and technically assured.  
● A risk-based approach should be used to ensure the focus of assurance is where the greatest risk is.  
● Invariably the introduction of information standards through IT systems requires the information to be followed from capture to output(s), of which there can be many, including secondary use and BI/MI reporting. Capturing the flow of information together with any mapping or manipulation at each stage is a key activity to undertake at an early stage in order to identify all of the areas of impact and risk. |

Principle P11: Agree Project/Programme Management Approach

| Purpose | To decide on the level of local and central/national control required to deliver a new information standard,  
● To determine the roles and responsibilities of each ‘organising’ body and thus their accountability and  
● To agree the scope of work to be undertaken and the structure of any project/programme required to deliver its obligations. |
| Justification | The need for some central control has been proposed as essential if a new information standard is to be successfully implemented across the NHS. It is therefore necessary to determine what role the central body plays, e.g. as a national controlling programme at one extreme or a funding organisation at another with local organisations responsible for delivery.  
● The impact on clinical users and administrators, business managers, suppliers and secondary use organisations and the degree to which this can be controlled at a local level will help determine the role of the central body. |

6.1.5  Value Stream 5: Delivery Activity

Principle P12: Monitor Delivery
| Purpose | ● To provide a comprehensive mechanism to track the progress of standards enablement through IT updates, training and live use and various other intermediate steps. |
| Justification | ● There are a large number of stakeholders that are likely to be very interested in the progress of important changes to systems processing Pathology data. These include those directly involved such as the project/programme co-ordinating the change, user communities and supplier communities, and also organisations such as Royal College of Pathologists, NHS Improvement, Secondary Use Services who have a wider non-operational interest in the successful adoption of standards that will, for example, reduce clinical risk or improve population health. ● From a project/programme perspective, the provision of such information may highlight areas of good and bad performance which could be an indication of specific problems with systems, suppliers or regional influences or indeed areas of good practice which could be shared with others. |

**Principle P13: Capture Lessons Learnt**

| Purpose | ● To capture details of any lessons learnt from any of the activities involved in the implementation of the standard or the delivery of the project/programme. |
| Justification | ● It can be extremely beneficial to subsequent project/programmes of work to learn from the experience of previous work. A good example of this was PMIP which produced a fairly extensive Lessons Learnt report. |

**Principle P14: Undertake Benefits Realisation Activity**

| Purpose | ● To perform a formal benefits realisation exercise to determine whether the original benefits were achieved and whether cost and effort in doing so was worthwhile, i.e. whether the original business justification was correct. |
| Justification | ● This, like a Lessons Learnt report can prove invaluable to similar projects/programmes that might follow. |
7. Recommendations

During the research undertaken to create this paper a small number of recommendations of follow-up activities related to the findings herein have been captured and are described below:

**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 an initial like-for-like replacement for PMIP Pathology Bounded Code List (PBCL) covering Clinical Biochemistry, Haematology and some Microbiology. It should be reviewed to determine 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. Note that any organisation implementing such a standard would be more supportive of the UTL data model has wider utility.

**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.
Appendix A: References

Achieving the vision for NHS Clinical Information Standards  

NHS England Connected Digital Systems - Interoperability  
https://www.england.nhs.uk/digitaltechnology/connecteddigitalsystems/interoperability/

NHS Improvement Pathology Networks  
https://improvement.nhs.uk/resources/pathology-networks/

NHS Scotland National Laboratories Programme  
https://www.labs.scot.nhs.uk/projects/standardisation/

Digital Health - Special Report: Diagnostic Digital Pathology  

ISB 1557 - Amd 39/2003 EDIFACT v1.003  
## Appendix B: Glossary

<table>
<thead>
<tr>
<th>Abbreviation/ Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>AMR</td>
<td>Antimicrobial Resistance Report</td>
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<tr>
<td>CAB</td>
<td>Choose and Book Programme</td>
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<td>CCG</td>
<td>Clinical Commissioning Group</td>
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<td>CDR</td>
<td>Communicable Disease Report</td>
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<td>CTAD</td>
<td>Chlamydia Testing Activity Dataset</td>
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<td>COSD</td>
<td>Cancer Outcomes and Services Dataset</td>
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<td>EPS</td>
<td>Electronic Prescription Service</td>
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<td>FHIR</td>
<td>Fast Healthcare Interoperability Resources</td>
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<td>GP2GP</td>
<td>GP to GP Programme</td>
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<tr>
<td>GPSoC</td>
<td>GP’s Systems of Choice</td>
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<td>GPITF</td>
<td>GP IT Futures</td>
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<td>HSCIC</td>
<td>Health and Social Care Information Centre</td>
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<td>IRF</td>
<td>Issue Resolution Forum</td>
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<td>ITK</td>
<td>Interoperability Toolkit</td>
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<td>LHCR</td>
<td>Local Healthcare Record</td>
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<tr>
<td>LIMS</td>
<td>Laboratory Information Management System</td>
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<td>MDT</td>
<td>Multi Disciplinary Team</td>
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<td>NCRAS</td>
<td>National Cancer Registration and Analysis Service</td>
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<td>NHAIS</td>
<td>National Health Application and Infrastructure Services</td>
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<td>NHS Connecting for Health</td>
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<td>NHS Digital</td>
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<td>NLMC</td>
<td>National Laboratory Medicine Catalogue</td>
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<td>NPEx</td>
<td>National Pathology Exchange (X Lab Systems Ltd)</td>
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<td>NPfIT</td>
<td>National Programme for IT</td>
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<tr>
<td>PCT</td>
<td>Primary Care Trust</td>
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<tr>
<td>PBCL</td>
<td>Pathology Bounded Code List</td>
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<tr>
<td>Acronym</td>
<td>Description</td>
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<td>PHE</td>
<td>Public Health England</td>
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<td>Pathology Messaging Implementation Project</td>
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<tr>
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<td>Summary Care Record Programme</td>
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<td>SCT</td>
<td>SNOMED CT</td>
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<td>Units of Measure</td>
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