Pathology Standards:
The Past 30 Years

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1. Executive Summary

This report was commissioned by NHS Digital to review the current Pathology Order Communications environment in England and to document the lessons learnt from previous initiatives and programmes of work that have attempted to digitise Pathology Order Communications with various degrees of success.

In order to produce this report the authors have provided a brief history of Pathology Order Communications over the past 30 years, undertaken a review of the limited evidence sources (see References), drawn upon personal experiences from a number of initiatives they were involved in and interviewed a range of individuals who have either participated in these initiatives or who either continue to work, or previously worked in the Pathology, General Practice or NHS IT fields.

The interviews in particular highlighted a number of factors which are currently impacting the order communications solutions or are influencing the field to the extent that they need to be considered by any future changes to this environment. This document reflects on these with the Current Limitations, Drivers for Change and Lessons Learnt sections. A series of common themes emerged throughout these and these have been highlighted in the Conclusions section and encapsulated in the diagram below:

These will be explored further and used to inform the Implementation Principles which will underpin and govern any future Pathology or Diagnostic Services Messaging Programme.
2. Introduction

This report is the first of three that will explore the Pathology messaging domain across the NHS in England. This report is structured as follows:

Part A: The Current Pathology Information Exchange Domain

- a description of the pathology domain, the business processes, the systems being used and the clinical communities involved
- a reflection on the history of Pathology Order Communications - a potted history of the key events over the past 30 years which have created the current state of play in terms of IT systems and the exchange of pathology data between them
- the limitations of the current ‘solutions’
- the factors which are influencing or applying change to this environment

Part B: Lessons Learnt

- the Lessons Learnt from previous work in the Pathology ‘messaging’ domain
- In conclusion

The second report the themes listed in the conclusions section together with the experience of key people operating in the pathology information exchange domain today and present a series of key implementation principles which should be used to underpin adoption of new standards and when considering any future changes. This second report will also include a draft roadmap for the development of a new solution space to support the needs of the current pathology landscape and the changes that are currently foreseen.

1.1 Audience

The primary audience for this document will be the Pathology Team within NHS Digital and other interested members of the Information Representation Services.
## 2 Part A: The Current Pathology Information Exchange Domain

### 2.1 The Pathology Order Communications Environment

The Pathology Order Communications environment and message flows between the Laboratory Information Management System (LIMS) and associated systems is now highly complex and dependant on a variety of legacy and proprietary messaging standards. Various systems have been introduced over time at a local level to address the variations in the local business needs of individual laboratories and their networks. This has included the 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. Whilst Order Communications systems did exist during the PMIP project they were very much in their infancy and deployments were quite limited.

The above diagram shows a typical laboratory’s data flows and illustrates the interoperability challenges and system complexity associated with how these systems interact with each other.

Some key systems and business processes detailed in the above diagram are as follows:

![Diagram of Pathology Order Communications Environment](image)
1) **Order and Results Management/Order Communications System**

Order Communications systems such as Clinisys ICE, EMIS tQuest, or Ideagen DART have been widely introduced by individual pathology services that allow a GP to order pathology tests on their patients. These systems are usually accessed via an API from the GP system with patient demographics context linked accordingly. On collection of a patient sample orders are electronically transferred to the local laboratory via HL7 v2 message where they are booked into the LIMS. Samples can then be analysed and the corresponding results are then sent back to the Order Comms system and complete the order and be added to the patient record where they can be accessed by the GP. Depending on local governance arrangements it may also be possible for the GP to additionally access test results for their patients requested elsewhere e.g. during an inpatient stay in hospital or A&E visit. Primary Care Order Comms systems are usually maintained by the pathology laboratory IT manager. Depending on local arrangements the primary care Order Comms system may also be distinct from that deployed in the acute hospital (as part of the Trust EPR for instance).

2) **Message Delivery/Middleware**

Primarily a software application that was introduced to address the deficiencies of the LIMS in its ability to support the management and handling of GP results (particularly associated with PMIP). This includes ensuring results are appropriately routed to the correct GP practice and in some cases to apply the appropriate Read Codes to the test results. As a consequence the middleware application is a crucial system within the interoperability landscape. The middleware has also become a key component of externally facing Order Communications systems as those described above. Support of the middleware is usually the responsibility of the pathology laboratory. Evidence would indicate that due to the amount of reconfiguration work required some laboratories have installed different middleware software on the back of installing primary care orders communications. As an example Lancashire Teaching Hospitals use EMIS Keystone to manage their PMIP messaging and have subsequently deployed Clinisys Labcomm as part of the ICE Order Communications system.

3) **Analysers Connectivity and Management/Middleware**

Separate laboratory middleware applications are also used in the integration, control and management of laboratory analysers and associated systems. These are usually diagnostic supplier specific and allow the laboratory to consolidate multiple analyser LIMS connections into a single interface and tend to be supported by either ASTM128 or HL7 messaging standards.

4) **Laboratory to Laboratory Request and Result Management/NPEx**

A significant number of laboratories are now connected to the X-Lab National Pathology Exchange (NPEx) in order to support the electronic management of laboratory to laboratory referrals and associated results. 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 data sets 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 Laboratory Information Management System (LIMS). Connection of individual LIMS to NPEx is not standardised and varies (e.g. HL7 v2n or PMIP for instance) depending on system supplier and local requirements.

5) **Connectivity and Message Management/Trust Integration Engine**

The Trust Integration Engine (TIE) is a piece of software that acts as a messaging and routing engine that provides a single platform to manage the various messages flows and data source connections within the acute trust environment. This may include management of the connection between the
LIMS and trust EPR or PMI as well as routing of the various order and result messages to/from other hospital systems. The TIE is not normally involved in the handling of GP results via PMIP.

6) Laboratory Information Management System (LIMS)

Key functionalities of a LIMS include:

- Registration of patients and all requests for all tests
- On-line, real-time linking of the LIMS to automated analytical instruments (see middleware above)
- Sample tracking and workflow management
- Automated, rules driven validation of test results
- Real-time recording of quality control data
- Electronic delivery of results to clinical users
- Implementation of decision support systems to enhance clinical outputs
- Support of data analysis for audit, clinical risk management, disease surveillance and epidemiology [e.g. cancer registration, screening programmes, communicable disease reporting, and external quality assessment (EQA) data management] although often requiring specific informaticians input and programming.

2.2 A Brief History of Pathology Messaging

From a historical perspective, the electronic transfer of pathology results began in the UK in the late 1980’s/early 1990s and there have been many initiatives since that time that have influenced where we are today. Some of the key actions, activities and events are described below.

Circa 1990

The earliest message standard in use in England was the ASTM 1238 messaging standard which was being championed by Dr Jonathan Kay at the John Radcliffe Hospital in Oxford who was successful in ‘selling’ ASTM 1238 as the only (at the time) message standard that could convey test results to GP and Laboratory system suppliers. Many of the leading GP System Suppliers and some of the LIMS suppliers implemented this although it was only implemented at a local level with each LIMS community try to make it happen in their patch. Having to speak to many GP system suppliers at the time when there were 100+ operating across primary care didn’t make this very easy.

1992 to 1995

In 1991/2 the NHS ‘Exeter’ systems (to become the NHAIS system) used by FPCs (to become FHSAs, PCGs, PCTs and then CSUs) adopted EDIFACT as its messaging standard for GP Registration messaging across England which was then adopted by Wales, N Ireland and Scotland with the result that ‘EDIFACT’ became the vehicle of choice for messaging with GP systems.

On the back of this success, the NHS Information Authority used EDIFACT as its messaging standard to develop messages to convey Pathology, Radiology and Discharge Messages between 1992 and 1995. This received reasonable support from GP suppliers who had spend considerable effort on developing the GP Registration messages but little support from the LIMS suppliers who had invested their efforts into HL7 v2.x messaging, mainly under the influence of the PAS systems and other large Hospital departmental systems many of which had a significant customer base in the USA where HL7 v2.x was the de facto standard. This was also the period where the NHS messaging network was RACAL Healthlink using X.400 as the message transport system - not something many suppliers had experience of and there were few X.400 systems on the market that were affordable by GP Practices. As a result, even the new EDIFACT messaging solution for Pathology didn’t see much uptake by GP system or LIMS suppliers.
Mid to late 1990’s
A new breed of suppliers spotted the opportunity left by the LIMS system suppliers and built ‘message transformation and messaging’ solutions which transformed HL7 v2.x messages into EDIFACT messages and also sent them across the X.400 network to GP systems who they also provided an X.400 client to. Again all this happened without any ‘national’ programme of any kind to encourage either the development of systems to support the standards or the implementation of any solutions that had built in support for them.

Circa 1999-2001
Following the limited adoption of the EDIFACT message standard during the mid-1990s the NHS took the bold step of making this a universal feature of result delivery to general practice (GPs) and embarked on two linked projects to achieve this. In the first, the Pathology Messaging Enabler Programme (PMEP), standards were defined and infrastructure installed to link 200 laboratory systems to a little over 10,000 GP systems.

During this period the vast majority of Laboratories purchased a Middleware product to

(a) create the EDIFACT messages and
(b) send them over the X.400 network.

However, there was no national funding for any of this work and each Laboratory and GP Practice had to decide locally whether and when to buy a solution. There were exemplar business cases to help Laboratories in particular enable their systems and a communications campaign to try and persuade Laboratories and General Practices to buy these new solutions and although there was some adoption the rate at which this was happening was far too slow to deliver the benefits everyone was expecting.

Circa 2002-2004
Although PMEP was reasonably successful in ‘enabling’ the LIMS with Middleware interfaces and enabling GP systems the final implementation stage was left to the local communities to get on with it which for a variety of reasons was not happening at the rates expected. And thus the second project, the Pathology Messaging Implementation Programme (PMIP) was created specifically to make implementation happen.

Contracts were established with GP and Middleware suppliers and implementation programmes were agreed and managed resulting in almost all GP Practices across England receiving Pathology results electronically by the end of 2004.

There were a number of reasons why PMIP was successful where others had failed including:

- Timing - “the stars were aligned” (S Withey, PMIP Programme Manager) - fewer suppliers, mature standards, middleware widespread, the right people involved, funding available, etc...
- Clinical Leadership and Governance - influential and driven GP and Pathology clinical champions worked together to develop a clinically safe solution and persuade their colleagues across the country to adopt it
- On the ground support was provided to Labs by a team of PMIP Facilitators all with a LIMS background
- Funding was only released to GP suppliers following live messages flowing

The scope of the PMIP project was initially limited to Haematology, Biochemistry and textual based Microbiology results and whilst there were plans to ensure full coverage of results across the whole spectrum of Pathology this was never realised in any subsequent phase of the project.
However, a number of key benefits were realised through PMIP including the removal of the need for laboratories to produce and manage the delivery of hard copy printed reports for the disciplines mentioned.

**Between 2007 and 2009**
As part of the National Programme for IT (NPfIT) a programme of work was established that investigated the feasibility of utilising HL7v3 and the NHS Spine to support the electronic ordering and resulting of primary care pathology requests. Outputs from this programme included the development of the National Laboratory Medicine Catalogue (NLMC) and the successful introduction of HL7v3 messaging to support the NHS Newborn Bloodspot Screening Programme delivered through 11 Laboratories. For a number of reasons the wider programme did not progress as envisaged and the NLMC was ultimately shutdown in 2015.

**2009 to the present day**
NHS England’s Digital First Pathology report, published in 2014, contains the following statistics:

- 800 million pathology tests conducted annually in England and Wales
- 300,000 patients have a pathology test every working day
- 50 million reports sent electronically by laboratories to GP’s annually
- 500 million Biochemistry and 130 Million haematology tests carried out annually

More recent figures provided by NHS Improvement indicate we are now looking at around 1.12 billion annual pathology tests reflecting an increase of approaching 40% in around 5 years. Pathology laboratories however still continue to rely on the outdated PMIP EDIFACT message standard and the now no longer maintained and developed, Pathology Bounded Code List (PBCL) to support the transfer of an ever increasing number of pathology results to primary care.

### 2.3 Current Limitations
There are a number of limitations associated with the ongoing use of the ISB 1557 standard (PMIP EDIFACT message based solution set) not least of which is that the underlying READ codes ceased maintenance and development in Oct 17. Whilst the list below is not exhaustive, examples of these limitations include the following:

**Use of NHS002 message**
Some laboratories and hospitals continue to use the pre-PMIP ‘NHS002’ pathology EDIFACT message variant in order to bypass the more rigorous ‘NHS003’ variant (the PMIP version which mandated the use of a clinically agreed set of READ-coded tests - the ‘PBCL’ - and latterly a move to an agreed set of Units of Measure (UOM)). The NHS002 variant allows any content to be conveyed in the message as a code is not mandatory. For example, this includes transmission of radiology results and even patient discharge summaries. Use of the NHS002 message requires the recipient GP to apply appropriate Read Codes to the result upon receipt which is not as clinically safe as the Laboratory determining the clinical term and code. In some cases (e.g. receipt of a Cytology Report) many GPs opt to print the report and scan it directly into their Document Management System and manually enter the data that’s important into their GP system.

**Misuse of NHS003 message**
It has been noted that the NHS003 message is also being utilised by some laboratories to carry test results beyond what was originally agreed as safe by the clinical communities (GP & Pathology). Examples include the use of a small number of high level, less specific, Read Codes that may only represent a discipline rather than a specific test.
Message Rejection or Cancellation
In the event of a laboratory transmitting a test result in error currently there is no automated mechanism that allows for message rejection on receipt by the GP system or alternatively a follow-on message cancellation to be sent by the laboratory. In the event of this being required the only option is a manual intervention process.

Pathology Bounded Code List (PBCL)
A review of the Pathology Bounded Code List (PBCL) by the Royal College of Pathologists in 2011 highlighted that the list had not been adequately maintained and no longer meets the needs of the NHS.

Three main issues were identified;

1. There are a large number of inconsistencies and duplications
2. It does not cover the full range of laboratory tests used by the NHS
3. Read coding is being discontinued in favour of internationally recognised SNOMED CT codes.

The final release of the PBCL (1.036) was published in October 2017. As a consequence of the lack of updates this has resulted in laboratories increasingly utilising localised workarounds to address the deficiencies within the PBCL. There are obvious clinical safety implications here if the presence of a Read Code in a message confers different information to that intended by the originator or the content structure is different to that specified in the message definition; each is clearly a recipe for potential mis-diagnosis and degradation of the electronic record.

Lack of concurrency between systems and SNOMED CT
Whilst not specifically related to PMIP it has been reported by some laboratories who have expended considerable effort and resources to convert their legacy version of SNOMED to the current UK standard SNOMED CT within their histopathology system in order to support the mandatory COSD (Cancer Outcomes Services Dataset) data submission, that having carried out this work the laboratories concerned now find that the Cancer Registry system is unable to receive SNOMED CT. They now have to translate their SNOMED CT code back to their original legacy version of SNOMED (e.g. v3) in order for the Cancer Registry to consume the information they provide. This is clearly far from helpful and illustrates the need to ensure concurrency and alignment around mandating the use of standards and their adoption.

Reliance on Legacy IT Systems and infrastructure
Many legacy LIMS systems have now been deployed for well over 25 years and whilst continuing to meet their prime operational purpose very well, are based on an outmoded design that fails to take account of modern technologies and information exchange requirements. Most LIMS were designed to support the primary publication of hardcopy, paper based reports and whilst they have been enhanced to accommodate electronic result publication their ability to adopt new interoperability standards such as SNOMED CT or FHIR for instance is extremely limited in most cases.

2.4 Drivers for Change
In addition to the limitations described above there are a number of key drivers and influencing factors pushing not just the LIMS and middleware providers, but also the whole healthcare ecosystem, towards the adoption of new pathology standards and new supporting solutions.

The key Technical drivers include:

- The urgent need to migrate from using the PBCL and Read Codes to a new replacement such as the UTL (Unified Test List) and SNOMED CT coding.
● The need to replace the outdated EDIFACT messaging standard due to (a) its inflexible nature and lack of modern IT industry tooling and (b) lack of any IT staff with any knowledge of EDIFACT within both suppliers and the NHS.

The key **Business** drivers include:

The NHS Long Term Plan and the resultant consolidation of pathology services into the 29 networks as proposed by NHS Improvement.

● The formation of these pathology networks is driving the procurement for new, pathology network wide, LIMS systems. This provides an ideal opportunity to encourage the LIMS suppliers to ensure compliance with the new standards.

● Networks are changing the nature of service provision and result delivery. It can no longer be taken for granted that primary care requests will be analysed at a local laboratory to the GP practice. A good example of this is the recent introduction of HPV primary screening for Cervical cancer and the associated regionalisation of laboratory services to support this.

● Laboratories are increasingly utilising IT systems such as the Xlab Systems National Pathology Exchange (NPEx) to support laboratory to laboratory referrals. Interoperability between systems such as NPEx and the LIMS is however limited due to the use of different messaging standards and coding systems.

● The increasing need to share data and information. Pathology results need to be coded effectively such that they are portable across a number of systems and retain their semantic meaning and context.
3 Part B: Lessons Learnt

This section reflects on the lessons learnt from the numerous projects, programmes and streams of work that have influenced the Pathology Order Comms IT environment over the past 30 years, whether good, bad or indifferent.

This has been achieved by:

- Undertaking a review of the final PMIP Lessons learned log from 2004 (see Appendix B) and speaking to some of the original PMIP Programme Team and.
- Interviewing a number of individuals who have worked both within the Pathology service and also in the external clinical services that use Pathology services. These included a number of experienced stakeholders within the Pathology IT, Pathology Clinical and General Practice Communities.

3.1 Lesson Categories

A number of related observations were identified from undertaking these ‘lessons learnt’ exercises from which it has been possible group related items together into an initial set of Lessons Learnt Categories. These have been summarised in the table below:

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| Clinical Governance | • PMIP was clinically led and clinically championed from the outset.  
|                   | • Clinical stakeholders from both Primary Care and Pathology were fully involved in the decision making processes across the various project elements.  
|                   | • The ‘IRM’ (Issues Resolution Mechanism) was a key component of PMIPs success with the group being clinically led with technical support where needed.  
|                   | • As a result of the above clinician involvement the project was not seen as “another centrally mandate with no understanding of what we do”.  |
| Business Case     | • PMIP succeeded because it had a very clear business case - it was going to digitise tens of millions of paper forms per year, improve data quality, improve clinical safety, aid decision making and reduce costs.  
|                   | • The NPfIT project did not have a clear business case and therefore gained little support from those communities expected to adopt new messages. It also failed to engage with one very important set of suppliers.  
|                   | • The current ‘PMIP/EDIFACT’ solution is seen by many as something which works very well and any future ‘upgrade’ has to offer significant advantages from a business perspective for stakeholders to be supportive.  |
| Benefits realisation | Benefits realised:  
|                    | Although PMIP was closed before a formal benefits realisation exercise could be undertaken a number of key benefits had actually
### Category | Details
--- | ---
**Commercial Framework**
**Funding & Resources** | • Funding of supplier implementation was seen as a key enabler to delivery and was only paid for each Practice going ‘Live’
• Establishing a team of regional Implementation Facilitators with the right skills and knowledge ensured that delivery at the local level was delivered on time
• The PMIP regional facilitators played a crucial role in establishing inter-agency partnerships and facilitated the working relationship between both the laboratories and the GP practices

**Requirements Management** | • Requirements were managed a well understood and accepted process supported by the IRM across all stakeholder groups
• Standards thus gained early buy in and traction with stakeholders.
• Decisions were highly informed and evidence based
• Pragmatic approach to implementation adopted that balanced business requirements, supplier abilities and project timescales

**Supplier Engagement** | • LIMS, GP and Middleware Supplier engagement and involvement in the project has been seen as key to the success of PMIP.
• Crucial to the success of PMIP was the engagement with the middleware suppliers without whom very little would have happened
• One of the main reasons the NPfIT Pathology Programme failed to deliver any substantive change was the disregard of the middleware suppliers

**Laboratory Stakeholder Engagement** | • It was very important to understand the complexity of LIMS systems and the Hospital IT environments within which they operate
• There was however a shortage in the availability of suitable IT expertise. It should be noted that this is still an issue today.
• It was crucial to ensure that senior laboratory managers understood the benefits of introducing messaging standards and
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<td>how this would transform and improve laboratory services.</td>
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<td>Communication and End User Engagement</td>
<td>● The PMIP Communications Strategy (written material, regional road shows, etc) was widely recognised as a success with regular updates to all stakeholders</td>
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<td>● Weekly progress reports published utilising the real-time data held in the Tracking Database (TDB) which itself had feeds from NMAS.</td>
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<td></td>
<td>● Project was fully supported by extensive documentation and open and transparent communication. This included a number of centrally managed services that were established to support information dissemination to stakeholders including a website and appropriate contact listings</td>
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<tr>
<td>Compliance and NMAS</td>
<td>● The National Messaging Assurance Service (now NMAS - R) was a key component that provides automated testing for GP systems and LIMS/middleware solutions.</td>
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<td>● It is still used routinely today by laboratories for message validity checking.</td>
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<td></td>
<td>● NMAS sent messages to the Tracking Database which was (and still is) a national solution for tracking the status of NHS IT systems (and other information).</td>
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<td>● NMAS was also used to support the payment of GP system suppliers (as part of PMIP)</td>
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<td></td>
<td>● Evidence from NMAS is still routinely used to support laboratory ISO15189 UKAS accreditation</td>
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<td></td>
<td>● Lack of automated message comparison has been noted as a deficiency in other more modern messaging solutions</td>
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<td>Project Planning and Management</td>
<td>● In the PMIP Programme it was apparent that extensive project planning was undertaken and this included:</td>
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<td>○ early identification of business processes impacted by the change and impact on working practice</td>
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<td>○ provision of appropriate and effective resources</td>
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<td>○ identification of risks and ensuring that these were addressed, owned and reviewed regularly</td>
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<td>● It was noted that the development of a detailed design of the implementation processes was critical. This was underpinned by consultation with expert stakeholders giving a balanced understanding of potential implications for both project rollout and ongoing service management.</td>
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<td>● A key enabler of project delivery was access to and availability of sufficient resources with the appropriate level of skills and expertise.</td>
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<td>● In order to maintain credibility within the business any Project Board should include senior representatives of the business and members should have the credibility to drive the project forward.</td>
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| Missed Opportunities | - Whilst extremely successful PMIP has been seen by many as ‘unfinished business’ with the programme having been closed down prematurely.  
                      - Noted requirements that were not addressed included;  
                        ○ support for complex microbiology reporting  
                        ○ support for cervical cancer screening and other screening programmes  
                        ○ lack of standardised units of measure(UoM)  
                        ○ support for radiology results             |
| PBCL Maintenance  | - A noted lesson from PMIP was the high turnaround times required for Read code additions and the planning required around new test inclusions.  
                      - Maintenance cycles for future dictionaries such as the Universal Test List (UTL) will need to take account of this and be developed at pace |
| Problem led vs Solution led | - The NLMC is one example of a number of NHS initiatives that have had no concrete adoption path. Although it was recognised as a key component within a future Pathology Order Comms environment it was not seen as locally implementable in isolation.  
                      - One of the challenges the NLMC faced and also the NPfIT ‘HL7v3’ upgrade was that they were perceived by many as overly complex and more akin to a solution looking for a problem. |

### 3.2 Themes for Success

Further analysis of the lessons learnt categories (above) has identified a number of key themes associated with the successful projects and programmes of work in this field. These have been summarised in the table below and these will be taken forward into a subsequent report along with further analysis to develop a set of principles for successful adoption of Pathology messaging standards that should govern any future Pathology or Diagnostic Services Messaging programmes of work.

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<th>Theme</th>
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<tr>
<td>Business Justification</td>
<td>A sound Business justification for the implementation of any business or technical change is essential to its success. It requires a well run and appropriately sized project/programme to deliver its aims and realise its benefits. There must be a clearly identified business need and appropriate support from the businesses involved and all of their appropriate stakeholders in the development of a viable and detailed business case.</td>
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<tr>
<td>Business Need</td>
<td>The businesses impacted by any new information flow or any change to</td>
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<tr>
<td>Theme</td>
<td>Description</td>
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<td>An existing information flow must see a clear net gain for themselves as a business. That could be in the areas of improved clinical safety, reduced risk, better informed clinicians and administrators, reduced workload, reduced direct costs or reduced in direct costs.</td>
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<td>For information flows between businesses there must be a net overall gain when the impact on each business is considered.</td>
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<tr>
<td>Where appropriate, obtain the support of key business stakeholders who are prepared to ‘champion the cause’. This needs to include 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 professional bodies.</td>
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<tr>
<td>Clinical Engagement</td>
<td>Where appropriate, obtain the support of key clinical stakeholders who are prepared to ‘champion the cause’. Engagement and support should be sought from Pathology Clinical Leads, General Practitioners as well as their respective professional bodies</td>
</tr>
<tr>
<td>Supplier Engagement</td>
<td>All suppliers expected to participate in, or be impacted by, a new or changed solution should be engaged. This may involve establishing contact with a new set of suppliers as well as existing ones. Failure to engage with all supplier stakeholders is likely to lead to project failure.</td>
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<tr>
<td>Clinical Governance</td>
<td>The most successful projects have strong clinical involvement, if not clinical ownership, to ensure that projects are focussed on clinical improvement and deriving key business benefits.</td>
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<tr>
<td>Communications Strategy</td>
<td>Establishment of an effective communications strategy and appropriate message channels to keep all stakeholders fully informed is essential for their continued support.</td>
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<tr>
<td>Planning and Delivery</td>
<td>The ‘Central vs Local’ dilemma more often results in a ‘central’ approach at the expense of local buy-in. A light-touch central programme with a local delivery focus using local stakeholders will often be much more successful. Setting a standard and expecting the supplier community to deliver it rarely if ever works. The Tracking Database as used by the PMIP programme is a good example of recording and monitoring many disparate elements of a complex programme with many measures. Consideration should be given to similar solutions to help track end-to-end activity, costs, trigger payments/penalties, measure KPIs, etc.</td>
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<tr>
<td>Theme</td>
<td>Description</td>
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<tr>
<td><strong>Assurance and Tooling</strong></td>
<td>Assurance is inherently onerous and once achieved is often broken. Serious consideration, using a risk-based approach, needs to be given to the assurance requirements for all individual elements of the solution space from IT systems through to people. Automation and tooling can help to reduce the assurance burden and also help to improve both systems and processes.</td>
</tr>
<tr>
<td><strong>Benefits Realisation</strong></td>
<td>Although it is usual for benefits realisation activities to be undertaken at the end of a programme there are sometimes clear benefits that are achieved very early on. Whether expected or unexpected, any programmes should be sufficiently flexible to capture, validate and publish such benefits on an ongoing basis as this will assist overall support for the programme. Similarly, if expected benefits are not realised, consideration should be given to identifying the reasons why and changing or stopping the programme before resources are wasted further.</td>
</tr>
</tbody>
</table>
4 References

PMIP Project Lessons Learned Log Version 2.0, April 2004

Primary Care Reporting Messaging

Informatics and the Clinical Laboratory, Richard G Jones, Owen A Johnson, and Gifford Batstone,

Digital First Clinical Transformation through Pathology Innovation


Approval as an Information Standard

Replacing the National Library Medicine Catalogue
https://isd.digital.nhs.uk/trud3/user/guest/group/0/pack/38/subpack/77/releases

Replacing the Pathology Bounded Code List

EDIFACT Pathology Messaging Standard
## 5 Appendix A: Contributors

<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Experience</th>
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<tbody>
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<td>Dr Steve Bentley</td>
<td>GP and former Senior Clinical Consultant, NHSD</td>
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<tr>
<td>Mr Dave Drew</td>
<td>Pathology IT Manager, Sheffield Teaching Hospitals</td>
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<td>Mr Andy Harris</td>
<td>General Manager, X-Lab systems Ltd</td>
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<td>Mr Dave Johnson</td>
<td>Pathology IT Manager, Lancashire Teaching Hospitals</td>
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<td>Strategy and Operations Manager (Cancer Screening Programme), Public Health England</td>
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<td>Dr Jonathan Kay</td>
<td>Clinical Pathologist and Informatician</td>
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<td>Mr Jim McIntosh</td>
<td>former PMIP Implementation Manager (South West Region)</td>
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<td>Mr Peter Taylor</td>
<td>Pathology IT Manager, Doncaster &amp; Bassetlaw Hospital</td>
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<td>Martin Myers</td>
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<td>Mr Simon Richards</td>
<td>former PMIP Programme Assurance Lead (NMAS)</td>
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<tr>
<td>Dr John Williams</td>
<td>GP, PMIP IRM and Clinical Lead</td>
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<tr>
<td>Mr Simon Withey</td>
<td>former PMIP Programme Manager</td>
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## Appendix B: About the Authors

<table>
<thead>
<tr>
<th>Name</th>
<th>Biography</th>
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<tbody>
<tr>
<td>Paul Sanderson</td>
<td>Qualified Biomedical Scientist with 39 years of clinical pathology and healthcare IT experience including LIMS system implementation management and solution design, system interoperability and data standards (including SNOMED). Career history of having worked for the NHS, NHS CfH, iSOFT and Roche Diagnostics.</td>
</tr>
<tr>
<td>Tim Tett</td>
<td>Experienced Healthcare IT Consultant and solutions architect for 34 years with extensive experience of GP systems. Has worked extensively with the NHS/NHSIA/NPfIT/NHS CfH/HSCIC on numerous programmes including in the National Integration Centre, PMIP, GPSoC as well as with PHE on the modernisation of various screening programmes</td>
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