Root Cause Analysis Investigation Report

Incident Investigation Title:	Pathology Contract Tests and Reporting of results
Incident Date:	First Reported 20 December 2012 (Multi-incident investigation)
Incident Number:	StEIS number 2013/1282; Datix (web1488)
Author(s) and Job Titles	Pauline Johnson Interim Deputy Director of Quality and Safety, (Brent, Ealing, Harrow and Hillingdon CCGs)
Chair of the Investigation	Madhukar Patel, Chair of RCA investigation and Brent GP
Investigation Report Date:	28 March 2012

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Executive Summary

A Brent GP noted that individual patient results were presented as a long list and that it was possible to view, action and if the GP chose to file and archive, then all the results for that patient would be filed. He was concerned about the ability for results to be filed automatically into the patient's notes without the GP having confirmed each of the results as normal or identified as requiring action. He flagged this up to the Chief Operating Officer of Brent Primary Care Trust/CCG on 20 December 2012. This was considered a near miss and was logged as a Serious Incident on the StEIS and Datix systems.

When the GP raised this with the PCT, a preliminary enquiry into the concerns was raised by the PCT contract manager with the pathology service contract manager from NWLHT, to determine the cause. It was thought to be an isolated incident and reassurances were given that appropriate support would be given. The GP subsequently contacted the PCT with other issues relating to the pathology service including missing results, codes had changed and samples returned as unable to process.

Upon further investigation, it became apparent that the assumption that the GP was alone in not being aware of the communications sent out by TDL the new service provider, were erroneous. Steps were immediately taken to resolve the issues raised. Within days, another GP contacted the PCT concerned about spurious results, missing results and samples not processed, and it became clear that the remit of the investigation would have to be broadened to take account of both the formatting of results and the processing of samples. It was noted that reference ranges had changed and also the presentation of the results into groupings that did not make sense.

The Pathology service for Brent and Harrow GPs was provided by North West London Hospitals Trust (Northwick Park Hospital) until May 2012 when the contract was taken over by The Doctor's Laboratory (TDL). They were awarded the contract in January 2012, with the service transferring in May. The CEO of Harrow PCT had initiated a market intelligence exercise in 2009 to determine if there was a market for pathology services.

Correspondence from 2011 highlights that another reason for the Pathology Service being tendered out was due to problems with the infrastructure at the North West London Hospitals laboratory. A letter from the NHS Brent and Harrow CEO dated 30 June 2011 to the CEO of NWLH, acknowledged the 'historic lack of investment at Northwick Park and the urgent need to replace pathology reporting systems in the Trust'. This was reiterated in a NHS Brent board paper dated 19 August 2011, which noted the previous system being 'under strain and, if the procurement is not the preferred option, there will have to be both capital and revenue investment'.

The procurement was undertaken over a protracted period of time and many people were involved. Ownership at Board Level was an issue and there was a lack of involvement at a senior level. At the time of the first expressions of interest, anecdotal evidence suggests that Brent PCT was not really engaged; the re-tendering was driven by the then CEO in Harrow and

subsequently became low key. The procurement lead was an interim who subsequently left the organisation, but returned to carry out the courier service procurement.

Despite the procurement being discussed and subsequently carried out over a lengthy period (over 2 years), when the paper relating to the procurement was presented to the PCT Board in September 2011, the non-executive directors were not sighted on the procurement and sought assurances that the provider was able to deliver a safe and effective service. GPs on the two board subgroups for Brent and Harrow also highlighted concerns about the risks involved in the transition of the service and thought that there would be a risk analysis of the issues to take forward into the OMC. This did not happen in that there was no input from primary care clinicians (GPs) on the transition board for the project; the Operational Management Committee (OMC) was established and held meetings but these were not quorate because no GPs were present.

It is unclear why the primary care workstream, which was to have been established in August 2011 to start work on Key Performance Indicators, data reporting requirements, clinical and operational management group attendance and implementation of order communications, was never put in place. Instead, the communication about KPIs appears to have been undertaken through the medium of emails to Brent GPs via the CRO for pathology for the PCT who had also been involved in the procurement. The CRO and GP lead for Harrow was not involved in any discussions regarding KPIs. It also appears that discussions about the other key aspects of the implementation and mobilisation of the contract with TDL did not involve GP clinical representation.

The team is unaware of any primary care involvement in the transition, implementation or monitoring process, apart from the two Clinical Directors and other CCG board members who may have been involved in discussion about the contract. The team has no evidence of grass roots primary care involvement in this contract. The Clinical Directors are in post to represent the GP community but they do not appear to have cascaded any information out to GPs or collated views for feedback to the service provider.

A risk analysis was not undertaken nor where the concerns taken forward to the OMC because attendance at this group was problematic. It is unclear whether the unavailability of the nominated representatives was escalated to the PCT management or whether any attempt was made by the PCT to find alternative representatives from the wider GP community, but this was clearly a risk for the PCTs and TDL, and limited the availability of the primary care perspective on the service and sharing of information out to primary care. It ran counter to the expectations of the PCTs who had conducted a risk analysis of the procurement and identified the risk of PCT capacity to effectively input into the contract negotiation and ongoing monitoring.

More importantly, it did not achieve buy-in and ownership of the service which would have been key to early resolution of the problems experienced in December 2012 to January 2013. However, the constitutions of the CCGs (then in shadow form) are quite specific about who can represent the interests of GPs.

Communication was an issue within the PCTs and out to primary care. Information flow via emails to key personnel in the PCT was an ineffective way of communicating with practices, as there was an assumption that someone else on the circulation list was dealing with cascading the information. GPs therefore, remained largely unaware of key changes within the pathology service in particular a Notification in November 2012 regarding important changes to the Pathology was not sent out to GPs.

Both the Brent and Harrow CROs for pathology advised the investigation that they were unaware of a communication strategy. This was despite an email setting out the agreed process being sent in June 2012, some six weeks after the service went live. A communication and escalation process was devised at the OMC with representation from PCTs and the communications model is identical to that approved by the senior manager on behalf of PCTs / CCGs and GPs and acknowledged by at least one of the CROs.

In respect of communications post transition, internally, with respect to NHS Brent, once it was identified there were issues with the pathology service in early January 2013, there was difficulty in providing succinct information to practices. The system at the time was for messages to be sent to the locality coordinators and for them to be send messages onwards to practices. The pathology service issues raised concerns that this was not a streamlined approach as it created additional steps in the process and does not allow for staff absence. There were also concerns on how up to date the distribution lists and whether they only covered the principal GP rather than all relevant GPs.

To address the matters concerning internal communication and alerting Brent GPs a meeting was held with the NHS Brent Communication team. The Communications team recognised this to be an issue and have taken steps to install a central alerting system that will be operated through the Trust intranet site. This intranet site is due for completion mid-2013. The Communication team has also taken steps to update the distribution lists current used.

The Standard Operating Procedures (SOPs) for reporting abnormal results out of hours was different in each department: Biochemistry rang the GP Practice with the result and contacted the appropriate OOH provider whereas Haematology assumed that the OOH provider was the same for all practices and phoned all results to them. This highlighted the fact that TDL did not have up to date lists of practices in Brent and Harrow or who the OOH provider was for each; this has since been rectified and lists should be kept up to date by the CCGs. TDL are to work with the CCGs to agree the codes used to ensure that results are allocated appropriately and review the procedures for notifying abnormal results with the consultant pathologists and GPs.

Consultant Pathologists are the quality assurance mechanism for the service and advise the Trust whether the contractor is compliant with the standards required by the hospital Clinical Governance System. The CCGs could have this dialogue with the pathologists should they so wish, in order to assure themselves that there is a robust clinical governance process in place between the service provider and the CCG, going forward.

The pathologists also liaise with key stakeholder groups within the hospital trust and in respect of liaison with, and support for, GPs on whose behalf the CCG procured this service they were in continuous contact with GPs who were raising issues at the time, to offer clinical and operational advice. They have also been out to GP practices and held GP open forums to discuss issues of concern

The pathology service is not currently registered with the CPA but is working towards this. This is allowed for under the Deed contained in the Analytical Services part of the contract and requires it to be completed within a 9 month timescale. There is also reference in the contract to a nine (9) month relief period but this only applies to the imposition of financial penalties for breaches of Key Performance Indicators.

Lord Carter identified one of the barriers to change in pathology services as a lack of knowledge and understanding of laboratory services amongst commissioners and senior managers. The CCGs should use the expertise of the pathology contract manager for technical contract support and not just as an operational lead for when things go wrong.

The usual contractual levers are KPIs and NHS London have prepared a list of KPIs for Direct Access Pathology (at appendix 1). The contract manager could support CCG contract managers and clinicians, through the medium of the OMC and CRC, to review this part of the contract as the terminology appears to afford sufficient flexibility to adjust the group of KPIs in place, at any point in time. This gives local control rather than rely that this will be taken forward through the CSU.

The procurement was to have provided improved access to pathology services for primary care via the order comms rollout (ICE). This is in place within the hospital service, but has not yet been rolled out across primary care, despite the funding being made available from the PCTs, at the start of the service. TDL have offered to fund the rollout to primary care but there is a lack of clarity regarding funding for the training to support this.

The Courier service was a separate procurement to the pathology service and has been implicated in the volume of high (and low) potassium results. The specification for this service was to have been carefully drafted to include GP input so that a service that was fit for purpose was procured. Despite GP representations, the service was procured to the same financial envelope that did not allow for temperature control of samples in transit.

These problems persist and the Harrow GPs are experiencing a significant number of high potassium results. It is suggested that this issue is explored further with a view to enhancing the service provided to mitigate for fluctuations in temperature and resulting spurious results. This should be augmented by a revised training schedule for the Brent and Harrow practices on the drawing and storage of blood prior to transportation to the laboratory.

Organisational changes over the duration of the procurement and transition NHS Harrow and NHS Brent were separate up to April 2011 when the eight North West London re-configured into

3 sub-clusters, and a Brent and Harrow sub-cluster was formed. In April 2012, the two organisations separated again to form shadow CCGs in preparation for the implementation of the Health and Social Care Act (NHS Brent CCG and NHS Harrow CCG).

Lack of capacity has been identified as an underpinning problem for all of the difficulties experienced. Organisational changes throughout the procurement have resulted in a loss of managers and added to the pressures faced by clinicians and managers in keeping their eye on the ball, in continuity of representation and organisational memory. The PCT is nearing its transition to CCG and should bear this in mind and learn from the mistakes of past reorganisations to ensure some continuity of key people and accessibility of relevant information relating to all services.

The switch over of IT and equipment at the same time was a service requirement for TDL, however, it compounded the issues that GPs were already experiencing. A key concern for GPs has been the presentation, and grouping, of patient results due to the change over to the new IT system. Despite assurances from TDL (in their report of 08 March 2012) that they are compliant with standards and that this is a national issue, or that it does not appear to be a laboratory problem, the DH Informatics team have sent a representative out to a practice to see first-hand the issues presented to GPs by this format, and have agreed to instigate a national enquiry.

The other issue reported by GPs was with regard to test results; GPs were raising concerns that they were receiving many more abnormal results than expected; some tests that were requested were never reported on and for others, only a partial result was forwarded. Some reports issued were incomplete, therefore omitting a number of test results. There was an operational issue with the new robotic sorter which resulted in a number of samples being filed incorrectly as 'analysis complete' and subsequently discarded. There was also a problem with one of the lines in the calcium analyser as a result of which, samples were transferred to another laboratory, and a number of issues were attributed to human error.

Adding to the confusion was a change in the reference value ranges which although a communication had been sent to the PCT for onward transmission to GPs, this never happened and so GPs were taken by surprise when the ranges changed (due to harmonisation as agreed nationally, and change of equipment and reagents).

When there was an issue within the pathology service due to the changeover of equipment and IT system, TDL did not follow their own escalation procedure and alert the PCT or GPs about the problems that they could experience and what remedial action both should take. NWLHT were also experiencing similar problems for their results. TDL subsequently advised that they were pre-occupied in addressing the problems and this the delay in communication and recognised that with hindsight, they should have alerted the PCT and GPs earlier.

Changing the IT system also changed the way that samples were being logged at reception and action has been taken in sample reception to note on the form exactly what had been received and so reduce the number of reports identifying 'no samples received'. TDL have also transferred one of their senior managers to sample reception to carry out GP data review and raise the level of accuracy by staff at the point of data entry and continue to liaise with GP practices to confirm accurate listing of GPs at each practice.

The report provided by TDL on 08 March, was light on detail in parts and so it was difficult to identify lessons learned. TDL enjoy a good reputation and it is understandable that they would wish to protect this. However, in light of the requirements to put patients first and the duty of openness, transparency and candour, as recommended by Francis[i], it is felt that all involved could have been more open throughout the process.

The outcome of the RCA highlights that there are lessons to be learnt by all three parties: the service provider TDL, the PCTs and NWLHT and this has been acknowledged within the constructive meetings of the RCA.

Whilst the team is unaware of any reports of actual patient harm as a result of these issues, there have been many incidents of patients attending for repeat blood tests at both the practice and within the hospital and some patients had to be referred to A&E Department because of high potassium levels.

The RCA team recognises, and gives credit to, the GPs of Brent and Harrow for their vigilance and diligence in ensuring that their patients have not come to harm as a result of the issues with the pathology service.

MAIN REPORT:

Incident description and consequences

Incident description:

Pathology results were received from the Pathology Service in a different format than previously experienced. GP practices in Brent received pathology results presented in a manner that now makes it possible for one result being viewed, actioned, filed and archived with the subsequent result that other reports within the grouping, will be filed and archived in the patient's records without necessarily being viewed or actioned. This was a significant change from the manner in which results had previously been received in Brent and Harrow and represents a significant clinical risk.

Secondary to the above; spurious results, missing samples, missing test results and multiple, batched test results were later reported by GPs. There was also a failure on the part of the service provider to report some abnormal results and other abnormal results were not being flagged as such. GPs were also concerned that reference values appeared to have changed.

Incident date: Initial concern reported on 20 December 2012

Incident type: Formatting of blood results

Specialty: Pathology

Actual effect on patient: Unknown at that juncture

Actual severity of the incident: Potential severity assessed as Major

Pre-investigation risk assessment

A Potential Severity (1-5)	B Likelihood of recurrence at that severity (1-5)	C Risk Rating (C = A x B)
4	5	20

Background and context

In May 2009, NHS Harrow notified the existing provider of the pathology service, North West London Hospitals Trust (NWLHT) that it intended to commission a new pathology service because they wished to transform and enhance community requested pathology services to deliver benefits for the eight North West London PCTs. NHS Harrow led a market intelligence exercise which established that there was a market for pathology and the potential to achieve significant savings. In January 2010, North West London Hospitals Trust, NHS Harrow and NHS Brent initiated a joint Competitive Dialogue process to procure a pathology service provider to develop and provide pathology services to the participating Trusts and to work with them to

generate additional income from these services. A full chronology of the process that led to this procurement and the timeline of the procurement is included in Appendix 2 of this report.

A joint Pathology Project Board steered the procurement process and, at their meeting on 04 July 2011, recommended the appointment of The Doctors Laboratory (TDL) as preferred provider for the provision of services. The contract was awarded in May 2012 and the transition from NWLHT to TDL commenced. On or around 10 December 2012, TDL switched to new equipment and a new IT system. There were issues occurring for GPs at the time, with the existing service and the changeover to the new equipment and IT system compounded the problem. On 20 December a GP identified that pathology results were displayed differently on GP systems than previously. Of concern was the fact that the EMIS LV GP clinical system was now able to file results into the patient's record without the GP having seen or reviewed them. It later transpired that this was also occurring in the INPS Vision GP clinical systems and EMIS Web.

Subsequently, GPs began noticing a number of spurious results; the reference ranges of the results were noted to have changed, samples were going missing, reports were being forwarded to the wrong GP, and there were multiple results coming through to clinicians with up to 300 results at a time being reported. Concerns were raised with the PCTs and in January 2013, this was logged as a Serious Incident.

Terms of Reference

Purpose

To identify the root causes and key learning from the multiple-incidents and use this information to significantly reduce the likelihood of future problems within the pathology service and any potential for harm to patients

Objectives

To establish the facts i.e. **what** happened (*effect*), to **whom**, **when, where**, **how** and **why** (*root causes*)
To establish the cause of the changes observed in the processing and reporting of results
To look for improvements rather than to apportion blame
To establish how recurrence may be reduced or eliminated
To formulate recommendations and an action plan
To provide a report and record of the investigation process & outcome
To provide a means of sharing learning from the incident
To identify routes of sharing learning from the incident

Agreed Terms of Reference:

- To identify any clinical risk or harm to patients in the interval between contract go-live and the issues becoming apparent and remedial action taken
- To review the communication about, and resolution of problems that occurred on switch over to the new IT system and equipment once these were flagged to TDL
- To understand the clinical engagement in the overall procurement process and to include a review of the communication to primary care around the change in the provider of the pathology service.

Key questions/issues to be addressed:

1. Was due diligence paid in terms of the procurement of the new pathology service?
2. What were the quality standards for the contract as the KPIs were seen as too broad?
3. Do we think that the Quality Assurance process that was in place was sufficient, and were there robust governance arrangements in place?
4. Can we identify if any actual harm came to patients as a result of missing test results and potential clinical management issues related to the receipt of spurious test results?
5. Could better engagement from PCT in the procurement process and subsequently, have reduced the impact of the service issues?

Key Deliverables

Investigation Report, Recommendations, Action Plan, Implementation of Actions

Scope

Investigate the causes of the changes to the formatting and reporting of results, spurious results and batching of results. Investigate both internal and external factors that may impact on the quality of the pathology service or contract.

Investigation type, process and methods used

Multi-incident investigation

Process – gathering information from interviews / audit of email trails and relevant documents. Meetings with the service provider, GPs, primary care managers from Brent and Harrow, the pathology contract manager, commissioning/operational manager for the pathology service to discuss and gather evidence. (Minutes at appendix 3)
Research (relevant articles in references) and visits to Laboratories to see process first hand.
Meeting internally with comms team (minutes and outcomes of meeting in appendix 4).
Document review of electronic documents on shared drive.

Methods used – Gathering and mapping the information and identifying contributory factors and assessment of root causes using 'fishbone' diagram (appendix 5)

Arrangements for communication, monitoring, evaluation and action:

The report will be made widely available to primary care (GPs), Overview and Scrutiny Committees for Brent and Harrow. It will be presented to the Quality, Safety and Clinical Risk Committees and the Governing Body meetings of the Brent and Harrow CCGs.

Investigation Commissioner Jo Ohlson (Chief Operating Officer, Brent CCG) on behalf of Rob Larkman (Accountable officer Brent, Ealing, Harrow and Hillingdon CCGs)

Investigation team

Health representation :
Dr. MC Patel, MRCGP, General Practitioner, Brent [Chair]
Dr. Irfan Sayed, MRCGP, General Practitioner, Harrow
Dr. Alan Selwyn, MRCGP, General Practitioner (GP IT Advisor)
Pauline Johnson, MA, BSc(Hons) RGN, RM, RHV, Interim Head of Quality and Safety BEHH CCGs
Andrew Atherton, MSc, BA, PDip, HNS; Head of Primary Care Network Development, Brent CCG.
Isha Coombes, MA, BSc, Commissioning Manager Harrow CCG.
Tony Afuwape, MSc, BSc, IT Advisor, Brent CCG

Mark Browne, Non-acute Contracts Manager Brent and Harrow CCGs Ian Winstanley, Deputy Borough Director, Brent CCG Matthew Longmate, Pathology Service Contract Manager, North West London Hospitals Trust. The Doctors Laboratory representatives: Tim Herriman: Group Laboratory Service Director Cyril Taylor : Laboratory Service Compliance Director John Matthews : Chief Information Officer Jan Stewart : Director of Quality Management
Resources See appendices and References
Stakeholders/audience See Communications
Investigation timescales/schedule 15 January to 12 March 2013

Level of investigation

SI investigated at a level 2 (Comprehensive)

Information and evidence gathered

The issue of the formatting of pathology results was the trigger for this investigation. The GP who highlighted the initial concern, raised the issue at the Harness Locality Clinical Forum and then with the Chief Operating Officer for Brent PCT. He had already written to the CEO at North West London Hospitals Trust (NWLHT) and this was when he was advised that TDL had taken over the service. At the time of the incident (December 2012 – January 2013) the GP community within Brent and Harrow appeared to be largely unaware that the pathology service was now provided by a new service provider, The Doctor's Laboratory (TDL).

In order to understand why this was, the RCA investigation team (RCA team) looked at the procurement process, the involvement of primary care in the procurement, subsequent communication to GPs and Practice Managers, and any training offered on the new system. Additionally, the reporting process within the PCT / CCG was reviewed in order to understand information flows both in respect of the dissemination and sharing of information and the gathering and providing feedback on pathology service related matters.

The Procurement Process

In May 2009, Harrow PCT (NHS Harrow) issued a letter to NWLHT the existing provider of the pathology service to Harrow GPs, notifying them that with effect from 2010/11, they intended to follow a tendering process to commission a new pathology service. Their stated intention was to lead the development of a joined-up approach to the commissioning and possible market testing of Direct Access pathology services.

Between July and September 2009, NHS Harrow led a market intelligence initiative with potential providers to establish whether there were opportunities to transform and enhance community requested pathology services to deliver benefits for the eight North West London PCTs: Barnet, Brent, Ealing, Harrow, Hammersmith & Fulham, Hillingdon, Kensington and Chelsea and Westminster). This exercise established that there was a market for pathology and the potential to achieve significant savings.

NHS Brent, NHS Harrow and North West London Hospitals Trust initiated a joint Competitive Dialogue process in January 2010 to procure a pathology service provider to develop and provide pathology services to the participating organisations and to work with them to generate additional income from these services. A full chronology of the process that led to the procurement, and the timeline of the procurement, is included in Appendix 2 of this report.

The formal procurement process started with a Contract Notice published in the Official Journal for the European Union (OJEU) in March 2010. Following the final stage of competitive dialogue, the two remaining bids were subjected to clinical and commercial evaluation in May 2011. The joint Pathology Project Board, chaired by Fiona Wise (Chief Executive of NWLHT), steered the process and, at a meeting on 04 July 2011, recommended the appointment of The Doctors Laboratory (TDL) as preferred provider for the provision of services.

North West London Hospitals had also flagged up a problem with their LIMS (Laboratory Information Management System), on 25 May 2011 to the CEO of NHS London and the Accountable Officer of Brent and Harrow PCTs, who was also the SRO for Pathology across North West London. The problem with the LIMS was that it was not likely to be sustainable beyond 6 – 10 months when either a significant upgrade or replacement would be required. To mitigate this risk the replacement process needed to be underway by the end of August 2011 if a decision was made not to proceed with the procurement of a new pathology service.

Aims of the Pathology Procurement

The aims of the project were to ensure that the future configuration of pathology services provided capacity and capability to grow the pathology business and provide a robust, cost effective clinical service for NWLHT, NHS Brent and NHS Harrow. The service needed to be fit for the future and able to deal with increased volumes of activity going forward. The target outcomes for NHS Brent and NHS Harrow in entering into a joint procurement can be found at Appendix 6 of this report.

The final model also had be compliant with the aims of the NHS London Pathology group, which had made recommendations for pathology services in London following Lord Carter's national review of pathology services[ii]. The NHS London[iii] review recommended that pathology laboratories and clusters of laboratories require a high level of interoperability to support both primary and secondary users of pathology.

The NHS London review also recommended that 'Robust logistics and information management and technology (IM&T) are therefore fundamental to successful implementation of any networked service, providing well-ordered specimen reception with the ability to, trace and track samples and provide accurate and timely results that can be relied on. IT should be configured to support the work of clinical networks and MDTs. The needs of GPs should be incorporated so that they can access the results whether requested by them or not.' The procurement would seek to ensure this flexibility and improved IM&T capabilities.

Lord Carter described the need to rationalise the number of providers of pathology services through the development of pathology networks and single integrated management structures and to ensure that patient pathways remained intact. The report also identified several barriers to change which are:

- Fragmentation of arrangements for collecting and transporting samples
- A lack of end to end information technology (IT) connectivity
- Variability in test repertoire, investigation protocols and reference ranges

- Uncoordinated use of point of care testing (POCT)
- A lack of knowledge and understanding of laboratory services amongst commissioners and senior managers
- A complex workforce lacking in appropriate planning and development

The procurement process was paused in March and April 2011 to allow time to consider the implications of the NHS London review of pathology for the sector. It was considered prudent to proceed as the final London solution was likely to take 2-3 years to realise, and the existing pathology system at NWLH was in a critical state and not expected to be operational beyond October 2012.

The procurement scope included all of the general diagnostics pathology services i.e. Haematology, Biochemistry, Microbiology, Histopathology, Cytopathology. Out of scope of the procurement were:

- Consultant pathologists (they remain employed by the NWLHT)
- Transport (a separate procurement was required for this element)
- The mortuary
- Specialist Genetics Laboratories within the Kennedy Galton Unit of NWLHT

Procurement Evaluation Process

Three bidders entered detailed dialogue with the procurement team and following that were invited to submit Best and Final Offers (BAFO) in April 2011. The BAFO submissions were received on 16th May at which point one of the bidders advised that they had decided to withdraw.

The clinical and commercial evaluation was conducted against published criteria. The clinical submissions were assessed by a panel of 26 clinicians (including GP representatives from NHS Brent and NHS Harrow), managers and pathology staff, and were based on written submissions by the bidders and presentations made to the evaluators during an evaluation event.

A panel of 6 managers performed the commercial evaluation including the Assistant Director of Commissioning from North West London Commissioning Support Unit (NWLCP) representing NHS Brent and NHS Harrow. The panel was chaired by the NWLHT Assistant Director of Finance.

Financial Assessment of the preferred bid

Full financial evaluation of the preferred bid was included in the part 2 paper presented to the 01 September 2011 NHS Brent and Harrow Trust Board meeting. This is not included in this report because it contains commercially sensitive data.

As the preferred proposal put to Board did not include the full scope of the current service, it was noted that there were a number of areas for negotiation and agreement between NHS Brent and Harrow and NWLHT. These included:

- Consultant pathologists
- Costs of the procurement project management
- Ongoing contract management
- Implementation costs

- Service overheads

Overall, the proposal from the preferred bidder was thought to deliver significant savings to the health economy and should enable them to manage future financial pressures in pathology.

Feedback from Brent GPCE and Harrow CCG

The paper presented to the PCT Boards in August 2011 advised that the Brent GP Clinical Executive (GPCE) and the Harrow CCG sub-groups had reviewed early drafts of the paper that was presented to the Trust Boards. The sub-groups had received details of the financial implications and clinical input into the decision making process. Both groups were reported to have said that they:

- Noted the financial benefits
- Sought assurance about the ability of the preferred bidder to deliver a safe and efficient service and were assured that this has been provided by the process followed by the procurement project board
- Highlighted concerns and risks involved in the transition process. The groups are reported to have discussed this at length and understood that this would inform the PCT input into the operational group that was to be set up to monitor the service and ensure a smooth transition
- Approved proceeding with the appointment of the preferred bidder

Overall benefits of the procurement as they were stated

In addition to the financial benefits referred to (and detailed in the part 2 paper) there were a number of other significant benefits to the health economy of the procurement.

- The existing Laboratory Information Management System (LIMS) was deemed to be in a critical state and no longer stable or sustainable, both in terms of hardware and software, with an expected remaining lifespan of 6-10 months (as at September 2011). A full OJEU procurement and implementation programme would have been required to replace this and which may not have been deliverable before the system failed.

- The existing model of receipt for direct access Pathology samples places immense strains on the service with many thousands of sample tubes arriving in the early evening. This was seen to cause backlogs and delays in reporting results to clinicians and, in some cases, directly impacted on the quality of the sample and therefore the clinical utility of the results. The delivery of a full order communications system across Primary Care and Secondary Care was required coupled with new automated analytical platforms to mitigate this risk and ensure samples remain stable throughout the process.

- The existing necessity for an absolute 1 hour turnaround for emergency pathway specimens was becoming increasingly difficult to deliver due to both volume increases and the limitations of the existing systems and equipment.

Other benefits, more difficult to quantify, would result from the proposed partnership. These included:

- Improved Primary Care access to service through order communications roll-out

- Reduction of duplication through visibility of results across the local health community
- Ability to support a robust demand management scheme
- Detailed activity reporting to understand requesting patterns and educate requesters in appropriate use of Pathology Services
- Ability to limit financial liability of existing growth through marginal pricing above baseline activity

Risk Analysis

NHS Brent and Harrow commissioners / project board, were aware of a number of issues associated with the procurement project, the most significant being described below and were presented to the NHS Brent and Harrow Trust Board to inform the discussion and decision making process when agreeing for the Project Board to proceed to appoint a preferred bidder.

Issue/Risk	Description and mitigation
Current LIMS is not robust and sustainable	The LIMS was not likely to be sustainable beyond 6 – 10 months when either a significant upgrade or replacement would be required To mitigate this risk the replacement process needed to be underway by the end of August 2011 if a decision was made not to proceed with the procurement
Over or under counting of test numbers	The integrity of the data being extracted from the LIMS had been flagged as a risk as the LIMS was beyond its normal life cycle and not originally designed to give patient level data. The project team has taken all possible steps to validate the data and ensure that it is reproducible.
Ability to manage demand	Unplanned increases in demand are a risk Agreement on contract monitoring arrangements was to be negotiated before contract sign off. It had already been agreed that volumes in excess of baseline activity levels, will be at marginal rates. Detailed information of activity at patient and GP level would be made available which would support demand management initiatives
Transport arrangements	The current transport contract had expired and is being rolled over on a month by month basis. NHS Brent and NHS Harrow would have to go out to procurement immediately to identify a transport provider. *The specification would have to be carefully drafted with GP input to ensure that the service commissioned will dovetail with the KPIs agreed in the final pathology contract to ensure turnaround times can be achieved.*
Final agreement not yet achieved with NWLHT on recharges of full service costs	Consultant pathologists are out of scope of the procurement and other overheads such as rent and rates, contract management costs and implementation costs would need to be apportioned between the three Trusts Negotiation and agreement on these areas were to be undertaken in September 2011 and agreed before contract sign off.

PCT capacity to effectively input to the contract negotiation and ongoing monitoring	Both Harrow CCG and Brent GPCE have agreed to identify lead clinicians. Management resource to be identified.

A risk overview of the Pathology Procurement was undertaken by the three authorities on 30 September 2011 and this is included in Appendix 7 of this report.

NHS Brent and Harrow Trust Board meeting held 01 September 2011.

The pathology project team and the managers and clinicians involved from NHS Brent and NHS Harrow presented the details of the procurement (as set out above) to the Trust Board at an extraordinary meeting held on 01 September 2011. They informed the PCT Boards that the Board of NWLHT had given approval to move to the Preferred Bidder stage at their July meeting and advised the Brent and Harrow Board that the offer from the Preferred Bidder represented good value, meeting the objectives of the project of consolidating and modernising the service, delivering a significant saving to the health economy and potential for gain share as additional volume is brought in from new clients / sources.

They presented the detailed financial and commercially sensitive information to the Trust Board in the private session (part 2) of the meeting. The importance of the mobilisation process was emphasised to the board with the intention to sign off the contract in the week of October 3, 2011 and then to initiate a separate procurement for the transportation of pathology samples. Subject to board agreement to progress to appointing the Preferred Bidder, there would be a consultation and TUPE period of three months with the existing staff at the NPH laboratory. The aspiration at that point, was that the Preferred Bidder would take over the service from 5th January 2012 and it was noted that the Preferred Bidder had a good track record elsewhere.

On this basis they recommended that the Board:

- Approve the preferred provider of Pathology Services
- Authorise the Chief Executive and Director of Finance to secure the best possible position in negotiations with NWLHT on the recharges of overheads relating to consultant costs, rent and rates, contract management charges, project costs and costs of implementation.

Attention was drawn to an appendix in the paper to the Board, detailing the process chronology and board members were advised that those wishing to have the detailed specification would be provided with it. One Board Member suggested that 'given the complexity of the process and issues involved, that chair's action be sought prior to contract signature'.

The Boards of NHS Brent and NHS Harrow approved the recommendation from the Pathology Project Board to move to contract agreement and signature with the Preferred Bidder for the provision of Pathology Services and Transformation to the three parties - North West London Hospitals NHS Trust, NHS Brent and NHS Harrow, and subject to chair's action.

At the meeting, and should the appointment of Preferred Bidder be approved, the following action plan was tabled:

Dates	Actions
August 2011	Primary care workstream established to start work on Key Performance Indicators, data reporting requirements, clinical and operational management group attendance, implementation of order communications and so on.
September 2011	Detailed contract negotiation with the preferred bidder to agree: • Schedule 3: Performance mechanism: Finalise list of KPIs • Schedule 5: Continuity plan • Schedule 6: Contract management • Schedule 17: Mobilisation plan Detailed negotiation with NWLHT to agree cost apportionment for overheads and costs of consultant pathologists
Week beginning 3rd Oct 2011	Contract sign off with the preferred bidder SLA sign off with NWLHT
Week beginning 10th October	Initiate procurement process for transport
Oct – Dec 2011	Consultation period and TUPE arrangements for current NWLHT pathology staff. Monthly meetings of operational and clinical management groups
5th Jan 2012	Preferred bidder take over current service and implementation phase begins with full implementation by end September 2012 at the latest

Chairs Action

On 04 January 2012, the Deputy Borough Director / Procurement Senior Manager (senior manager) prepared a paper for Chair's action as recommended in the 01 September meeting of NHS Brent and NHS Harrow. This paper is not included as an appendix to this report because of the commercial and financial information contained therein. Chair's action prior to contract signature, was requested by the Boards because as reported in the minutes, the issues were too complex and because a number of significant issues had not been fully resolved at the time that the Boards met in September.

Chair's Action means that the Chair is taking the decision and having it effected without calling a further meeting of the PCT Board (in this case). It's quite a common thing to do where a situation arises that has to be dealt with very quickly, so quickly that it is not possible to wait for a formal meeting of the PCT Board. The chairperson may consult informally with the PCT Board

members, and would usually subsequently report the decision to the PCT Board although in this instance, the Board had already met.

The guidance from the chair listed what the paper should contain which in summary, meant that the paper had to be able to stand on its own so that anyone picking it up will understand what is being asked for, why, how things have meant amending the previous decision making and assurance processes that it had already gone through.

Approval was given to contract signature and to the agreement reached on the apportionment and payment mechanism between NHS Brent, NHS Harrow and NWLHT. With regard to the risk of the potential for LIMS system failure, this was added to the corporate risk registers for both Brent and Harrow PCTs.

Risk Assessment for Transition and Implementation

The risk overview of the Pathology Procurement that was undertaken by the three authorities on 30 September 2011 (included in Appendix 7 of this report) concentrated on the financial aspects of the tender (including VAT). Whilst this is important, there should have been a risk analysis of the clinical and service risks throughout transition for what is essentially a clinical service. The team found no evidence of any risk assessments being done from the PCT point of view given that they initiated the procurement and as commissioners were responsible for procuring an effective safe service. It is a risk for the CCG going forward and a key recommendation as the team would advise that the CCG carries out risk assessments on all procurements and services changes including QIPP.

The team asked TDL for their risk assessment of the service transition and implementation but was advised that they had not undertaken any risk assessments. Advice since suggests that a a detailed and substantive risk assessment, including change control, was undertaken for every element of the transition although this has not yet been made available to the investigation. Clearly, the PCT were unaware that this existed and were not able to learn from, or contribute to this. As the teams established to oversee the transition and implementation did not include primary care representation, all three (3) organisations were exposed to the risks that followed.

Timeline of significant events preceding the incidents

TDL were appointed as Preferred Bidder in September 2011 with the aspiration that the service would go live on the 5th January 2012. This did not happen because of issues with leases and licenses and the need to secure additional capacity in the power supply. Details of preparatory work undertaken are set out in the Blood Sciences timeline at appendix 8).

The TDL contract as Pathology Provider to the three authorities (NWLHT, Brent PCT and Harrow PCT) commenced on the 01 May 2012. The contract management of this service is through the NWLHT pathology contract manager on behalf of the three commissioners. The team was advised that the intention was that the performance management of the contract would be undertaken by the Commissioning Support Unit (CSU), with local support from the non-acute contracts manager for Brent and Harrow.

The responsibility for this rests with the senior manager for the procurement and contract (and successors) ,from the PCT who should ensure appropriate GP and PCT input into the process. However, the Contract Review Committee did not progress beyond the first meeting and the

OMC could not continue because of the lack of attendance from the PCT and GPs. The senior manager left the organisation in October 2012 and whilst the local non-acute contracts manager attended those meetings that were held, there was insufficient presence from the PCT to allow performance management of the service.

There has been no active engagement from PCT management of the monitoring of the service from the point of the senior manager's departure, to date. This was evident at the first RCA meeting and it is noted that the transfer of the responsibility to CSU only takes place in April 2013. There is an SLA between the PCTs and NWLHT covering the recharge elements of the pathology service that are not covered by TDL, mostly relating to the recharge for the consultants who remain employed by NWLHT, but also includes a proportion of the cost of the contract manager whose expertise in respect of contract monitoring and negotiation is available to the CCGs.

The TDL laboratory based at NWLHT (NPH) processes bloods for all of Harrow GPs and most of Brent GPs with the Imperial Hospitals Trust (IHT – based mostly at St. Mary's Hospital) processing samples for a small number of Brent GPs in the south of the Borough. This information only came to light as a result of this investigation and the review of pertinent documentation. The communication process therefore needs to reflect this fact.

Communication

Communication to GP practices and from GP practices on service wide issues was agreed to be as set out in the Communication and Escalation protocol to be found at appendix 9 of this report. For day to day individual practice or patient queries, the practices were to continue to use the telephone numbers previously supplied to them for contacting the relevant department within the NWHT laboratory.

Key Performance Indicators

Emails available to the RCA team show that on 09 September 2011, the pathology contract manager (NWLHT) sent an email to the commissioning lead and the CRO / GP lead for Brent and for Harrow. The attachment to the email was the appendix from Schedule 3 of the Contract (Performance Monitoring and Service Levels) containing the KPIs and service deductions against them (see appendix 10 of this report). This email was sent with the following instructions:

'*We legally, cannot make any material changes to the contract and the service deductions are not intended to be punitive. All of the KPIs must be measurable, realistically achievable and within the providers sphere of influence; as such, the attached does cover the majority of enforceable KPIs within any private Pathology contract.*

In summary the KPIs are:

- *Turnaround times*
- *Commenting on results in an agreed manner*
- *Contacting clinicians regarding abnormal results*
- *Availability of IT systems*
- *Telephone response times (laboratory queries)*
- *Maintenance of legislative accreditations (CPA, MHRA etc)*
- *Management reporting within specified times.*

The email asked for final feedback no later than the morning of 15 September from any colleagues who wanted to comment – any additional items will be subject to review and approval by our legal advisors who's view on suitability, legally and operationally, will be final'.

This was relayed on 12 September, via the CRO for Brent to the seven CCG GP members / Clinical Directors for Brent; a reply was received that day from one GP member, but no other replies are evidenced. The KPIs were not cascaded to the Harrow GPs because there is no evidence to suggest that this was also received by the Harrow CRO. He confirmed to the team that he did not receive them and advised that he has asked for the KPIs on many occasions.

The GPs were asked to comment within 2 days on KPIs and to which they couldn't make any material change, which may account for the lack of response. However, the team is aware that the CRO were given the opportunity to comment on the performance schedules from their inception in January 2011, but had not done so. The reasons for this are unclear; whether PCT management had omitted to request comments, or whether it was due to workload pressures. What is clear is that, throughout the transition and implementation phase, there was no significant involvement from the CROs into the transition and implementation phase..

Primary Care Workstream

A second email trail starting on 28 September 2011 was sent by the pathology contract manager to the pathology procurement project lead, and the Brent and Harrow non-acute contracts manager advising that:

'*in this phase of the procurement there is no room for material or substantive changes to the documents as it may be claimed that we have offered a commercial advantage to the preferred bidder and therefore grounds for challenge.... we are getting to a point where the process is complete for a number of schedules so final versions will be sent through so you can familiarise yourselves with the content and thus be comfortable to sign in the week commencing the 10th (October).*

TDL would really like to meet with you and the CCG Contracts Manager, and the GP Leads if possible, to ensure that there is a good understanding of the Primary Care facing elements of the model.'

A meeting was proposed at which the above and the recharge mechanism would be discussed and the following timetable set out:

Mon 10th - Complete collation and printing
Tues 11th - Sign contract (all 4 parties)
Wed 12th - Issue Staff consultation papers
Thurs 13th - Formal staff consultation starts

The CROs for Brent and Harrow were invited to this meeting; confirmed as 12 October 2011 and contributed the following to the proposed agenda:

Key areas:
(1) OOH abnormal results pathway.
(2) Lost specimens (i.e. path form reaches lab but no specimens).
(3) New User Interface (show what it will look like) = live is better than screen shots.

(4) Project Management for education/training of HCP (healthcare practitioner) in using the future TDL Software that will sit at the User end.
(5) The setting up of a NWLHT Pathology CQG, (similar to NWLHT CQG). This would be a standing committee with Clinicians from Harrow and Brent to clinically monitor TDL (TOR would have to be agreed).
(6) Performance Management of the TDL Contract (KPI / SLA) would be monitored at the Pathology Operations Meeting?
(7) Unlabelled Specimens Protocol (will we pay?)

The CRO for Brent also added that Key for GP leads is a clear Project Timeline (with "gates") showing the delivery of the new Pathology software/hardware once the contract with TDL has officially been signed with the Trust (NWLHT) and also Brent and Harrow PCTs.

This meeting went ahead on 12 October 2011 and information available to the RCA team shows an agenda and notes from the meeting that shows that this initial meeting covered a lot of the areas that was intended to be discussed in the Primary Care Workstream. There is evidence to suggest that the CRO were invited to a meeting on 05 September 2011 from a paper with handwritten notes from the Pathology Project Board. This appears to have been the embryonic Primary Care workstream (or preparations for) and which demonstrates the input of at least the one CRO in discussions around risk assessment, KPIs and the implementation of order comms.

The future meeting was to have been on 03 October but there is no evidence that this took place, and certainly, requests to the CROs did not indicate that this was a regular occurrence. The team is not aware of anything else that might have constituted a primary care workstream although there is evidence to suggest that the CROs were unable to attend other meetings regarding pathology due to excessive workloads.

After the contract was awarded, the main vehicle for communication to and from GPs and the PCT around the pathology service would have been the Primary Care Workstream. This was to have been established to start work on Key Performance Indicators (KPIs), data reporting requirements, order communications and so on, nor was there the appropriate attendance at the OMC. The team were are not able to establish a reason for this but what is clear is that the PCTs were not able to did not comply with the requirement to provide input into the OMC, or the reasonable expectation that they would be key participants in the agreed Primary Care workstream.

There was an agreement in respect of how key information would be fed from TDL, through the PCT to general practice and back to the pathology contract manager and TDL as required. The pathology contract manager confirmed at one of the RCA meetings that the PCTs had agreed the communication protocol and which had subsequently been amended following discussion between the relevant parties at one of the OMC meetings.

This would seem to shift the onus from the CROs to communicate onto the senior manager and non-acute contracts manager for Brent, to ensure that information was cascaded out to GPs. However, because the amended process was not ratified at future OMC meetings as they were not quorate, then the process described in the communication and escalation procedure and reaffirmed in the 21 June email below, continued to apply.

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Clarification of Communication process

The following email sent on 21 June 2012 from the pathology contract manager was provided to the RCA team and was intended to re-iterate or clarify the understanding that the agreed communication process was as set out in the protocol. This email is set out in full as it contains relevant information:

I thought that I would take a moment to contact you both to catch up with events over the last few weeks within Pathology as we have not had an opportunity to meet more recently.

As you are aware the contract with TDL went live as of the 1st May 2012 and as such has been live for some 6 weeks.

So far there has been a large amount of preparatory building work that has been undertaken which has been carried out safely and with no disruption to service provision……The main phases of construction works for the new laboratories is about to start followed shortly by a change in equipment based on what has been included in the contract. This will bring the Pathology service to the forefront of current laboratory technology and automation and afford us the scale and performance we require going forwards.

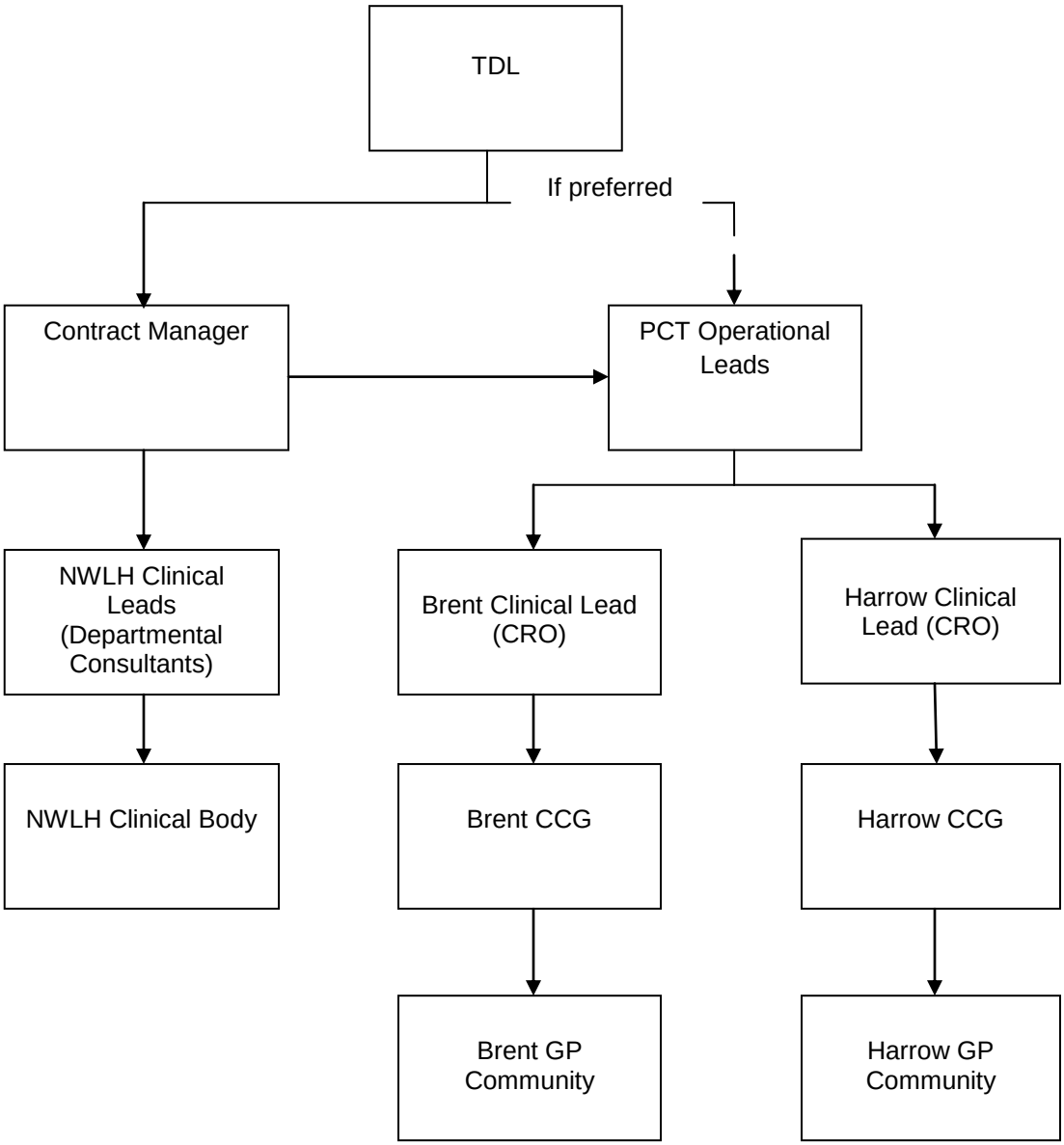
As different manufacturers utilise different methods to generate results there will undoubtedly be a number of assays which will require a change in the way that a clinician interprets or acts upon the results; this is mostly related to more complex investigations such as hormones and tumour markers for instance and may mean that patients will require new baselines created with respect to some of the more prognostic markers viewed over time.
To ensure that patient safety is maintained there is a very thorough process of comparison statistical analysis and verification both at a technical and clinical level that is being governed by the consultant Pathologists in each discipline. From this there will be a process of communication of changes required and this will take place in a stratified way to ensure that the clinically important impacts are understood before changes are made.

We will stratify the communications into:
· For information: a minor change to result interpretation or clinical practice that will not result in patient harm if not observed
· Important: changes to results interpretation or changes in clinical practice required which may affect patient care but not be of significant impact to a patient if not observed
· Critical: changes to results interpretation or changes in clinical practice required which may directly cause harm to a patient if not observed

Obviously all of the above are important but there is a need to ensure that critical information is well identifiable and acted upon with due care.

With regard to communication within the Primary Care GP community I am a little concerned that a number of practices are unaware that the contract has gone live… I would like to ask if we can reflect now on the channels of communications that we have to get information disseminated to the clinical users of the service before we are in a position to have to communicate critical information out.

My understanding of the agreed flow is as follows:



Please do make comment if this is not your expectation so we can create a pathway that is effective and minimises patient risk. (Apologies if I have the wrong acronym for the commissioning boards).

Dates are being circulated for the initial contractual meetings and your attendance would be gratefully received where possible.

The diagram set out above is the one included in the communication and escalation procedure (included at appendix 9) and was made available to the RCA team. The procedure also includes the escalation process to be followed when there is a significant impact to patient safety or service provision such as in the case of a failed instrument, as was the case with this incident. If this escalation protocol was in place, then the team is at a loss to understand why it was not followed when these issues arose.

In September 2012 an email from NWLHT was cascaded to all GPs informing them of the problems that the Trust were experiencing with the IT system used to send out Pathology and Radiology results to GP practices and providing them with the relevant information to access missing results (Revive system). This also provided the contact numbers for Pathology and Radiology for those practices that were not on Revive. This is thought to have been received by all the practices concerned because it was sent out by a different route, however we are unable to validate this as some practices did not receive it.

On 28 November 2012, a communication was sent to the respective PCTs advising them of the impending transition date of the blood sciences department. This was sent from the pathology contract manager to the COO for Brent and Harrow PCTs, the two CROs for Brent and Harrow, the chair of the Harrow CCG and the commissioning manager from Harrow, asking that it be communicated to all practices, GPs and others that routinely access pathology services. This was received in Harrow but not Brent. The email included an attachment 'Important changes to your pathology service (which can be found at appendix 11).

In addition to this communication, on 11 December 2012, a standard comment was attached to all reports to GPs indicating changes in the reference ranges due to service transition: viz 'Effective 11/12/12, Please note changes in reference ranges for selected Chemical Pathology investigations, made at the recommendation of the United Kingdom Pathology Harmony Project[iv]'.

Communications (summary)

Communication between TDL and primary care clinicians as described above, was clearly not in place as many GPs were unaware that the new service under contract with TDL had gone live in May 2012. The email from the pathology contract manager to the PCT senior manager and the non-acute contracts manager, on 21 June 2012, some six weeks later was intended to re-iterate the agreed communication process as set out previously in the communication and escalation procedure.

The senior manager formally approved this mechanism and the Brent CRO noted the contents and appeared to indicate his understanding of the agreed process. Therefore, TDL continued to use this process without identifying concerns about gaps in communication to PCT management as these were not immediately obvious. That the communication channels described in the email and used by TDL, were not able ensure that the relevant information about the service was relayed to GPs, was evident in December 2012 – January 2013 when problems started to arise with the pathology service.

The CROs were copied into information from TDL but without understanding their role in the communication process, they did not ensure that the information was forwarded on to the wider GP community. It also appears that the recipients of the emails each assumed that it was the others' role to do this.

The team was advised by the CROs that they were not aware of a communication strategy relating to the dissemination of information about the pathology service and the communication and escalation procedure made available to the RCA investigation, did not appear to have been seen by them. Had there been primary care representation at the OMC then this could have been developed jointly and cascaded to primary care as an appropriate way of communicating effectively with the pathology service.

GPs would have had forewarning of the changes to the IT systems and switch-over to new equipment and would have been able to use this process to ascertain the cause of the formatting of results and spurious results that they experienced in December. There would have been immediate communication from TDL to primary care and there would certainly have been a different outcome.

As previously noted, the escalation process was not followed by TDL when problems arose with the issuing of blood results, and it is thought that TDL were concentrating on resolving the issues rather than alerting the PCTs and GPs that they were experiencing difficulties. It is probably also true to say that TDL were unaware of the extent of the issues that GPs were faced with.

The team questioned whether the procedure as described was realistic in its expectations that two very busy CROs would be an appropriate conduit to cascade information out to the wider primary care and in any event, this expectation was not shared effectively with the CROs as to secure their agreement. There is also a mechanism already in existence which although it has been recognised as cumbersome, it was a recognised communication channel and did work.

Performance Management and Operational Management of the contract

Schedule 6 of the contract sets out the agreed monitoring arrangements through the bi-annual Contract Review Committee (CRC; Terms of Reference (ToR) and membership included in schedule and as set out in appendix 12), and monthly Operational Management Committee meeting (OMC, ToR and membership set out in schedule 6 – also at appendix 12 of this report).

The team has access to one set of minutes dated 28 August 2012. It appears that of the four invitees from the PCTs for the 28 July meeting, only one was able to attend; subsequent meetings on 28 August and 25 September had two and one management representatives from the PCTs but no GPs were able to attend any of the meetings.

From the OMC meeting on 28 August 2012, TDL were tasked with developing the Performance and Quality monitoring reports. The pathology contract manager was asked to create an activity reporting tool and basic trend analysis. These contract monitoring tools were to be developed through the OMC, in conjunction with GPs and PCT managers but as they failed to attend, these were prepared by TDL and the pathology contract manager. The only representative was the local non-acute contracts manager who was deputising for the senior manager and who has since left the organisation (as of 18 February). It is not known what handover was provided to the senior manager at the time but who left shortly after (October 2012) as the handover notes from the senior manager do not reflect this work.

It was at the OMC meeting, that the pathology contract manager was tasked with creating a communication and escalation procedure. As discussed, this procedure was shared with the PCT managers but was not formally adopted by the CROs. Therefore, when the pathology contract manager circulated a communication about the new Blood Transfusion service using this procedure, the appropriate action was not taken by the PCT, which would be to cascade the information to GPs.

The inaugural meeting of the CRC was held on 02 October 2012 and consisted of the non-acute contract manager for Brent and Harrow and representation from NWLHT and TDL. There are no minutes of this meeting available to the team despite asking TDL and checking the shared drive within the PCT. The only minutes available to the team (at the time of writing) from the CRC and OMC meetings held, are the OMC meeting of the 28 August 2012 and which appears

to have been the Inaugural meeting of that forum. The ToR as set out in the contract was adopted and it was noted that this meeting was not quorate as no GPs were present. The discussion regarding the chair of the group elicited a requirement for the Harrow CCG chair to be approached but the team is not aware of the conversation, just that this did not happen.

Generally speaking, the decisions made at a meeting of an organisation are only binding if enough members are present at the meeting. This minimum number of members, called the "quorum" of the assembly, is beneficial because it protects the association from decisions being made by unrepresentative subsets of the membership. Minutes should be taken, and read and approved at the next quorate regular meeting in the usual manner; meetings held without quorum have very little ability to make important decisions that are binding upon the organisation. At subsequent meetings, there were also no GP representatives available, so meetings were cancelled and therefore the minutes recording decisions, were not approved.

However, TDL suggest that the contract is silent with regard to the need for the presence of GPs – in other words both Committees can be quorate without any GPs being present. It would be unusual if that were the case as decision could be made about services that impacted on the GPs for whom the CCG had commissioned the service, without any clinical representation from the CCG / GPs.

There was a meeting held on 05 September 2011 and one planned for the 03 October that appeared to be the Primary Care Workstream, however, these did not continue. The meeting held on 12 October 2011 may have proved to been an alternative date as information recently available suggests that the agenda (see Appendix 13) covered the primary care interface, clinical and operational management, and performance of the service. Also discussed was the change to the reference ranges and the integration of IT systems. Of note is that the meeting also dealt with general operational questions such as lost samples, unlabeled samples, the telephoning of abnormal results out of hours and so on. None of this was relayed to the wider GP community and represents a missed opportunity to involve GPs in information exchange about the pathology service.

This meeting did include GP representation in that the CROs for Brent and Harrow attended, but the team is advised that no further meetings took place and is suggestive of a lack of ownership from the PCT perspective in that there was insufficient, relevant input into key decisions regarding the pathology service, particularly in ensuring that it meets the needs of GPs. This absence may also reflect one of the barriers to change cited by Lord Carter which is a lack of knowledge and understanding of laboratory services amongst commissioners and senior managers.

The continuity provided by the senior manager for the procurement and transition within the PCT, was lost when they left the organisation at a crucial time in October 2012. It is thought that two or more managers took a caretaker role rather than truly engaging in the management of the contract to ensure PCT input into the transition and implementation. The team has since discovered that the files made available at the initial handover were still with the 'caretaker' of the service and not with the current responsible senior manager, again suggestive of a lack of ownership of the responsibility for the pathology contract. These files contained a great deal of information about the planned primary care workstream and other key documents including the work schedule going forward.

Quality Assurance and a Consultant led service

Schedule 4 of the contract is the Governance and Consultant Led policy for the service. Consultant Pathologists are consulted on strategic and operational issues and any significant change in the service to the hospital or GPs, is expected to be informed through the management structures between the contractor and the Trust (NWLHT). They set the standards and procedures for the total quality system of the contractor, and the appropriate clinical and senior biomedical staffs support the design of the quality and performance framework for the service model, as part of the contractor organisational requirements.

The schedule also confirms that Quality and Performance Management is integral to the operational management arrangements between the contractor and the Trust. This should more accurately be the Trusts, to include all three relevant signatories to the contract. The consultant pathologists monitor quality measures on a regular basis in their respective disciplines and take action when performance falls short of the agreed standards.

The role of the Consultant Pathologist includes, but is not limited to:

- review of Quality Control and Quality Assurance data;
- liaison with the Trust's users of the pathology services;
- determine action limits for telephone reporting of abnormal results;
- determine clinical priorities in the work of the department;
- request repeat analysis of any patient test or tests;
- ensure additional investigations are carried out as a consequence of results found on specimens;
- appropriateness of test requests and specimens;
- monitor requests and influence demand from the Trust's users of the service;
- audit, research and development, and
- direct patient care.

It is understood that the consultant pathologists undertook comparative studies of every test that had changed, including statistical assessment and clinical assessment in order to understand what had happened during this incident. We are informed that they liaised with some GPs who had raised concerns and provided clinical guidance where appropriate. They are also reported to have monitored trends in poor assay performance and verified that the quality improvements were successful. They ensured that TDL had appropriate mechanisms for change management in place and identified many functional issues in the IT system. When asked if they were now able to reassure GPs that the service was safe as a result of the measures in place, they advised that it was too soon to say, as the measures taken needed to be sustainable before it could be referred to as safe.

Consultant Pathologists also ensure that the laboratory Standard Operating Procedures (SOPs) are present, correct and appropriate to the contractor. Schedule 6 of the contract, also contains the right for Consultant Pathologists to advise the Trust whether the contractor is compliant with the standards required by the hospital Clinical Governance System. It is not explicitly the right of the other two parties to receive this advice, as it was never requested by the PCTs at the time however; the CCGs are at liberty to ask if any of the clinical team (pathologists) could verify if TDL/PCTs have appropriate clinical governance arrangements in place.

General Practitioners appeared to be unaware of the process that TDL intended to follow for the telephoning of urgent bloods as they raised concerns that some results had not been telephoned through but were sent using the same process as routine reports. The telephoning of urgent bloods are as set out in the Standard Operating Procedures (SOPs) and whilst these

are the same NWLH SOPs that had been in place for a number of years with only slight variations, these have only recently been shared with general practice and there has been a request that these be reviewed with GP input.

The Consultant in this service is expected to act as the patients' advocate and where the management of the patient demands flexibility, they can request that samples are fast tracked, repeated or referred externally for analysis. The calcium issue is a prime example; many batches of results were re-run and verified. This resulted in a deluge of corrected reports as a result of the consultants identifying issues, asking for remedial actions and the service re-reporting appropriately. Specialist assays with poor performance were also sent to alternative laboratories and certain assays were taken out of service at NWLH to be run at other TDL laboratories at the request of the consultants.

The actions taken by the consultants, eventually stemmed the flow of spurious results and it is now known that they and TDL have developed a comprehensive action plan to address deficiencies in the system during transition and deal with artifacts as they arose although they did not immediately initiate contact with GPs as this was an emerging, complex situation where GPs were already on heightened alert. However, Consultants did say that they are continually monitoring trends and results to ensure that what is reported is as accurate as possible, given the circumstances.

The pathology contract manager (in his role as General Manager for Pathology at NWLHT), along with the Consultant Biochemist, met with local trust stakeholders who had collated incidences of issues. This operational and consultant clinical support was also provided to primary care by phone, email and by visiting practices in order to support community users.

Through detailed investigation of issues being raised by primary care and secondary care, they were able to ascertain the root causes of the issues as broadly falling into the following categories:

- General Equipment Stability
- IT Systems and sample handling systems set-up
- Laboratory staff familiarisation with equipment and systems
- Customisation of a system to meet end users clinical needs

It is also notable that the general service provision issues seen by GPs were not exclusive to primary care but were also present in the acute trust (NWLHT). These were actively managed by the General Manager for Pathology with TDL, which led to their resolution.

Accuracy of results received / Reference Ranges

One of the first changes that GPs became aware of when the new system was introduced was a change in the reference ranges of the tests that they were ordering. Although this had been communicated out to GPs on 28 November 2012, we have seen that the communication process was not effective and quite clearly did not work. Laboratory test results play a crucial role in the decisions that doctors make about the health of a patient, from diagnosis to monitoring and prognosis. Test results are usually interpreted based on their relation to a

reference range[v] and so this communication was crucial to GPs understanding and preparedness for the changes.

The article referenced above notes that 'Reference values are dependent on many factors, including patient age, gender, sample population, and test method, and numeric test results can have different meanings in different laboratories. The laboratory report containing test results should include the specific reference range for the test(s) ordered. Whether or not a test result is within the laboratory reference range, the result must be considered within the context of the patient's personal circumstances, and with the benefit of the doctor's knowledge of the patient's past medical history, current medication and the results of any other investigations. Also, when interpreting laboratory results it is important to know that the sample was collected and handled correctly.

Doctors trust laboratory results. That trust is well placed because Clinical laboratory testing has to meet very high standards. A test method must meet rigorous criteria before it can be used in clinical practice and a laboratory must demonstrate that it is able to perform tests in a clinically acceptable way. A professional accrediting organisation for pathology, Clinical Pathology Accreditation (CPA) (UK) Ltd, monitors laboratories and sets standards that a laboratory must meet in order to be accredited to perform clinical testing. Some of these standards are routine quality control tests and demonstrate that they have policies and procedures in place to help ensure that the sample is collected and handled in an appropriate way and that results are reported with information to help with interpretation of the result.

These requirements ensure that the tests performed by clinical laboratories for patient care will produce results that can be trusted'. However, the incidents that occurred throughout the period beginning 20 December, have shaken confidence in the pathology service and undermined that implicit trust.

Clinical Pathology Accreditation

CPA UK Ltd was formed by the main UK organisations of laboratory professionals to operate a scheme of voluntary accreditation for laboratories. Laboratories participating in the scheme are inspected every four years and have to renew their registration every year, confirming that they are continuing to operate according to strict guidelines. Although the scheme is voluntary, a significant number of UK clinical laboratories are currently accredited by the scheme, and the phrase 'CPA accredited laboratory' is a guarantee that the laboratory has been inspected and approved as a provider of results which meet accepted standards.

The team understands that at the time that these issues arose, the TDL Laboratory on the NWLHT site was not accredited and that the nine month timeline for this is set out in the transition plan. The other reference to a nine month timescale that the team were aware of was the relief period and which is a contractual agreement in relation to the time from commencement of the contract, within which no financial penalties will apply to the provider under the terms of the contract, whilst the service 'beds in'. The application for accreditation (also on a nine month timescale) after service commencement was required because"there had been a change in legal entity and re-application was carried out in line with the Contract".

Causative Factors

With regard to training, this was to be cascaded training using the practice managers to ensure that the new system was understood and that specific issues and concerns would be escalated appropriately. The team was advised that in the handover from the senior manager, it was

suggested that there had been a meeting with the practice manager's forum to go through the new system and this was supplemented by a series of emails. It became apparent only when the investigation began that this did not take place; the practice manager's forum in Brent meets quarterly, and in Harrow, monthly. There is no recollection of this discussion taking place amongst practice managers in Brent, nor is there any reference to this discussion in the minutes.

Emails sent to the CRO intended to advise practices and GPs that the system was going live, were not forwarded on to practices and therefore, none were alerted to this through this medium, nor did any of the GPs or practices receive any training on the new system. TDL advise that they would not have offered this as they could not have been aware of the changes in format of results that subsequently followed.

However, TDL approached 6 Harrow and one Brent practice to participate a pre go live test:

1. Practice E84015 Brent - - Clinical system Vision (INPS)
2. Practice E84009 Harrow – Clinical system Vision
3. Practice E84057 Harrow – Clinical system EMIS
4. Practice E84068 Harrow - Clinical system Vision
5. Practice E84008 Harrow – Clinical system Vision
6. Practice E84061 Harrow – Clinical system EMIS

IT System

The old Laboratory Information Management System (LIMS) used by NWLHT was Cerner Millennium. This was a 12 year old system which ran on obsolete hardware and had a failing operating system. In addition there were concerns of the system not having sufficient data storage capacity to accommodate the expected volume in pathology data. It was therefore deemed that Cerner Millennium was not "fit for purpose" with a risk associated to its stability and deterioration as it approached its operational expiration.

As part of the changeover in the provision of pathology services it was agreed that the contractor (TDL) would introduce its own LIMS into NWLH as soon as practically possible following the signing of the contract and before the old LIMS failed.

The Cerner Millennium LIMS continued to be used by TDL until 11 December 2012 when the new system Clinisys WinPath LIMS came on stream. TDL also provided dedicated interfaces to Indogo4's Keystone Enterprise a middleware technology used to manage the pathology data flows to the GP clinical systems which supported the National Pathology Messaging Implementation Programme (PIMP) specification.

Below are two diagrams depicting the data flows between the systems before and after the change:

Diagram 1: Laboratory Data Flow before the Change with Cerner Millennium LIMS

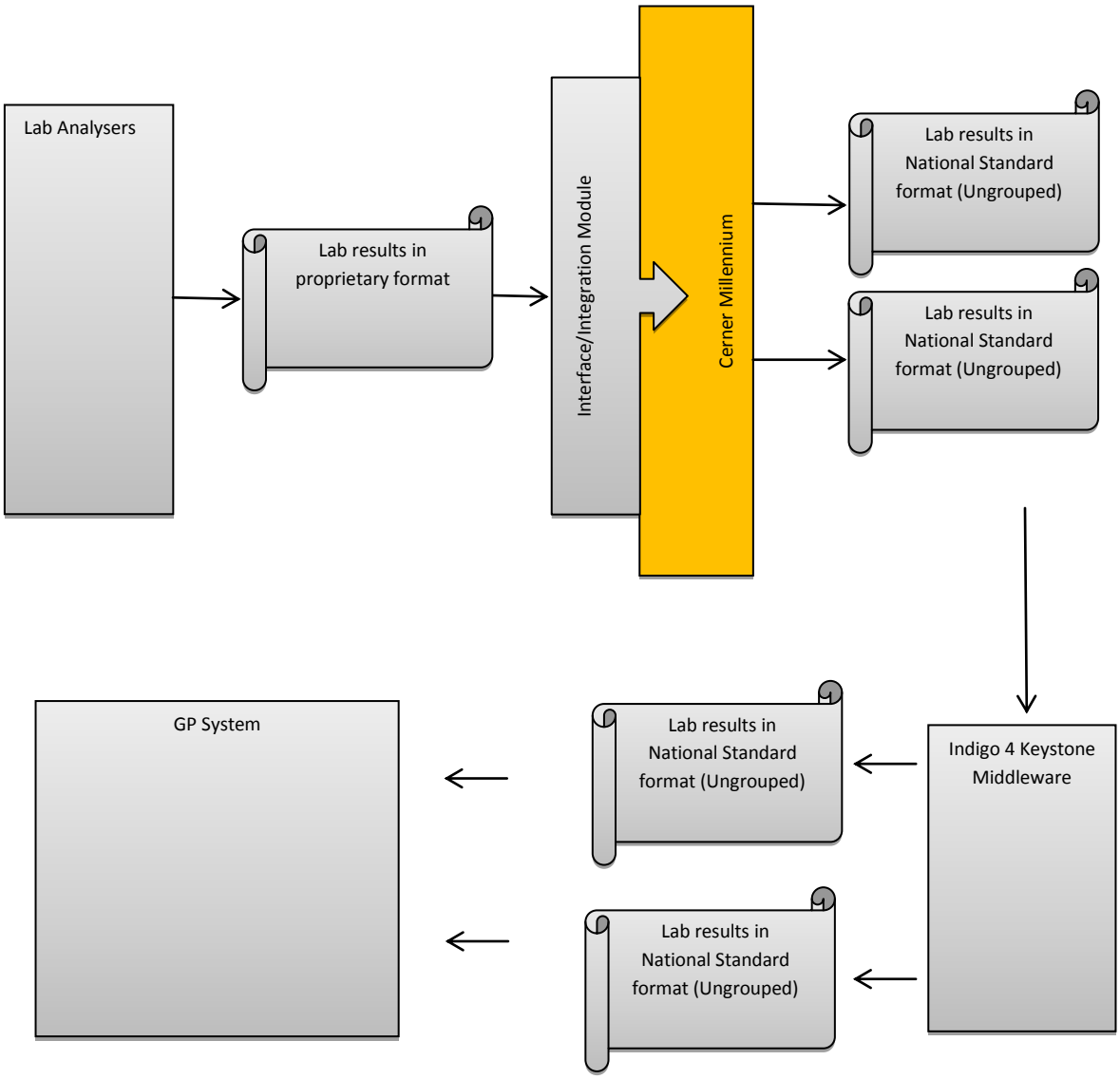
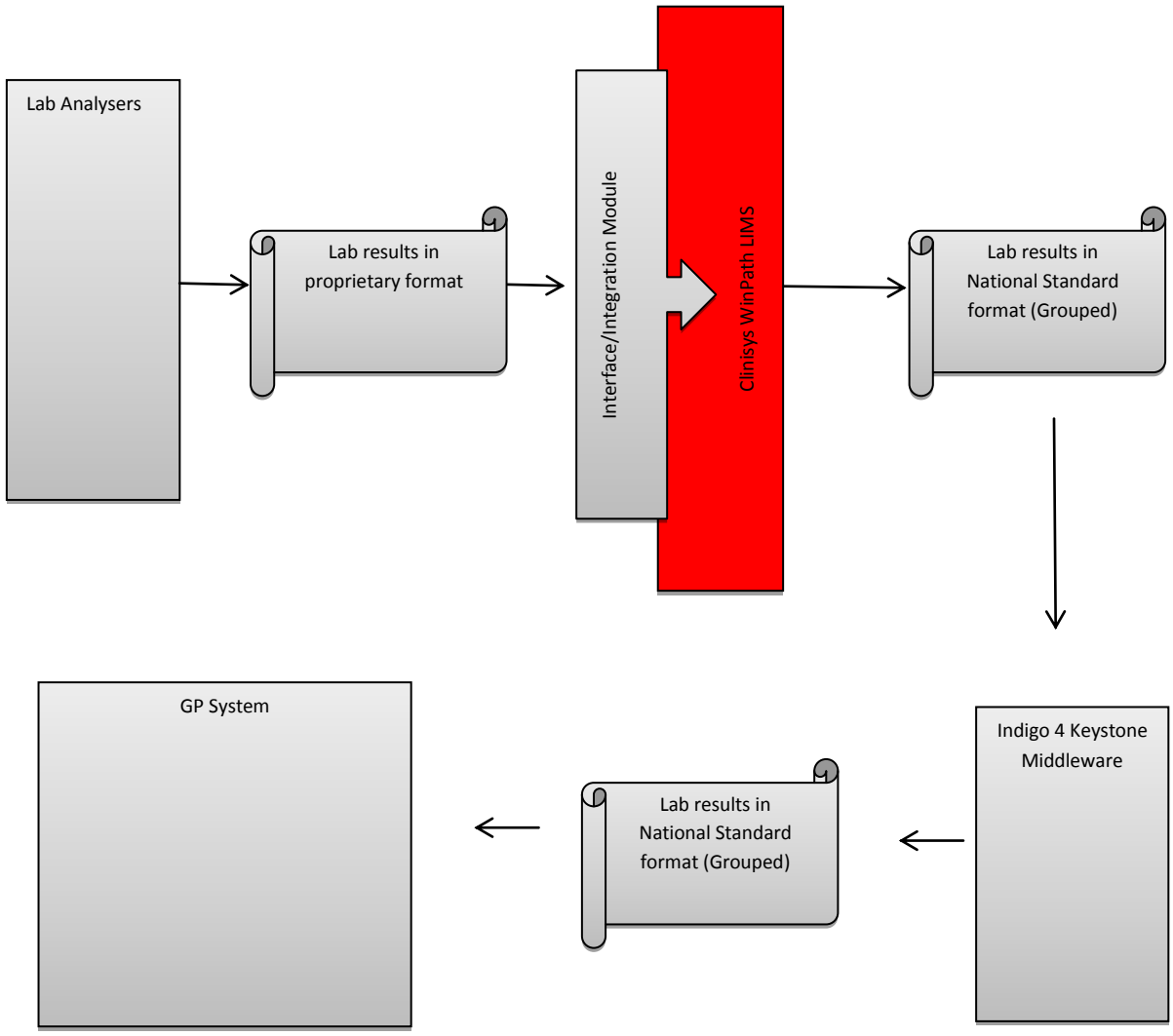


Diagram 2: Laboratory Data Flow after the Change with Clinisys Winpath LIMS.



Before the changeover, the old LIMS (Cerner Millennium) was only able to send pathology results individually under one header/profile and as a result GP practices were receiving results ungrouped. The inability of Cerner Millennium to send the pathology messaging in batches meant that it actually provided a better service to GPs in terms of presenting the data by patient and allowing each result to file separately.

With the changeover the new LIMS is now grouping a full set of results together as batteries and sending under one file. Practices are now receiving multiple test results under one heading/profile. As a result the GP clinical systems are displaying the results to the GP in a way

that presents a clinical risk to the management of the patient. The mechanisms of messaging for both LIMS are compliant with CfH's National Pathology Messaging specification.

However it is the display of the messaging in the receiving GP clinical system (i.e. EMIS, Vision etc.), which are compliant to national PIMP messaging standards, that causes the risk as the example below illustrates;

1. The 1st test result available from the Laboratory is displayed as an entire report which has the title of the header result (this is not necessarily the primary test result requested) and the other test results are displayed as subsets. The clinician might be inclined to read the header result (e.g. for a normal B12) and miss the abnormal (e.g. folate result) listed as a subset under B12 header (which can be displayed a different location on the screen). Indeed if there is a long list then important results such as a grossly abnormal TSH result could 'scroll off' the screen and be missed. In addition if the GP opens and accepts the result it will file the entire report, therefore, inadvertently file the subset results without clinical review.

The filing of the subset of a patient's results without the necessary clinical interface is a concern and could have serious consequences on the clinical management of the patient. As this appears to be happening across the country due to the National Standard format of results, this concern has been escalated to the Department of Health and the Secretary of State for Health. On 29 January, Connecting for Health (CfH), EMIS and Vision(INPS) were notified of this as a problem and then on 05 February, the clinical safety teams for Vision (INPS) and EMIS were alerted. To date, there has not been a formal response from CfH.

On 07 March 2013 the National Clinical Lead for GPs and Clinical Director for Electronic Prescription Service within the Department of Health Informatics Division (National Clinical Lead), visited the practice of the chair of the RCA investigation and observed first-hand the issues experienced by GPs using EMIS LV. He acknowledged that this is a problem and has advised that he will now escalate this nationally with the intention of setting up a national enquiry to look into the issues presented. He has also acknowledged that the grouping of results is unsafe and the team will agree how to progress this concern.

Equipment and Resources

Schedule 9 of the contract identifies the new equipment that TDL intended to purchase as soon as practicable after day one of the contract, and in accordance with the transition plan. For example in haematology, the automated FBC analysers; an automated ESR analyser with the potential to connect to a Tosoh HbA1c analyser; a standalone medium-capacity coagulation analyser will also be installed, together with tube sorter robotics; automated pre analytics, fully tracked and integrated Biochemistry analysers, with post analytic sample filing and sorting. Similar upgrades in equipment introduced in biochemistry, microbiology, cytopathology and histopathology means that the laboratory will be a fully automated, state of the art technology to support sample analysis.

The introduction of this new equipment over time replacing the existing NWLHT laboratory equipment will be undertaken in a phased way in line with the transition plan. It is anticipated that there will be sufficient capacity in the new analysers for current and projected workloads and sufficient analytical provision for unexpected downtime and to maintain the specified turnaround times (TaT). All analysers are to be connected to the LIMS database.

The IT system and key equipment were changed over at the same time which potentially exacerbated any problems with one or the other. However, it is understood that IT and analysers had to be changed simultaneously as the in-use analysers and IT were considered to be at risk of affecting the service. Blood sciences had to be a single transition due to fact that samples arrived together on the same request form and mapping analysers to existing IT system was not possible. Protocols are in place for back-up at a tertiary site should the NWLH laboratories suffer catastrophic failure and the back-up plans were mobilised whilst the investigation of the calcium assay performance was underway. Samples were transported to the Whitfield Street laboratory in line with the contingency on 12 January, although this was not relayed to the PCT until a meeting on January 15, 2013.

Certain assays are available as a single test and the RCA team was keen to know why the 'odd' groupings that were received GPs. The team is advised that this is because the results often sit in a group profile and this is standard practice across pathology facilities, e.g. Haematinic profile as opposed to individual request for B12, Folate and Ferritin.

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TDL advise that new analysers always require new reagents to be IVD (In Vitro Diagnostic) registered, which may have an effect on blood results that is usually highlighted during validations. In respect of the Biochemistry assays the vast majority of commonly requested tests covering GP work were changed from the Abbott to Roche analysers. The team are advised that:

> "As part of the comprehensive validation process, the Head of Biochemistry looked at comparisons between original reagents / methodology and proposed reagents / methodology and took a view on whether the methods gave comparable results, and whether any change required specific advice on method change and whether the proposed method was suitable to move to for routine clinical use"

A number of assays have been highlighted as potentially having problems since the transition, these include:

- Creatinine
- Albumin
- Vitamin B12
- INR
- HbA1C
- Potassium

As described, the Consultant Biochemist and Haematologist completed a detailed statistical method comparison for assays that had a change in methodology or platform in order to validate

the performance and clinical impact of the changes. This process identified that there would be some variability in results for a number of the assays but not of significant clinical impact when adjusted reference ranges were applied. This change in reference ranges was communicated from the pathology contract manager to the PCTs to be communicated onto GPs.

The communication was stratified as important - which indicates that there are changes to results interpretation (or changes in clinical practice required) which may affect patient care but not be of significant impact to a patient if not observed. This communication was not received by the GP communities in Brent and Harrow.

A number of the tests listed above are covered in more detail in the section looking at the impact on patients and practices.

In the period 20 December 2012 to 25 February 2013 TDL logged 33 incidents. These were investigated in line with their SOP, Incident Reporting and Management in Q-Pulse, this together with the SOP for the Management of Non-Conformity can be found at appendix 14.

Organisational factors impacting on the risk to the procurement and transition

Organisational changes during the procurement and transition were primarily due to the PCTs response to emerging national policy. The NHS White Paper issued in July 2010[vi] setting out the Government's long-term vision for the future of the NHS, signalled the coalition government's policy (subject to consultation) that GPs should lead commissioning and that by April 2013, GP commissioning consortia will be responsible for commissioning many of the services currently commissioned by PCTs.

In 2010/2011, NHS Brent and NHS Harrow went through re-organisation to take account of the management costs reduction required[vii]. On 1st April 2011, the North West London Cluster (NWLC) of 8 PCTs formed 3 sub clusters:

1) Inner: Kensington & Chelsea, Hammersmith & Fulham and Westminster PCTs,

2) Outer: Hounslow, Hillingdon & Ealing PCT and

3) Brent & Harrow PCTs (Brent & Harrow sub cluster).

The sub clusters started working with commissioners on how they could support GP commissioning, in advance of the Health and Social Care Act 2012[viii] passing legislation (the King's Fund provide a very useful summary and visual timeline[ix]. From April 2011 and as the Brent and Harrow Sub-cluster, Brent and Harrow operated as a single Board with six non-executive directors drawn from the Brent and Harrow PCT Boards.

In April 2012, the NW London Sub-cluster changed again to four PCTs for Inner NWL and four for Outer and which included Brent, Ealing, Harrow and Hillingdon (BEHH) in order to support the 2012 Shadow CCGs which were set up in October of that year, prior to them being authorised in April 2013.

An analysis that is available from the King's Fund[x] suggest that CCGs will differ from PCTs in two key ways (the first is very important in the context of this report). First, management resources will be lower for CCGs, and as a result of this more of their functions will be shared between CCGs or delegated to commissioning support services and other organisations. So the organisations themselves will be smaller than PCTs even if the population size they cover is comparable. In some cases the extent of sharing or delegation of commissioning functions may raise the question of whether the size of each individual CCG is the most important issue.

Second, while the degree of variability may be similar for CCGs and PCTs, the factors driving it could be very different. PCTs are administrative constructs, whereas the shape and size of CCGs has been influenced by a number of factors, including clinical flows, perceived 'natural' population groups, the pattern of professional relationships across a local area, and existing administrative boundaries. A CCG may be small (or large) for different reasons than those that determine PCT size.

With regard to the first key difference, the management resource is already lower in PCTs due to the three month shadow period before authorisation. This means that the work entailed in the transition from one organisation to another has to be carried out with a shrinking resource whilst still maintaining business as usual. Managers are leaving to secure permanent roles, interims are covering vacant positions, and the movement of key staff means an inevitable loss of capacity and organisational memory.

FINDINGS:

Chronology of events

Chronology (timeline) of events	
Date & Time	**Event**
12.12.12	TDL contract go-live date using a new IT system and new Equipment. Communication out to GPs to advise that largely, GPs would see no difference apart from improved performance which will become apparent over the next few months as the services bed in and alerting them to 3 key changes: 1. Reference Ranges – will change for a number of tests 2. Serum Folate – this test will replace the red folate test 3. Autoantibodies screen – this profile will be replaced with number of condition specific profiles. The full text of this email can be found at appendix 15 of this report.
17.12.12	TDL advised (subsequently) that issues with the new robotic software meant that some HbA1c assays remained un-analysed (samples taken on 12, 13, 14 December). Remedial action taken by TDL but not flagged to the PCT
20.12.12	A Brent GP raised concerns with the PCT to advise that the formatting of results had changed in such a way as to permit the filing of results into patient's notes without the pre-requisite clinical interface. An internal investigation was undertaken to look into this.
21.12.12	TDL laboratory staff noted that the post analytic sorting robot was filing incomplete assays as completed. This was not reported to the PCTs at that time because the scale of the incidents was not apparent to TDL at that time.
22.12.12	Senior TDL staff on site with BMS (Biomedical sciences)staff to investigate the post analytic robot issues that had occurred the previous day.
23.12.12	Roche diagnostics attended the NPH Laboratory to undertake an assessment of the post analytic robot issues of 21.12 12. The cause was found to be a software issue and remedial action taken. The PCTs were not alerted to this at this time.
02.01.13	The GP who raised the concerns about the filing of results on 20.12 12 contacted the PCT to advise of further issues: a) Results missing since 18.12.12 for one GP and 21.12.12 for another b) Samples returned and labelled too old despite being sent same day as taken c) Automated request forms being filed as origin unknown or identified as originating at the hospital d) Some codes had changed making it difficult to reconcile with QoF e) Some samples being filed on the NWL browser
09.01.13	The issue was logged as a SI on Datix and StEIS
10.01.13	COO of Brent PCT advised that the issues arising had been added to the PCT Risk Register.
10.01.13	A GP contacted TDL querying a low calcium result. This was investigated but was not conveyed to the PCTs at that time.
10.01.13	Another Brent GP contacted the PCT to advise of several issues with spurious results and missing results, some retrievable and some not.
10.01.13	A Brent GP advised that circa 300 results had been received by the practice and that many of them dated from October 2012. TDL later advised that it was due to corrective action due to database review.
10.01.13	Conference call between Brent COO, Operational Manager for Pathology contract and the GP who originally raised the alarm to agree responsibilities and timelines: 1. Urgent communication to all Brent GPs about the risk of missing pathology results with the way that results are currently communicated by TDL 2. Ensure logged on Datix and complete Root Cause Analysis

	3. Investigation to be undertaken 4. Meeting with Brent, Harrow and TDL to identify all issues relating to flow of pathology results and agree remedial action 5. Other issues raised (e.g. Community services access to results to be separately logged and investigated
10.01.13	Brent GP contacted LMC regarding the concerns of GPs and this was forwarded to the COO for her response and action and received on 11.01.13.
11.01.13	Harrow PCT were alerted to the escalating issues and asked to enquire if Harrow GPs were experiencing the same volume of spurious results, missing results and missing samples as the Brent GPs are reporting.
11.01.13	One Brent surgery undertook an audit of blood test results and identified: • Excessive number of spurious results necessitating patients to be re-bled • Confidence lost in the service; • Lost results particularly problematic for those practices with sessional doctors • Confusion as to which codes to use (GMC, GMP prescribing codes etc)
11.01.13	NHS Brent and NHS Harrow contacted all practices to advise of recent changes to the Pathology Service based at NPH in that the service provider was now TDL. GPs and Practice Managers needed to be aware of the following factors: a) Format of the report has changed to a single report issued rather than multiple reports per request b) Due to the bedding in of equipment and refinement of laboratory processes, there has been some delay. Practices would see some retrospectively reported results appearing over the following few days. c) Urgent meeting scheduled with TDL for the following week to address these concerns; a root cause analysis is to be undertaken and the concerns to date have been logged on Datix (as a Serious Incident) Contact details for the pathologists were appended to the foot of the letter, the full text of which can be found in appendix 16.
13.01.13	Brent GP reported Urinalysis shows unusual ACR/microalbumin TDL advised.
14.01.13	Harrow GP advised of problem with abnormal calcium and raised MCV levels. They queried this with TDL who re-ran 300 samples with many amended normal results.
14.01.13	Other Harrow GPs reporting problems with the laboratory service: a) Lab results collated in an unusual way and Vision website had become less functional; b) Spurious results and failure to process
14.01.13	One Brent GP advised wrong result on H. Pylori test – was sent report for a different patient (patient not positive at all, but negative)
14.01.13	Brent GP - HbA1c specimen inadvertently discarded in hard to reach patient.
14.01.13	The Chief Operating Officer (COO) of NHS Brent contacted the COO at NPH to see if they were experiencing problems with INR results. NWLHT advised that they too were experiencing issues with INR results.
15.01.13	The first meeting of the Root Cause Analysis (RCA) into the Pathology issues was held and included representation from NHS Brent, NHS Harrow, Brent and Harrow GPs, primary care managers from both CCGs, the contract manager for pathology from NWLHT, the local non-acute contracts manager, the Deputy Borough Director with a responsibility for pathology, Directors and managers from TDL and the IG manager from Brent and Harrow CCGs. Minutes can be found at appendix 3 of this report. Action points can be found in the Chronology of events at appendix 17)
16.01.13	A letter was sent to all GP practices from the Accountable Officer for NHS Brent and NHS Harrow advising of the outcome from the meeting (in appendix 16 of this report) A letter of apology from TDL was also included in the communication.
22.01.13	RCA meeting (2) held with CEO of TDL present (minutes at appendix 3 of this report and Action in Chronology at appendix 17)

29.01.13	RCA meeting (3) (minutes at appendix 3 of this report and Action in Chronology at appendix 17)
29.01.13	Format of results raised with CfH, EMIS and Vision (INPS)
05.02.13	RCA meeting (4) minutes can be found at appendix 3 of this report and Action points at appendix 17)
05.02.13	Clinical Safety teams in EMIS and Vision (INPS) alerted regarding format of results
05.02.13	GP in Harrow using Vision, flagged up to TDL that the grouping of his results did not make sense and asks TDL if this can be fixed. Advised TDL working with PCT to fix it.
06.02.13	CQC Inspector (1) contacted team regarding an issue raised with him by a GP
08.02.13	CQC Inspector (2) contacted team regarding conducting inspection of TDL Laboratory
08.02.13	Letter from MP to Accountable Officer of PCTs, seeking information and reassurance around patient safety following an alert from a constituent.
12.02.13	RCA meeting (5) minutes can be found at Appendix 3 of this report and Actions in Chronology at appendix 17)
13.02.13	GP in Harrow contacted TDL cc PCT and challenges the view that it is a Vision problem because never occurred before when working with NPH (previous system). Flags up a near miss where a grossly abnormal TSH was almost missed because it was received under a bulk FBC header and was so far down the screen that it scrolled off the page (copied to TDL). He was to ask Vision Helpline for their perspective.
13.02.13	TDL respond saying working with Indigo4. EMIS and Vision. National specification for these messages allows for multiple test sets to be sent in single messages. GP encouraged escalate to Vision.
15.02.13	GP IT Lead for Brent PCT advises that he has raised the issue with the Vision National User Group and others using EMIS. He suggests a high level alert be sent to all GPs in Brent and Harrow regarding due care and attention; to scroll to end of every list sent. He further suggests an interim safety measure (treating requests in bundles of no more than 3 sets) before a significant error occurs.
15.02.13	CCG Chair of Harrow raises his concerns about format of results and volume of erroneous tests still coming through; and courier service and high Potassium results.
18.02.13	Response to CCG Chair from Director of Quality and Safety re-affirming RCA process and report due to be published – but answering the questions raised.

Detection of incident

Please refer to the Incident description (p10) and Conclusion and Recommendations (53) for full details.

Care and service delivery problems

From the date of go-live, a number of issues presented themselves to clinicians as missing results, poor turnaround times and general poor quality of service provision. Specific issues that have caused difficulty in patient management include:

- Turnaround times, particularly noted by hospital clinicians in A&E and paediatrics;
- Un-reportable HbA1c results as a consequence of machine failure;
- Calcium results missing from some requests;
- A perceived increase in haemolysed samples;
- Second glucose results missing from glucose tolerance test requests.

Other symptoms of a problematic service transition were also apparent such as:

- High levels of incorrect Potassium results, either too high a value or too low;
- Calcium – excessive numbers of low calcium levels were reported by many GPs

- Unexpectedly low INR results with attendant problems with clinical management of the patient.

Incorrect abnormal results and differences in the reporting of results can occur in laboratories due to changing the analytical platforms. Assays can also be affected by various pre-analytical techniques e.g. phlebotomy and equipment used for the phlebotomy. All service related areas are susceptible to human and clerical error and laboratories are no different in this regard. Each area has now been thoroughly investigated and the following are advised to be the causative factors:

- HbA1c results – this was due to the failure of the robotic arm. Samples were compared across sites to perform a comparability check on the NWP analyser. There are reported to be no changes from the pre-transition analysers, reagents or staff running the analysers at NWP. A cross site check was performed in order to see if NWP analyser is reading high, as comments indicated that it was a significant new phenomena (full analysis at appendix 18).

- Calcium - abnormal Calcium results were due to a poor calibration of the assay on one line of the analyser. TDL have investigated with the supplier and this has been reported as such, which has now been modified so that this is unable to occur again.

- Haemolysed samples were due to the issues with transport and phlebotomy technique.

- GTT (second test missing) – was as a result of human error on the part of a laboratory technician who thought that the second test had been done.

- Potassium value is a more complex issue. The main causes of pseudo-hyperkalaemia in primary care are generally associated with the temperature and the length of time taken for samples being transported from primary care to laboratories[xi] and the method of venepuncture (see detailed analysis in Appendix 18).

  This has been confirmed by the Head of Department for Clinical Biochemistry at NWLHT who advises that the raised potassium results received by GPs is undoubtedly caused by the cold and is happening across the whole of Brent and Harrow. The problem is that it's very difficult to sort out the genuine raised potassium from the spuriously raised ones.

  The laboratories experience problems with high potassium results in the winter and the converse in the summer as the pump becomes more active if warmed up (attached at appendix 18 is some of the historical data in the form of power-point presentation).

- INR (low / high results) - The TDL and Consultant Haematologist investigation report into the low INR results and other laboratory related issues, concluded that the new analysers were functioning as expected. The causative factor is the changing of the reagent to a modern recombinant reagent, which has a different sensitivity to certain inhibitors.

  The Anti-coagulation Service staff at NWLH NHS Trust reported that since changing over to the new system their INR results on several warfarin patients have become inconsistent and previously stable patients have become brittle and erratic, needing changing warfarin doses.

- Vitamin B12 assays – the significance of the 9% drop in absolute values has been followed up with the Department's Clinical Biochemist and Technical Head of Department and the team are advised by TDL that this has no statistical significance.

- D-Dimer issues – this is a test that GPs as an aid to the diagnosis of deep vein thrombosis. There has never been a specific policy at NWLHT where a particular level of result would automatically be phoned. This therefore, will need to be addressed within the OMC meeting or contract review committee.

When interpreting laboratory results it is important to know that the sample was collected and handled correctly so this has implications for training on phlebotomy, including order of draw and storage. It is also thought that the introduction of ICE will assist phlebotomists in ensuring that requesting is more accurate as there is information to ensure the correct tests are being requested, the right tubes are being used and the request goes to the correct discipline (see appendix 19 for the benefits of the ICE pathology system)

Impact on patients

At the time of reporting, the evidence available to the group is largely anecdotal as there has not been a single report that a patient has come to any harm as a result of the issues with the pathology service, although as demonstrated, the potential for harm is there and many near misses have been reported. It is due to the diligence of GPs in the measures that they have taken to protect patients, that this has been the case.

The impact on patients in terms of repeat blood tests and the problems of clinical management for GPs cannot be underestimated. Patients have had to re-attend for repeated blood tests for haemolysed samples, and spurious or missing results, with attendant inconvenience, time off work and potential loss of confidence in the pathology service or GP service. One patient from a hard to reach group had to be recalled to re-bled but is unknown at the time of this report, whether they have attended.

The RCA team sent out questionnaires to practices across Brent and Harrow to elicit more precisely, what the impact was on patients and on the practices themselves (feedback from practices can be found at appendix 20). The following is an indication of the impact on specific patients:

i) Blood tests taken on female patient on 07.02.13 but results not received until 12.03.13 revealing Hb of 8.8 g/dL. By the time the results were received, the patient had had a further myocardial infarction (MI); repeat bloods 13.02.13 showed another drop in Hb necessitating admission to hospital. This delay in detection may have resulted in a further MI, but the GP advises that there exists no conclusive evidence.

ii) Patient had urgent ESR (for suspected temporal arteritis) taken and sent to laboratory in the morning. By evening, no report had been received and the lab technician advised that the sample was not processed even though marked URGENT and in an urgent labeled bag. The GP was advised that they had many samples to go through. Contact

with the laboratory next day, when GP was advised that the correct bottle had not been received although it had been confirmed with nurse at surgery that this had been sent. Patient had to be re-bled and result was received on this sample. Patient had to take high dose steroids empirically. No harm because GP ensured precautions taken.

iii) GP takes blood from 4 year old patient (can take up to one hour including local anaesthetic) ensured enough blood for ESR but results came back as 'not enough'. As CRP was normal, GP chose not to repeat blood test for ESR. No harm / inconvenience on this occasion. [NB GP flagged to TDL and found that the system was set up for different ranges as they had inherited 'normal ranges' from Ealing Hospital; expressed surprise not picked up before and will take up with colleagues at Ealing.]

iv) Raised potassium results:

a. one patient was sent to A&E for assessment after 2 raised potassium results where it was found that the actual reading was 3.6 (normal)
b. we are informed that one Harrow practice resorted to sending patients to the hospital for blood tests to bypass the courier service thus avoiding the problems with temperature control and delays in transport (see appendix 18 of this report).

v) Low INR could result in patients having the dose of warfarin increased with serious consequences. It is not thought that this was the case as the patients in question had had stable INR for a significant period and so the results were challenged and repeated.

vi) Low Vitamin B12 could result in inappropriate treatment over a significant period of time if this is a novel finding for that particular patient, and if appropriate measures were not taken by the GP.

vii) D- Dimer – this need to be included in the discussion about SOPs.

On another occasion it was reported that low Haemoglobin had not being phoned through to the GP surgery by the laboratory. The investigation showed that the message was not handed over securely to the day staff at shift changeover, which would have been the expected protocol. However, had the laboratory phoned the result out in line with the information available to them at that time, they would have contacted an out of hours provider who did not provide a service to that particular GPs surgery. This incident occurred as a result of human error and the communication about appropriate pathways for the laboratory to contact the correct out of hours provider on call was reviewed. It is a PCT responsibility to keep TDL appraised.

TDL were asked to undertake a Look-Back exercise. At the RCA meeting on 22 January 2013, it was understood to be underway. This entails reviewing all of the samples that they identified as not able to process and checking whether they had been requested to repeat the tests. This showed that approximately 40% had been repeated, so the other test results were batched by

practice and the practices contacted to ask if they intended to follow the patient up, or whether they had decided that this was not now clinically indicated.

The report received from TDL on 08 March suggests that contacting practices to chase samples not repeated to date, was to have taken place in the week of 11 March 2013. At the time of writing this report, we are still awaiting the outcomet from the Look-Back exercise.

Impact on Practices

The impact on practices can be presented in the following groupings:

i) Grouping of results and format of report
ii) Lost samples and reports
iii) Spurious results.

Grouping of results and format of report have been assessed as unsafe by the National Clinical Lead and further work is to be carried out in this area. The format could result in all of a patient's results being filed at the point when one normal result is archived. Abnormal results may be missed if a GP is not vigilant, and with potentially serious impact on the patient.

Lost samples and reports are time consuming as they result in the need to chase reports and repeat bloods, and this draws on already busy staff. TDL advised that these issues may be as a result of un-analysed samples or incomplete reports and that one cause of lost reports is that reports are unable to be returned to an unregistered doctor. It is therefore necessary for the CCG to keep the list up to date and appraise TDL, and to ensure codes are assigned to locums and non-medical requesters.

Spurious Results – results reported as Abnormal which subsequently are found to be normal, can result in adverse impact on the patient and the clinician. For the patient, they may be given unnecessary treatment or the inconvenience of the blood test being repeated and for the clinician it is the additional work load created for the practice.

Overall, for practices it is the anxiety caused by concern for the safety of the patient, the time and cost involved in chasing and repeating bloods and the loss of confidence in a service that GPs rely on for to carry out their work effectively. There is also the potential for patient records to contain incorrect information if the GP does not follow up with repeat bloods and which could cause issues when comparing results in the future.

Not all problems reported to the laboratory or the PCT as concerns regarding blood results, were TDL laboratory issues. It was found that patient details and clinical details had not always been entered onto the request forms and that receptionists had generated some reports that had not subsequently been verified by the GP.

There have been incidences where GPs have not received the laboratory results in their in-boxes. In one case, the reason for this was that the GP was switching over from EMIS LV to EMIS web and had therefore asked for the electronic links to be suspended for 24 hours. The results however, were placed on the NWL Browser which the GP could access. This particular case raises the issue of some abnormal results not being sent to a GP for a variety of reasons

but being placed on the Browser. The GP would then assume that these results are missing from their in-box and if the GP does not have the foresight to check the NWL Browser, then there is a potential for abnormal results not being acted upon.

There is another problem regarding results that the GPs may not be aware of, and that is when the patient has blood taken in a different location or by a different service. These results may not come back into the GP in-box if the originator is not identified as the GP practice. It is important that the requester takes full responsibility for the follow-up.

TDL have established a Helpline available 24/7 for contacting the laboratory. GPs have been advised of its availability but it is very rarely used. Most GPs continue to use the general pathology office telephone to raise issues like mis-spelt names and routine queries.

Courier Service

As the transportation of blood samples is considered to be the prime reason for high or low potassium, the team decided to look at the procurement for this service.

The courier service is a separate contract to the Pathology service and was procured through a separate tendering exercise. The PCTs have appointed the same courier organisation to run the service, Revisecatch Limited (Courier Systems) who were appointed in October 2012 for a period of 4 years and 7 months to tie in with the Pathology service. This company is working to the same specification as before so the problems that the laboratories and surgeries have experienced in the past are still evident today. The pathology service contract manager and many GPs pressed for the courier contract to include the requirement for temperature controlled transport.

The samples are transported by the courier system to the laboratory and it is variable in terms of how long it takes or how many pickups the couriers make in a round. They do have insulated bags but every time these are opened, cold air enters the bags. Quite often, the bags are overflowing when they arrive at the laboratory so it is thought that they may not have been zipped up. The bags are transported in metal panniers on the bikes and wind chill factor on the metal when the bikes are moving, cause the metals to be become very cold, adding to the chilling of samples.

Potassium leaks out of red cells if the temperature drops (probably below 15 C, though this may be patient dependent) due to reduced activity of the membrane pump which pumps potassium into cells and sodium out of cells. This also happens when there is a significant delay between drawing the blood and performing the analysis. The use of thermostatically controlled boxes was introduced into NWLHT in 2005 and remained in place until October 2009 when the work was outsourced to Courier systems. The NWLH laboratories now see the problem of high potassium results every winter, but this winter has been particularly cold, with prolonged spells of very low temperatures.

The RCA team is in possession of an email trail including comments from the procurement advisor to the PCT suggesting that the requirement that samples be transported in temperature

controlled containers, was akin to specifying 'anti-freeze for cars in Saudi'. As a result, the contract provides exactly the same service as before without any of the improvements that were required by GPs and NWLHT, however, included at section 1.14 of the service specification is the requirement for the contractor to:

'supervise and monitor the service to ensure service levels around pickup times, turnaround times, and delivery of all samples so that their integrity is not compromised (by time delay or adverse temperature) are maintained. NWLH and TDL will work with the Contractor to agree required temperature ranges and a process to monitor readings.'

Additionally at section 1.17 the following it is stipulated that:

'Couriers must transport samples in secure insulated storage boxes on their bikes so as to effectively moderate temperatures in extreme cold and hot weather conditions. The Contractor shall have the ability to be able to monitor temperatures, if there is deemed to be an issue with the temperature of samples, in order that this can be audited when / if an issue arises.'

This allows for the three trusts to insist on an audit of temperatures at any one time and detect problems with temperature fluctuation. It does not allow for temperature control.

During the specification development, the pathology contract manager provided support and suggested that the contract should ensure that all samples were carried in a temperature controlled environment, at a reasonable ambient temperature, to minimise the effect of temperature on the analysis of samples. This was not included in the service specification. The PCTs agreed a variation to the contract which required the contractor to have the ability to have temperature monitoring of storage boxes as set out in section 1.17 of the specification in the contract. Temperature monitoring does not give the same assurance as temperature control.

The CROs for pathology were to convene a meeting in late 2012 with the courier service. However, the contract was agreed in October 2012 so any amendments to the contract could not be made at that late stage because the decision on who to appoint would have been open to challenge. The issue of high and low potassium results due to transportation temperatures was still occurring in January 2013 when the pathology contract manager was again asked to assist. It was evident at that point that the contract had not yet been signed but the opportunity to enforce temperature controlled transportation was lost, however the principle stands that it is not possible to change the specification after Financial Closure of the contract.

The investigation team have been made aware that temperature controlled containers was excluded from the contract on the basis of cost. The clinicians were endeavouring to secure a better service to ensure elimination of spurious potassium results as a result of transportation, at the same time that the PCT management were insisting that the courier service be procured within the same financial envelope.

Since 2004, the number of potassium results ≥ 6.0 mmol/L has been monitored. The data for primary care can be seen in appendix 18 and shows a clear increase in the number of potassium results ≥ 6.0 mmol/L in the winter months. The findings also demonstrate a reverse pattern in the summer months, where the number of potassium results < 3.5 mmol/L increases.

Data since 2009 has been organised according to post-code/GP surgery and ~60 GP surgeries are monitored each month.

Visits to practices by NWLH laboratory staff in 2004, found a lack of understanding by phlebotomists about the extent of the sensitivity of potassium to cold temperatures. On one occasion during a visit to a GP surgery, samples were found by an open window, and on another occasion, samples were found next to an air-conditioning unit. The audit into high potassium results was repeated in January 2013 and a correlation drawn between the colder January weather and the increase in high potassium levels:

GP surgeries where the total number of potassium requests was less than 30 were excluded;

- the number of GP surgeries where the percentage of potassium results above 5.3 mmol/L (the upper limit of the reference range) exceeded 10% was 37 in 2013 (compared with 8 in January 2012);
- of the 20 GP surgeries with the highest percentage of potassium results >5.3 mmol/L (over 10%), 17 received between 13.7 and 19%; one had 21.8%; another 31.8% and one with 39.5% of results with spurious hyperkalaemia.

This suggests an urgent need to review and revise the courier contact, and this is included in the recommendations of this report.

Having verified that the high and low potassium values are not as a result of activities within the laboratory itself on previous audits, NWLHT has worked with practices to ensure that the phlebotomy process and storage of samples at practices prior to transportation, are suitable and have provided the necessary training. There is reference to training dating back to 2006-7 (Brent and Harrow) but the RCA team is unaware of any formal training to the GPs in Brent and Harrow.

Contributory factors

Individual (Staff factors)

- Some incidents within the TDL Laboratory are ascribed to human error
- High level of temporary staff (possibly not following safety procedures / due process)
- Staff TUPE transferred over to TDL with possible attendant dissatisfaction
- Disaffected staff and impact of results and loss of samples

Leadership

- Management reduction in Harrow PCT with loss of organisational memory
- Organisational memory; large number of managers involved in procurement / contract management
- Resources – managers and Clinical Directors unable to attend meetings due to workload
- Coming to end of transition from PCT to CCG will compound resource issue

Communication

- GPs were not aware of contract change from NWLHT to TDL
- No guidelines issued to GPs via PCT
- Changes to reference ranges not cascaded to wider GP community
- GPs not made aware of helpline numbers via PCT
- TDL not made aware of OOH Providers by practice
- Guidelines on Haematology and Biochemistry out of hours reporting are different
- Escalation process not communicated to GPs via PCT
- Not communicating effectively overall, even within the hospital trust and TDL
- Lack of update distribution lists
- Slow communication of issues

Organisational and Strategic factors

- Small number of GPs asked to be involved.
- Clinical Directors were invited to OMC and other meetings but did not attend due to other commitments
- Performance management of the contract was initially intended to be local contract manager
- Escalation: TDL although issues were escalated internally but not out to PCT
- Tardy response to issues raises by the GP community
- Organisational changes; Brent and Harrow two separate entities, then one and two again.
- Level of Assurance given to Accountable Officer in the way that the contract is set up
- Two different providers for Pathology and Courier service
- Lack of GP engagement – structure of reporting within PCT does not facilitate dissemination of information and capture of feedback

Team Factors

- Three organizations involved in the commissioning of the contract – no accountability matrix
- Governance arrangements: mobilisation, transition, implementation without GP involvement

Equipment and resources

- Robotic Arm malfunction and changes from Abbott to Roche (analysers)
- Changes to reagents used which may have affected test results
- IT system – hardware and software affected results formatting (National Standard Format)
- Both IT and Equipment changed over to new systems at the same time
- Testing – who was involved / what did it entail / did it include Vision and EMIS
- TDL testing of IT system within 3 practices was not what was expected (i.e. screen shots)
- No training / guidance on switch over – i.e. the changes to visual display, reference ranges

Root causes

- No measures taken by PCT to mitigate risks (in transition and implementation)

- IT system – Format of Results / IT systems and sample handling set-up;

- Equipment - Analyser and robotic arm malfunctioned / General Equipment stability;

- Communications and access to background information
  (Shared Drive, electronic and paper records will be affected by the transition from PCT to CCG);

- Lack of clinical engagement in the process
  (no grass roots GPs; used same clinicians, too thinly spread);

- Poor reporting and communication structure in both PCTs.

- Laboratory staff familiarisation with equipment and systems / customisation of system to meet end users clinical needs

Notable practice

With the change of contract to a different service provider, new equipment and systems were introduced. The Laboratory at NWLHT is now organised much better, offering an automated service and a better working environment for staff.

Shift patterns have been revised; the previous shift system that operated before could mean that urgent results to be phoned out at around that time that staff changed shifts and could often be missed as a result of the handover.

GPs in Brent and Harrow were very vigilant and took action to mitigate the risk of harm to patients as a result of these issues. They queried test results that were out of the 'norm' due to their knowledge of their patients and their actions have resulted in near misses rather than actual serious harm.

It is understood that TDL and NWLHT consultant pathologists undertook various measures including a detailed action plan (still awaited from TDL) in order to address issues and ensure sustainability of solutions.

Lessons learned

1. Patient safety should be the first consideration of any new service procured on behalf of the residents of Brent and Harrow;
2. TDL / NWLH should alert GPs immediately to issues arising in the service that would impact on patient care;
3. Effective leadership is required to oversee and coordinating the commissioning process
4. Communications need to more effective and timely within CCG and out to primary care;
5. Contract monitoring and performance management meetings need to be held regularly;
6. There needs to be an open and transparent process in commissioning new services with grass roots GP involvement;
7. PCT/CCG needs to respond quickly to concerns raised by clinicians;
8. Clinical representatives should have the capacity to attend meetings;
9. At a time of rapid change there needs to be management continuity and effective handover;
10. Effective alert mechanisms need to be in place immediately;
11. Temperature control of pathology samples is required to avoid future problems due to temperature fluctuation.

Post-investigation risk assessment

A Potential Severity (1-5)	B Likelihood of recurrence at that severity (1-5)	C Risk Rating (C = A x B)
4	3	12

CONCLUSIONS and RECOMMENDATIONS:

The Root Cause Analysis Investigation that was undertaken found that despite the procurement being discussed and subsequently carried out over a lengthy period (over 2 years), this was not widely known amongst GPs or non-executive directors. The latter were unaware of the detail of the procurement and when the paper seeking appointment of preferred bidder was presented in September 2011, sought assurances that the provider was able to deliver a safe and effective service. GPs on the two board subgroups for Brent and Harrow, had also highlighted concerns about the risks involved in the transition of the service from one provider to another, and thought that there would be a risk analysis undertaken of potential issues to take forward into the OMC.

Whilst there was appropriate senior management, clinical and commercial input into the procurement and evaluation of bids, from the appointment of the preferred bidder onwards, the input into the transition and monitoring of the contract was inadequate, given the financial value of the contract. The senior manager for the procurement, left at around the time of the contract award and since that time there has not been any senior management overview or input into the transition, implementation or monitoring of the contract. The PCTs were involved in the risk assessment undertaken on the procurement, but were not aware of the risk assessments undertaken for the transition period by NWLHT and TDL, nor did they undertake their own risk assessment of the service transition and implementation.

Recommendation 1 – There should be strong and consistent senior management of future procurements in order to ensure continuity of knowledge and input. The CCG should also ensure appropriate senior management of the end to end process as well as the continuing input of clinical expertise into the transition, implementation and monitoring of the contract.

Recommendation 2 - The financial aspect of the procurement is important but should not be allowed to overshadow the need to ensure the patient safety. All future service changes, procurements, QIPP schemes and so on, should always require risk assessments to be undertaken at all stages, and should include risk management and monitoring of identified risks, particularly through transition.

There was no input from primary care (GPs) or the PCT, on the transition board for the project. The Operational Management Group (OMC) was established and held three meetings that were not quorate because no GPs were present. It is thought that this is because there are very few GPs within the CCG body and they were faced with an enormous workload. The constitution of the CCG is such that very few GPs are mandated to represent the wider GP community and there is the potential to engage more grass roots GPs in the business of the CCG.

Recommendation 3 - The CCGs should consider how GPs could be more involved in the work of the CCG to add capacity and expertise to the few GP CROs who are finding difficult to discharge their responsibilities due to a heavy workload.

Regarding performance management and contract monitoring, it is not clear whether the unavailability of the nominated representatives was flagged up as an issue to the PCT but this was clearly a risk for the PCTs and TDL, and limited the availability of the primary care perspective on the service and sharing of information out to primary care. More importantly, it did not achieve buy-in and ownership of the service which would have been key to early resolution of the problems experienced in December 2012 to January 2013, and the CCG should be encouraged to engage grass roots GPs more in the business of the CCG.

Recommendation 4 - The CCGs and NWLHT should establish as a matter of urgency, the pathology Operational Management Committee with appropriate, consistent, clinical representation. It is suggested that there is a need for wider engagement from general practice into the work of the CCG.

Recommendation 5 – The CCGs should look to implement the NHSL Direct Access pathology performance indicators and should engage the contract manager more in technical contract support to support the discussions around this.

The procurement was to have provided improved access to pathology services for primary care via the order comms rollout (ICE). This is in place within the hospital service, but has not yet been rolled out across primary care despite the funding being identified at the time of the appointment of the preferred bidder it is thought that this is no longer available. However, at the RCA meetings, TDL have offered to fund the roll-out of ICE, and the supporting training programme.

Recommendation 6 - The order communications solution for GPs is not yet in place. TDL have offered to fund ICE and the supporting training. It is suggested that the roll-out of ICE and the supporting training programme should be implemented as soon as practicable.

Communication was an issue within the PCTs and out to primary care. The CROs for pathology from Brent and Harrow were unaware of the agreed communication process between the service provider, the PCT and GPs. Information flow via emails to key personnel in the PCT was therefore, an ineffective way of communicating with practices, as there was an assumption that someone else on the circulation list was dealing with cascading the information. The system that relied on messages to be sent to the locality coordinators and then onwards to practices was cumbersome and did not allow for staff absences. There were also concerns about how up to date the distribution lists were as they only list the principal GP rather than all relevant GPs.

Recommendation 7 - Overall, the communication to GPs should be improved and they should be consulted through their locality groups if necessary, on how best this may be done. A lot of the issues that arose during the service transition and after, could have been managed far more effectively had the communication to and from GPs been more robust. The establishment of the OMC will greatly assist in two-way communication between GP practices, the PCT and TDL.

It is not surprising therefore, that GPs remained largely unaware of key changes within the pathology service; important changes to the pathology service / Notifications were not sent out to GPs, and TDL did not have the correct list of Out of Hours providers for GPs in Brent. TDL were not aware of the out of hour's providers for the GPs in Brent and there was confusion about the use of 111 for urgent care. There were also concerns expressed by GPs about results being sent to an unknown box.

Recommendation 8 - The CCGs therefore, should ensure that GP lists are kept up to date and notified to TDL on a regular basis.

Recommendation 9- There needs to be clarity around OOH and the 111 service and this should be confirmed to TDL and updated as and when it changes.

Recommendation 10 - The issue of codes for locums and other authorised requesters should be addressed as soon as practicable.

There were already issues with some test results, although not on a large scale. On the 10 / 11 December, TDL switched over to new equipment and a new IT system at the same time which compounded existing problems. The switch over was communicated out to GPs but using the mechanism previously described which was ineffective. The presentation of results (due to the change in the IT system) and missing and spurious results (due to equipment such as the robotic arm and the calcium analyser) therefore, were of concern to GPs who were unable to understand what the issue was.

TDL should have been aware that if one abnormal result had been issued, it was likely that the rest of the batch would also be affected. They concentrated on resolving the issue and using their internal escalation procedure to move samples to another laboratory, but did not alert GPs or the PCT that there was an issue. They were therefore, very slow to respond to concerns and it was not until the first RCA meeting that the PCT and GPs became aware that calcium samples were being performed at another laboratory. Some problems were also ascribed to human error and the staff involved has been re-trained or have left the organisation and new staff recruited.

At the RCA meetings, TDL agreed to undertake their own internal investigation and a report was received by the team in early March, and whilst this addressed the technical aspects of what went wrong, it is very light on detail around some aspects of the problems experienced by the GPs. There is also a lack of acknowledgment of what went wrong and of learning from this.

However, TDL took appropriate interim measures when issues began to arise. These measures were of good effect in that the issues presenting to GPs began to reduce reasonably quickly, as represented by the number of queries and complaints received from GPs Quality Control was undertaken hourly until the service was assured that the equipment malfunctions were resolved.

Recommendation 11 - TDL should ensure timely communication to the PCT and GPs about future issues as they arise and continue to take interim measures. They should also ensure that they alert GPs and the PCT using the agreed protocol.

Recommendation 12 – TDL should ensure that regular updates are provided to the three commissioning organisations at the OMC, including for subsequent service changes and to flag up any issues arising that might impact on the service to patients.

Some GPs have expressed concern that particular results have not been communicated to them in a timely manner and have been advised that no protocol is in place for this. The SOPs used by TDL are based on the Royal College of Pathologists guidelines and were largely the same SOPs that were in place when NWLHT provided the service. The procedure for reporting abnormal results out of hours are different for the Biochemistry and Haematology services. The threshold for phoning results out is different to GP expectations and it will be beneficial for TDL to undertake a review of Standard Operating Procedures to align with user's expectations in both acute and primary care.

It has been agreed in principle that GPs, Consultants and TDL should work together to agree a RAG rating system based on communication that is Critical (changes to results interpretation or changes in clinical practice required which may directly cause harm to a patient if not observed); Important (changes to results or changes in clinical practice required which may affect patient care but not be of significant impact to a patient if not observed) or For Information (a minor change to result interpretation or clinical practice that will not result in patient harm if not observed).

Recommendation 13 – A working party be established between TDL, consultants and GPs to agree what should be phoned out and when. As tests change and guidelines change, then this forum must ensure an on-going dialogue.

A key concern for GPs has been the presentation of patient results and the ability to file all results in patient's notes when just one result is archived. This has been the case since the change over to the new IT system and despite assurances from TDL (in their report of 08 March 2012) that this is not a laboratory problem, that they are compliant with national standards and that this is a national issue, the DH Informatics team sent a representative out to a practice to understand what the problem was. They share the team's concerns that this is unsafe, as is the grouping of results, and have therefore offered to escalate this nationally.

Recommendation 14 - The CCG should pursue the offer from the National Clinical Lead of an enquiry into the matter of the National Standard format of results, and the grouping of results.

The main causes of spurious raised potassium blood results in primary care are generally associated with the temperature and the length of time taken for samples being transported from primary care to laboratories and needs to be addressed as a matter of urgency. A small, but contributory factor to spurious potassium results is thought to be the method of venepuncture, order of draw and storage of samples prior to transportation, which suggests that there is a training need for phlebotomists.

Recommendation 15 - A separate piece of work should be undertaken with the Courier service to ensure that temperature control of samples is put in place rather than periodic temperature monitoring.

Recommendation 16 – GPs should receive update training from the pathologists at a future educational session and relevant training should be provided for all phlebotomists.

The RCA process in dealing with a multi-incident investigation has been very time consuming, and due to the timescales associated with StEIS / Datix, reporting has been time limited. There been a slow response to data requests and / or an unwillingness to be involved in the issues, across all of the organisations involved. Within the PCT, there have been many changes in managers responsible for the procurement and on-going monitoring so this investigation has not had the attention that it deserves; added to which, files and key documents have not been readily available.

Recommendation 17 - Organisational change is a key theme of the NHS and there is a need to ensure learning from previous errors and ensure adequate management, leadership and resources, should the CCG undertake QIPP, service change and procurements in the future.

Recommendation 18 – RCA investigation teams should have a mandate to investigate. Future RCAs need powers of investigation, and dedicated time and resources.

Distribution List

Accountable Officer, Brent, Ealing, Harrow and Hillingdon CCGs.

CEO, The Doctors Laboratory.

Deputy Chief Operating Officer, North West London Hospitals Trust.

Chief Operating Officer, Brent CCG.

Chief Operating Officer, Harrow CCG.

Director of Quality and Safety, Brent, Ealing, Harrow and Hillingdon CCGs.

Chair of Brent CCG.

Chair of Harrow CCG.

Head of IT and Communications Lead, Brent CCG.

CRO Pathology, Brent CCG.

CRO Pathology, Harrow CCG.

This report should be available on the CCG website and GPs alerted when it is uploaded.

Action Plan

	Action 1	Action 2	Action 3
Root CAUSE	**Measures not taken to mitigate risk; Lack of access to key information**	**Poor reporting and Communication**	**IT system caused format changes**
EFFECT on Patient	Service efficacy may be compromised; impact of time spent on remedial action	Important information not reaching GP; patients may need to be recalled etc.	Results may be filed without clinical overview with impact on clinical management of patient
Recommendation	**1, 2 3, 17,18**	**3,7,8,9,10,11,13**	**4, 6, 13, 14**
Action to Address Root Cause	○ Ensure adequate senior resource into future procurements / service changes ○ Ensure Risk Assessment of transition and implementation and action taken ○ Involve more GPs in the process ○ Ensure continuity of leadership through organisational change; ○ Ensure systems to archive relevant information are available and used; ○ Handover documents to be sufficiently detailed to ensure continuity; ○ Improved communication to GPs	○ Improve Communication Process within CCG and out to GP community ○ Secure input of GPs to key decisions on service changes to be secured – consider how to Involve more grass roots GPs ○ Improve communication to service providers e.g. up to date GP lists ; codes for locums and non-medical requesters ○ ensure clarity of 111 and OOH services communicated to relevant stakeholders ○ Working party to review SOPs and service issues for pathology (applicable across).	○ The OMC should be established urgently and ensure relevant input from GPs and Senior CCG management ○ Input into CRC from the above group for continuity and information transfer ○ Continue Dialogue with National Clinical Lead and GP System providers about GP systems and national standard format of results ○ Ensure ongoing dialogue with TDL regarding SOPs and other service changes (SOP forum)
Level for Action (Org, Direct, Team)	**Organisation**	**Team lead by relevant senior manager**	**Team lead by relevant senior manager**
Implementation by:	**Senior Management Team / COO**	**Primary Care Team lead by relevant senior manager**	**Primary Care Team lead by relevant senior manager**
Target Date for Implementation	**Ongoing**	**Communication review by end June 2013** Involvement of GPs to be agreed by CCGE **Working Group set up by end May 2013**	**OMC and CRC by end of April 2013** Dialogue re systems ongoing to September '13 **Working Group set up end May and ongoing**
Additional Resources Required (Time, money, other)	**Senior Management capacity and overview**	**Time and staff resource required**	**Time and relevant resources to be freed up to implement**
Evidence of Progress and Completion	**Risk Assessment of future procurements, QIPP etc are undertaken** Entries of risks are entered into the programme / Corporate Risk Register	**Communication protocols agreed, in place and evidenced as working** Involvement of GPs discussed at CCGE and minutes reflect decision **Working group set up and to involve GPs**	**OMC and CRC are operational and have appropriate input** Calendar of meetings with National Clinical lead **Working Group established and meeting regularly with majority of group present**

	Action 1	Action 2	Action 3
Monitoring & Evaluation Arrangements	**Audit of Risk Register and procurement / service change documentation** Archived documentation available to successor organisation; **Corporate memory available – at least through transition;** Communication and GP involvement – see Action 2. **Availability of relevant documentation on shared drive;** Audit of documentation / minutes.	**Communication protocols evidenced** Communications received by relevant parties in a timely manner **Minutes / notes of working group**	**Minutes of OMC and CRC available** Evidence of action by National Clinical Lead (national enquiry established etc) or change in presentation of results **Minutes of working group available and outputs evidenced.**
Sign off - action completed date:	**Ongoing but with audit of next 3 procurements / QIPP projects**	**Deputy Borough Director (Primary Care and procurements) by end July 2013**	**Deputy Borough Director (Primary Care and procurements) to October 2013 for IT** **OMC and CRC ongoing**
Sign off by:	**COO / CEO**	**COO**	**COO**

	Action 4	Action 5	Action 6
Root CAUSE	**Equipment Failure, incorrect assays; Laboratory staff familiarisation with equipment and systems / customisation of system to meet user's needs**	**Lack of engagement in process**	**Pseudo Hyperkalaemia (spuriously raised potassium)**
EFFECT on Patient	Delay in processing results and / or receipt of inaccurate results; inconvenience of time taken out of day and of being re-bled	Service quality standards not monitored; no action to improve / develop service to GPs; sub-optimal contract monitoring	Delay in taking appropriate action; inconvenience for patients if re-bled
Recommendation	**12, 16**	**1,4, 5, 17**	**15**
Action to Address Root Cause	**Action taken by TDL to process bloods elsewhere in interim whilst functionality of equipment restored / as necessary;** Staff training to continue as needs identified or systems change **Support primary care in training on venepuncture and input into GP educational sessions**	Establishment of OMC and CRC **Senior management overview of end to end process of procurement / QIPP** Relevant clinical input and continuity of same **Involve Contract Manager in technical contract support and review of KPIs (incl. NHSL Direct Access Pathology Indicators)** Regular updates to CCGE and CCGGB	**Arrange meetings with the service provider (Courier Systems Ltd);** Separate group to be set up to review courier service contract and ensure temperature controlled environment; **Training to be provided on drawing and storage of blood prior to transportation** Pathologists to input into GP educational sessions as requested
Level for Action (Org, Direct, Team)	**TDL Directors and Pathologists / CCG contracting and Primary Care teams**	**CCG Clinical Directors and Operational Managers / CSU with local support**	**Contracting and Primary Care Teams / Pathologists NWLHT**
Implementation by:	**TDL**	**Clinical Directors** **COO and DoF**	**SRO / Deputy Borough Director / Pathology contract manager**
Target Date for Implementation	**QC by TDL - as agreed internal process unless requires escalation, ongoing;** Training for staff / training needs analysis – ongoing **Training to begin June 2013 and ongoing for primary care.**	**Involvement of contract manager via OMC and CRC by end of April 2013 / ongoing;** Resource for Local support to CSU in monitoring contract to be identified by 12 April 2013; **Dialogue with CSU regarding contract by 19 April / agreement by 30 April 2013**	**Meeting by mid April 2013** Courier Group to report by end of May 2013 **Training to begin June 2103 and ongoing as required.**

	Action 4	Action 5	Action 6
Additional Resources Required (Time, money, other)	**Time of key people** **Staff resource and time for training**	**Relevant people able to attend all meetings – staff resource;** Expertise to monitor contract.	**Senior Management and other staff support – time and money;** Staff resource and time for training
Evidence of Progress and Completion	**Updates on QC available from TDL at OMC meetings – minutes taken;** Training undertaken of staff as required	**Documentation of key services to evidence appropriate input or minutes noting escalate to CCG GB and Updates to CCG GB ongoing;** Involvement of contract manager via OMC and CRC minutes; **Local support to CSU in monitoring contract is identified and in place;** Revision of KPIs to include NHSL Indicators under discussion by end of May 2013.	Meetings of group to review courier service set up and minutes available by end of May 2013; **Training schedule agreed by relevant training providers by end of May 2013.**
Monitoring & Evaluation Arrangements	Minutes of OMC meeting to reflect**:** **Escalation procedure used effectively in future equipment failure;** Training delivered / certified competent.	**Audit of documentation and minutes;** Contract monitoring reports to QSCRC and CCGE / GB	Discussions with Courier minuted **Working Group established and to report by end of May 2013** Timescale for resolution - end of May 2103
Sign off - action completed date:	**TDL / Pathology Contract Manager / CCG SRO - ongoing**	**Deputy Borough Director Primary Care / contracts. End of June 2013**	**Deputy Borough Director Primary Care / contracts. End of June 2013**
Sign off by:	**TDL - Director of Service Compliance** **CCS SRO**	**TDL - Director of Service Compliance** **CCG - COO**	**COO**

Appendices

Appendix 1 – NHSL Direct Access Performance Indicators

Appendix 2 – Timeline of Procurement

Appendix 3 – Minutes of RCA Meetings

Appendix 4 – Communication meeting minutes

Appendix 5 – Fishbone diagram

Appendix 6 – Target outcomes of procurement

Appendix 7 – Risk overview of Procurement

Appendix 8 – Blood Sciences Timeline

Appendix 9 – Contract Key Performance Indicators

Appendix 10 – Communication and escalation procedure

Appendix 11 – Notification of changes to pathology service

Appendix 12 – Terms of Reference and membership for Contract Review Committee (CRC) and Operational Management Committee (OMC)

Appendix 13 – Agenda for meeting on 12 October 2012

Appendix 14 – TDL SOP for Non-conformity

Appendix 15 – Email of 12.12.12

Appendix 16 – Letter from Accountable Officer and TDL following first RCA Meeting

Appendix 17 – Full chronology of events during RCA

Appendix 18 – HbA1C analysis; Calcium analysis; Potassium analysis and powerpoint; Potassium survey and results; and INR analysis.

Appendix 19 – Benefits of ICE pathology systems.

Appendix 20 – Feedback from GP practices.

Glossary

ACR / microalbumin – Albumin Creatinine Ratio test on urine. An important prognostic marker for kidney disease.

Assay – an analysis or a test

B12, Folate and Ferritin – estimation of iron stores in the blood.

BAFO – Best and Final Offer, part of the tendering process where only selected bidders are asked to submit their best technical and financial proposal.

Biochemistry – biological chemistry that studies the chemical processes within and relating to living organisms.

Blood Sciences – refers to haematology, chemistry and blood transfusion

Cerner Millenium – HP/Cerner partnership as a supplier of healthcare information technology systems.

CfH – NHS Connecting for Health is part of the Department of Health Informatics Directorate.

Chairs action - the Chairperson is taking the decision and having it effected, without calling a meeting of the Board of the organisation.

COO – Chief Operating Officer

CPA – Clinical Pathology Accreditation (UK)

CQC – Care Quality Commission

CRC – Contract Review Committee

CRO – Clinically Responsible Officer

Cytopathology – a branch of pathology that studies and diagnoses disease on the cellular level.

Datix – software for risk management and client safety. Used to record and monitor Serious Incidents.

D-DImer – test that GPs use as an aid to the diagnosis of DVT (deep vein thrombosis)

EMIS – Clinical system used by GPs (used in Brent and Harrow in LV form and web form)

End to end – all the elements of a given process within one system. i.e. Pathology and courier service – gives more control to reduce errors.

ESR – erythrocyte sedimentation rate measures inflammation in the body

GTT – Glucose tolerance test to check how quickly glucose is cleared from the blood. Previously the gold standard test to diagnose diabetes mellitus.

H Pylori – helicobacter pylori (a bacterium).

Haematology – the diagnosis and treatment of disorders of the blood and bone marrow

Haemolysed – the disintegration of red blood cells with the release of haemoglobin (the iron-containing oxygen transport of red blood cells)

HbA1c test – a test that is now used to diagnose diabetes and also to monitor diabetic control.

Histopathology – microscopic examination of tissue in order to study the manifestations of disease.

ICE – Integrated Clinical environment, is a web based service that allows pathology requests to be made from wards, clinics and GP surgeries.

Indigo4 – data integration for the NHS; supplier of messaging and Ordercomms. Clinical data repository.

INR – International Normalised Ratio; measures prothrombin rate (coagulation of the blood).

IVD – In vitro diagnostic medical devices must be registered with the Medicines and Healthcare products Regulatory Agency (MHRA) UK

KPI – Key performance Indicator; helps define and measure progress towards a specific goal.

MCV – mean cell (corpuscular) volume for assessing iron and vitamin deficiency.

MHRA – Medicines and Healthcare products Regulatory Authority is government agency with a responsibility for ensuring that medicines and medical devices work and are acceptably safe.

Microbiology – is the study of microscopic organisms either unicellular (single cell) or multi-cellular (cell colony, or acellular (lacking cells). Includes virology, mycology, parasitology and bacteriology and so on.

NWLHT and NPH – North West London Hospitals Trust and Northwick Park Hospital

OMC (OMG) - Operational Management Committee (sometimes referred to as the Operational Management Group). It is a sub-committee of the Contract Review Group.

OOH and 111 – Out of hours GP on call services and 111 service which is the new 3-digit telephone service that is being introduced to improve access to urgent care services. Patients use the number when they need medical help or advice and it is not urgent enough to cal 999.

Ordercomms – electronic requesting; see ICE

Pathology – is the study and diagnosis of disease through the examination of organs, tissues, bodily fluids and whole bodies (post-mortems / autopsies).

PCT / CCG – Primary Care Trust /Clinical Commissioning Group (successor organisation).

POCT – Point of Care Testing (near patient testing) is medical testing at or near the site of patient care.

Preferred Bidder – the bidder selected by the vendor, using pre-determined criteria, as being the party to whom it intends to award the contract the service.

Q-Pulse – is an internationally recognised quality, safety and risk management system for an organisation.

Quality Assurance – is a series of management activities to ensure that a process, item or service is of the type and quality needed by the user. It is one part of the quality system.

Reagent – a substance or compound that is added in order to bring about a chemical change to see if reaction occurs. Bromocreosol (purple) as a reagent is an indicator of albumin.

Reference Ranges – or reference interval describes the variation of measurements of value in healthy individual.

Risk analysis – includes risk identification and assessment, and risk management to mitigate, reduce or remove risks.

Root Cause Analysis – is a systematic investigation technique that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which the incident happened. (RCA Toolkit - National Patient Safety Agency ***www.npsa.nhs.uk***)

SLA – Service Level Agreement is part of a service contract between provider and customer that specifies in measureable terms, what services will be provided.

SRO – Senior Responsible Officer

StEIS – Strategic Executive Information System is a web-based system developed by the Department of Health in 2002. It contains a Serious Untoward Incident module to which Trusts and CCGs add data and which allows the Strategic Health Authority to access information directly.

Sub cluster – North West London is a cluster of 8 PCTs. These have variously been grouped in a 2,3,3 formation and 4,4 formation known as subclusters.

TaT or Turnaround times – the time that it takes to perform the task and deliver the output.

ToR – Terms of Reference describe the purpose and structure of the committee.

TUPE – Transfer of Undertakings (Protection of Employment) regulations protects employees' terms and conditions of employment when a business is transferred from one owner to another.

UK Pathology Harmony project – funded by the Department of Health, this initiative was set up in 2007 to work towards harmonisation in UK pathology laboratories.

Vision (INPS) – GP clinical system (In Practice Systems)

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