

Inform Health & Associates
Innovation & Transformation

**A review of the Laboratory
Information Management System
outage at Leeds Teaching Hospitals
NHS Trust**

October 2016

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1.0 Executive Summary

- 1.1 The Telepath Laboratory Information Management System (LIMS) has been at the centre of Laboratory management at Leeds Teaching Hospitals Trust and at the predecessor organisations since the early 1980's.
- 1.2 On Friday the 16th September 2016 the Telepath LIMS suffered from a significant failure. A call was logged with Computer Sciences Corporation (CSC) the same day (CSC is the provider of the Telepath system). Much of the onsite work is provided by Specialist Computer Centres (SCC) who act as a key sub-contractor to CSC.
- 1.3 The cause of the failure was a mixture of hardware / technical failure and human error. There had been a failure to check the completeness and integrity of the back-up processes together with a failure to recognise and act upon visual hardware warnings following the successive malfunction of three of the disks in the array. The situation was further compounded by the unavailability of a full back-up copy that would have allowed the system to be restored.
- 1.4 Following this failure, and the inability to restore normal pathology services to patients within Leeds Teaching Hospitals, Bradford Teaching Hospitals and the surrounding GP community the Trust established a 'Silver Command' in order to formally manage the situation in accordance with the Trusts Emergency Planning procedures.
- 1.5 As a result of this significant disruption, and as part of the Trust's Business Continuity plans, contact was made with a number of other hospital laboratory services in order that samples could continue to be analysed and results returned to those making the requests. Arrangements were put in place by the Trust to transport samples to the receiving laboratories as well as transport the results.
- 1.6 The Trust maintained communications through-out this period with service users and with NHS England who received formal notification of this 'internal business continuity incident.'

2.0 Introduction

- 2.1 Leeds Teaching Hospitals NHS Trust is one of the largest teaching hospitals in Europe, a regional and national centre for specialist treatment, a world renowned biomedical research facility, a leading clinical trials research unit and also the local hospital for the Leeds community and nearby surrounding areas. The Trust, with an annual turnover in excess of £1.2 billion provides local and specialist services for an immediate population of 780,000 and regional specialist care for up to 5.4 million people.
- 2.2 The organisation employs more than 16,000 people across 7 West Yorkshire based hospital sites. The Trust believes that the future of healthcare is about building seamless integrated services, supported by specialist providers when people need them. The Trust have progressive and well established relationships with local health and social care partners to provide seamless care for patients between primary, community and secondary care services and are committed to driving forward integrated care in Leeds to ensure that these pathways continue to develop.
- 2.3 The Trust is committed to empowering and investing in staff and allowing them the autonomy and freedom to deliver safe, effective and personal healthcare for every patient, every time. The Trust also delivers leading edge innovation, achieves academic and educational excellence and constantly pushes the boundaries in healthcare, innovation and research.
- 2.4 The desire to innovate and modernise is equally evident in the Trust's Pathology and Laboratory services where state of the art technology is doing much to improve the efficiency, accuracy and quality of sample management and result reporting.
- 2.5 Leeds Teaching Hospitals has embarked upon an ambitious programme of IT enabled modernisation in partnership with primary and secondary care providers, the mental health care providers and the Leeds Local Authority. As well as making significant improvements to the internal and external technical infrastructure the Trust is also looking to establish its Electronic Patient Record programme around its current PPM offering, Order Communications and Clinical Decision Support applications in order to deliver the targets contained within the 5 year forward view.
- 2.6 However like many acute hospitals in the English NHS there are examples in Leeds Teaching Hospitals where information systems are reaching 'end of life' or where significant investment is needed to bring them up to modern day standards. One system that may be included in this category is the Laboratory Information System (Telepath) which suffered a significant failure on the 16th September 2016.

3.0 Background

- 3.1 The Telepath Laboratory Information Management System (LIMS) has been at the centre of the Laboratory management at Leeds Teaching Hospitals Trust and at the predecessor organisations since the early 1980's. During this period pathology services at the Leeds General Infirmary were merged with pathology services at the Bradford Royal Infirmary and more latterly pathology services on the St James Hospital site. The Telepath system whilst being initially developed as the Trent system was later acquired by iSoft Ltd and more latterly by The Computer Sciences Corporation (CSC).
- 3.2 The Telepath system is predominantly provided out of the Pathology Data Centre on the Leeds General Infirmary site and covers all Laboratory disciplines including, Biochemistry, Blood sciences, Blood transfusion, Cellular Pathology, Immunology and specialist tests. The Leeds service currently provides this comprehensive range of Consultant led and laboratory based services to inpatients and outpatients in Leeds and Bradford, 106 General Practices in Leeds as well as a providing a tertiary service for specialist tests to a much wider catchment population. This equates to the receipting, processing and reporting of approximately 17,000 samples per day making it one of the busiest laboratory services in the UK.
- 3.3 Departmental systems albeit providing Trust wide services across the 7 Leeds hospitals have for many years been managed by dedicated teams within those departments. Leeds Teaching Hospitals like many other large Teaching institutions exhibit a preference to have their critical systems managed by local IT services rather than by the Trust corporate IT service. The Telepath system is no exception to this and as such is predominantly managed by a dedicated team of Pathology based IT staff. Traditionally those colleagues now managing the Telepath system began their professional careers as Medical Laboratory Scientific Officers (MLSO's) and Biomedical Scientists developing their interest in computer science alongside the automation of laboratory services from the mid 1970's to present day.
- 3.4 Currently the Telepath system is supported by a diminishing number of dedicated personnel. The various laboratory disciplines in the main have someone responsible for IT as a key point of contact for system management and administration. However it is well recognised that over the years key posts have been lost and not replaced along with associated corporate memory of a 30 year old system. At the moment the Pathology IT service has responsibility for the local network and infrastructure management, business intelligence, report writing, user accounts and passwords.

- 3.5 Administration and management of the Telepath system is mainly an “in hours” operation across a 5 day week. The Pathology IT team do not offer an ‘out of hours’ service including any ‘on call’ provision. Currently some of the laboratory disciplines, Blood Transfusion for example, do not have a dedicated IT resource / key point of contact and as such there is a requirement to share and obtain this support from elsewhere in the Laboratory. Back up routines are managed locally by the Laboratory team on a nightly basis; processes are in place to electronically alert the Pathology management team that a ‘back up’ has taken place.
- 3.6 CSC is the prime contractor for the delivery of the support for the Telepath system. Whilst CSC provides the software support it subcontracts the hardware support to SCC on a break and fix arrangement. Some aspects of this support are ‘backed off’ to SCC who as an agent of CSC, provide most of the on-site support. At the end of June 2016 CSC / SCC had been on-site to assist with replacement of the cache battery. Batteries are often replaced by either new or re-conditioned batteries or a mixture of the two. The cache batteries have been replaced several times in recent years.
- 3.7 The automated ‘back-up’ of the Telepath system begins at midnight and runs for several hours. The system backs up to a disk array (RAID10) with disk 1 copying to disk 2 as a mirrored pair. This disk to disk back-up is overwritten every 24 hours. A second back-up however is designed to make a copy of disk 2 thereby providing the longer term backup of several months. The RAID10 arrangement and the associated 11 disks are more than 10 years old having been installed in 2006. The nightly disk to disk back-up runs a simple routine in that it uses an alphabetic algorithm with which it sequences the order of the laboratory departments. Biochemistry for example would come before Haematology.
- 3.8 On Friday the 16th September 2016 the Telepath LIMS suffered from a significant failure. A call was logged with CSC at 12.30 hours.

4.0 Method

- 4.1 All the information contained within this report was collected through a number of un-structured interviews with colleagues from internal and external organisations.
- 4.2 A site visit was undertaken to the Pathology department on the Leeds General Infirmary campus together with an inspection of the Pathology Data Centre.
- 4.3 Colleagues from CSC were invited to participate in the process but preferred to complete their own root cause analysis which they would be happy to share.
- 4.5 All the information provided was offered voluntarily by those attending for interview. Interviewees were reminded of the confidential nature of the process but were offered no guarantee that the contents of this report would be non-attributable. (no recordings were made of any interviews only hand written notes).

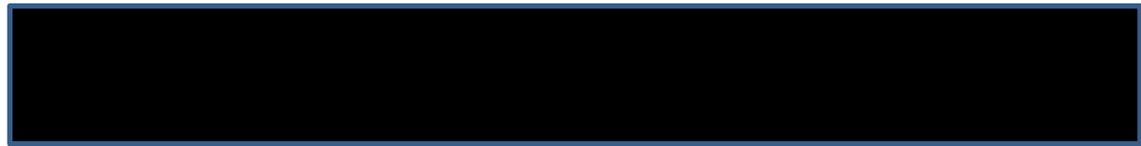
5.0 Key Findings

- 5.1 On the advice of CSC the pathology IT department staff were advised that the Telepath System should be re-booted once every six months as a means of removing minor bugs and glitches. The re-boot was scheduled to take place around midday each day and indeed did take place for many years. At some point during 2014 the system re-boot was moved from lunchtime to early in the morning as clinical colleagues were aware of deterioration in performance of the system during the re-boot process. This was affecting their ability to continue with outpatient clinics over the lunchtime period. In order to accommodate this, the second back-up described in section 3.7 was subsequently moved to an earlier time.
- 5.2 Over time (probably years) the duration of the first back-up had become extended and prolonged due to the continuous increase in the size of the Telepath data base. As a result, in 2016 the time taken to run the first back-up was likely to exceed 6 or more hours when originally the same process may have taken only 3 hours. It would appear that the Pathology IT team were not aware of the extended back-up routine. As such when the time of the second back-up was moved to an earlier time staff were not aware that the first back-up was still running. In fact the second back-up started and finished before the first back-up finished. This is illustrated in the diagram below. A disk to disk backup was taken each night and an email was sent if errors were detected. The Weekly tape backup did not send emails but relied on someone checking the backup logs.



In response to the A to Z back-up routine the second back-up only captured a limited amount of data from the first back-up as the diagram above clearly shows. As a result departmental titles that appear early in the alphabet such as 'Archive' and 'Biochemistry' are likely to be contained within the second back-up while departments appearing later in the alphabet like 'Microbiology' and 'Training System' are likely to have been missed by the second back-up altogether.

- 5.3 Pathology system downtime was organised early in June 2016 in order for a SCC engineer to replace the cache batteries. This was carried out in conjunction with CSC on the telephone and the SCC engineer on-site who physically replaced the batteries. It is believed that both batteries were changed in the presence of a member of the Pathology IT team.



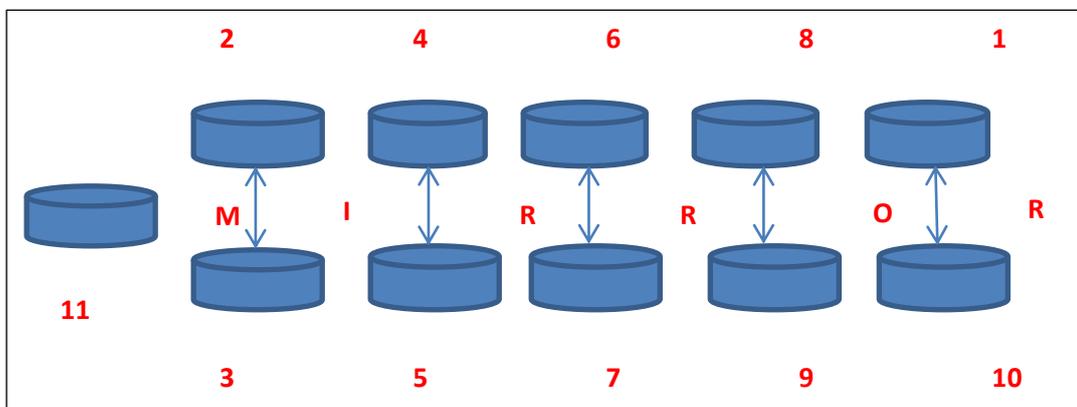
The disk log requested on the 20th September indicates that disk 9 failed at 16.57 on the 2nd August 2016. The log also indicates that disk 6 failed at 07.43 on the 11th August 2016. Disk failure is currently not reported remotely or electronically but would be noticed by close and regular inspection of the disk array on the front of the Telepath server. The photograph below indicates the position of the warning lights which turn from green to orange in the event of a disk failure.



All members of staff are expected to check status lights whenever the Data Centre is entered. This is not a part of the formal daily routine or the responsibility of specific individuals. The Pathology IT team have responsibility for the Pathology Data Centre.

Following the incident on the 16th September a paper checklist, located inside the Pathology data centre, is used to record the names of all those who enter. Upon inspection (12th October), the data centre was clean and tidy and generally in good order. All warning lights were visible.

On the 16th of September at 10.40 disk 7 failed. The failure of Disk 6 and Disk 7 resulted in a loss of the mirrored pair which in isolation would not have led to a system crash. However as previously reported Disk 9 had also failed on the 2nd August thereby removing all the resilience that a RAID10 system would normally provide. The diagram below helps explain this: (When disk 9 failed disk 11 would maintain the integrity of the array. When disk 6 failed, integrity would be maintained but without any resilience. When disk 7 failed a mirrored pair was lost causing the system to crash.) Losing two disks on the opposing sides of the mirror corrupts the other disks in the set, frustrates the relationships between the disks and ordinarily would potentially remove or significantly limit any opportunity to 'roll back'. The failure of three successive disks over a seven week period may on the one hand be explained by the age of the disks all being similar, but on the other hand it would be acknowledged that three disks failing across a seven week period would be highly unusual.



- 5.4 At noon on the 16th September 2016 members of the Pathology IT team entered the Server room and found three flashing orange lights indicating that three disks had at some point failed. Contact was made with CSC who was subsequently able to confirm that the failure event was as a consequence of a hardware failure (3 disks). There was an assumption by some members of the Pathology IT team that CSC were actively monitoring the performance of the disks using remote access tools. It has however since been confirmed that the contract between CSC and the Trust does not include the monitoring of hardware. The replacement parts were ordered and a delivery time was agreed. Pathology and Trust IT staff were now aware of the issues and communications were extended to the onsite management team, wards and departments. It was agreed that Trust and Pathology IT teams would reconvene early on Saturday the 17th of September (all those involved at this point fully expected to have the system restored by Saturday evening).
- 5.5 SCC was present on-site being supported by CSC on the phone and with remote connection to the Telepath system. Support was also provided by colleagues from the Trust IT department who offered telephone advice

through-out this period. The on-site SCC engineer replaced one disk and waited a period of time (10 - 15 minutes) to see if the array would begin to copy data to the new disc and rebuild itself. This did not appear to happen as indicated by the lights on the drives and confirmation of the CSC engineer who was observing remotely. The SCC engineer then replaced the other two disks one after the other. The rest of the process was uneventful. However when requesting the back-up files in order to run the restore it became apparent that the back-up file was incomplete (the reason for the incomplete back-up file is described in section 3.2). Communications were in place through-out this period to ensure that all members of the Pathology IT team and all members of the Trust IT team were aware of the situation. Conversations were also ongoing between pathology IT staff and the Trusts on call management team and Clinical Site Managers.

5.6 On Sunday 18th September it became apparent that finding a simple solution was going to be extremely challenging and that continued disruption to the Pathology service was likely. It was agreed that the inability to provide electronic pathology results to the Leeds Teaching Hospitals, Bradford Teaching Hospitals and the respective GP communities was a business continuity incident and as such 'Silver Command' was convened at 11.00 on the Sunday morning. Director to Director contact was established between the Trust and Bradford Teaching Hospitals and the Trust and the CCG. The meeting of Silver Command on Sunday 18th September involved everyone who had any connection or interest in the incident. Out of this meeting emerged 4 approaches which were:-

- **Complete restore** (At some later point this option was dismissed because of the inability to restore from an alternative back-up file.
- **Rebuild the system** (Which would have required access to clean images of the different Laboratory disciplines and a multi-agency approach)
- **Use Halia and Order Communication system** (This would have reduced the reliance on Telepath and possibly have provided a means to distribute results)
- **Send samples to other hospitals** (In doing so there would be reliance on their technology to distribute results)

The 4 approaches describe in the main (with the possible exception of option 4) 3 different aspects of Disaster Recovery (DR) which may have helped the IT teams prioritise their work and maximise their focus.

The on-call management team took advice on DR (the 4 options) but also focussed predominantly on maintaining safe patient care by providing a Business Continuity (BC) response. The Emergency Planning Advisor was

present and witnessed all options being addressed by the appropriate teams ie. DR by the Informatics team and BC by the On-call management team.

5.7 Having recognised that the nature of the outage was likely to be prolonged Trust staff focused their attention in four main areas. These were:-

- Patient Safety
- Ongoing Communications
- Restoring the system
- Transporting samples to other hospitals and coordinating the provision of results

5.7.1 **Patient Safety** – A Joint Decision Model was used in order to preserve patient safety and reduce harm as a result of this incident. The five step model is oriented towards:- 1) Gathering information and intelligence about the incident, 2) Assessing risks and developing a working strategy, 3) Considering powers, policies and procedures that may be relevant to the incident, 4) Identifying options and contingencies and 5) Taking appropriate action and reviewing the effects of the action. The five steps all contained a number of actions relevant to that stage.

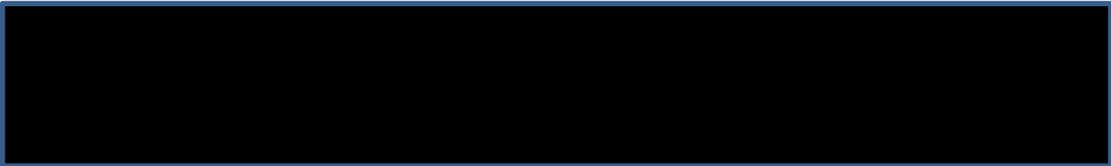
5.7.2 **Initial Communications** - External stakeholders were aware of the situation over the 17th and 18th of September. Representatives from both Bradford Teachings Hospitals and the Leeds CCG were represented at the Silver command meeting and some of the other subsequent meetings. It was confirmed that as with LTHT that Bradford Teaching Hospitals had a Business Continuity plan in place reasonably quickly in that they reverted to paper and had urgent results phoned through to the department requesting the test.

5.7.3 **Restoring the system** – Due to the alphabetical order of the back-up previously described variable amounts of usable back-up data were available for a successful restore across the various laboratory disciplines. A number of the 'restore' attempts caused the system to crash again between the 16th and 23rd of September. A number of back-up files were identified and associated with different time periods from 2010 to present day. This has allowed a 'piecemeal' approach to system and service restoration suggesting inconsistencies across the laboratory disciplines in relation to storage and retention procedures. For example:-

- Biochemistry - Back-up available from 14th December 2014
- Microbiology – Back-up available from May 2010
- Blood Transfusion – Back-up available from September 2016

- 5.7.4 There is some evidence to suggest that there is an expectation that not only would the Trust take responsibility for Disaster Recovery but that it would equally have responsibility for Business Continuity when the Pathology service became disrupted on the 16th September.
- 5.8 On an annual basis the Trust submits an Information Governance return to NHS England using the national toolkit. (IGT) The Trust currently scores 82% across all reported areas and has a 91% level of compliance with Information Governance training. The 2015/16 version 13 score of 82% is slightly above average and as such compares favourably with the other acute hospital Trusts in West Yorkshire. The Trust also provides regular training for Information Asset Owners a part of which covers the need to provide information system back-up routines.

6.0 Conclusion

- 6.1 The cause of the failure of the Telepath LIMS on Friday 16th of September is a mixture of hardware / technical failure and human error.
- 6.2 Whilst the Telepath system still provides a valuable service, continues to have a reasonably large UK user base and is well known to pathology IT professionals, it is old, difficult to maintain and is probably in need of replacement.
- 6.3 Changes to Pathology system administrative and managerial responsibilities over time have resulted in insufficient oversight of system performance.
- 6.4 
- 6.5 The System and Data Centre Pathology IT support team failed to recognise a number of warning signs that contributed to the critical incident on the 16th September.
- 6.5.1 Failure to check the completeness and integrity of the second back-up
- 6.5.2 Failure to recognise that the back-up times had become misaligned due to the size of the database and the adjustment of the second back-up time in 2010
- 6.5.3 Failure to recognise and act upon the amber warning lights following the failure of disk 9 on the 2nd August and disk 6 on the 11th August.
- 6.6 To ensure patient safety, Silver Command assumed overall responsibility for incident co-ordination and response with advice from Trust IT and Pathology IT teams on Disaster Recovery.

7.0 Recommendations

- 7.1 The majority of the recommendations made in this report align directly with the key findings detailed in section 3 and the conclusion in section 4. In conducting the interviews week commencing the 10th October it became apparent that some of the recommendations had already been considered and implemented. It is recommended that Trust Officers assure themselves of this as part of a separate exercise.
- 7.2 The recommendations
- R1 The Service Level Agreement (SLA) that describes the managed service currently provided by CSC / SCC should be reviewed and strengthened where required. The Trust must be assured that the level of service covered by this and similar contracts is adequate and that they do not expose the Trust to any unnecessary risks.
 - R2 All contracts with external service providers must contain a statement of compliance with regard to adherence with Standard Operating Instructions (SOI's) covering the major aspects of work for which the third party is responsible / liable.
 - R3 The Trust should work closely with CSC to seek confirmation that the successive failure of three disks in the RAID 10 array was indeed coincidental and not something more sinister that could reoccur in the future.
 - R4 Where possible system back-ups should be part of a centrally managed process. Regular checks (daily) must be in place to ensure that back-ups are complete and are capable of running a full restore. This process should be extended to all critical systems across the Trust or at the very least the major departmental applications.
 - R5 A clean image of the current version of the Telepath operating system and application across all laboratory disciplines must be retained and stored off site. This process should be extended to all systems across the Trust or at the very least the major departmental applications (critical systems).
 - R6 A system must be in place with immediate effect to accurately the names of those entering any of the Trust's data centres as well as all the activities that took place during access periods.
 - R7 Electronic alerting and warning systems must be in place to ensure that all those who have responsibility for data centres, system back-ups and electronic storage receive automated assurance that back-ups are intact and complete.

- R8 Large Departmental systems, their associated networks and data centres should be managed within the structure of the corporate Information Management & Technology Service. Current members of the IT Pathology team who spend more than 50% of their time managing information systems should equally move to the corporate service. This principal should also be applied to the other large departmental systems that have dedicated resources within their structures. This may include Clinical Imaging and Pharmacy.
- R9 The Trust corporate IT team should work with the Pathology IT team and Primary Care system suppliers (EMIS and SYSTM ONE) to understand how technology can provide a more cohesive solution to recognise the relationship between Practices and the hospital providers of Pathology services. The NPeX (X-Lab) may offer some Lab to Lab connectivity options that the Trust would find useful.
- R10 In relation to R9 the Trust should also re-examine any Memorandum of Understandings or reciprocal arrangements that it has in place with other NHS providers to take account of critical system and service failures in the future. Included in this review should be any system or service that relies heavily on technology.

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9.0 Acknowledgements

9.1 The author wishes to thank the following for contributing to the content of this report:

