WEST HERTFORDSHIRE HOSPITALS NHS TRUST

BUSINESS CASE FOR A REPLACEMENT PATHOLOGY LABORATORY
COMPUTER SYSTEM

1. INTRODUCTION

Pathology services play a critical role in the effective treatment and care of patients, in protecting the public health and in national screening programmes.

Pathology laboratories are constantly under pressure to maintain and improve quality in the face of increasing workloads and difficulties with staff recruitment and retention. As part of this drive to enhance the patient journey by maintaining and improving patient safety and reduce turnaround times, automation of result reporting is now accepted as a crucial part of this pathway. A fully integrated pathology patient record is essential if the broader benefits of centralisation, and to support the Acute Admissions Unit within a Trust seeking Foundation status, are to be achieved. In order to deliver rapid reporting and rapid access to results, which are accurate and easily accessible, it is imperative that the laboratory computer system is efficient and cost effective.

West Hertfordshire NHS Hospitals Trust, (WHHT) have a need to replace their pathology laboratory computer system in the near future due to the impending expiry date of the system. Support for the current system runs out in 2010.

2. EXECUTIVE SUMMARY

This Business Case (BC) identifies the need to replace the computer systems supporting Pathology - Laboratory Information Management System (LIMS) - services at WHHT. It evaluates potential options for meeting the future requirements in terms of costs, benefits and risks, and recommends a preferred approach. The financial, procurement and project management implications of moving forward are also considered.

In 2002 a business case was prepared, for the replacement of the LIMS at WHHT, which was installed in 1990. By the end of the 2002, the Bedfordshire and Hertfordshire Pathology Network had been formed and the project was extended to the four Trusts involved. This project was superseded by the pathology tender project, which was initiated in 2006. The Trust recently made a decision to withdraw from the tendering process, resulting in a requirement for the organisation to revisit
the need to replace the current pathology computer system. This is linked to the investment needs supported by the Board when considering WHHT’s position in relation to the tender project.

The case for replacing the pathology laboratory computer system is based on the need to ensure that:

A. Pathology can support the re-configuration of clinical services and “new ways” of working within the Trust to achieve rapid reporting and rapid access to results to fulfil the requirements of the Acute Admission Unit and the centralisation of acute services. A fully integrated pathology patient record is essential if the broader benefits of centralisation are to be achieved.

B. Functions that are already computerised continue to be supported. For several functions, staff are no longer able to follow manual-only procedures for the volume and range of investigations undertaken routinely. Together, these issues mean that a modern pathology service must be computerised.

C. Pathology services are responsive to changing demand.

D. The LIMS must be able to support rapidly changing technologies, which are nationally driven.

E. To support a modern Pathology Service within the Trust seeking Foundation status.

The pathology services covered by this BC are Blood Transfusion, Chemical Pathology, Haematology, Immunology, Microbiology, Histology and Cytology. Pathology is sited on the three Trust sites with an additional histopathology laboratory on the Mount Vernon Hospital site.

3. BACKGROUND

The Trust’s Pathology services have been operationally dependent upon computer systems for the last 19 years and they are among the most complex computer applications in the Trust. Without computers, a modern pathology service could not function, as evidenced by:

- The spread and complexity of functions currently supported. For several of these functions, staff are no longer able to follow manual-only procedures for the volume and range of investigations undertaken routinely.
- Dependence on automation to support the current high levels of productivity.
- Several national reports emphasising the key role of computers in current laboratory practice.
- Clinical Pathology Accreditation (CPA) requiring minimum levels of computerisation and associated support arrangements, and considering the use of computers as a key element of the accreditation process.
- Requirement for rapid data extraction to support Trust targets.
- The requirement for complex statistical analysis for clinical, managerial and financial reports.
There are high levels of automation in some areas, with many medical device interfaces (MDI’s) and some foreign system interfaces (FSI’s). This dependency underlines the need to minimise risk associated with current systems. There is, however, considerable scope for further integration and automation.

Laboratories across the Trust share a common computer system, which is Cerner Corporation’s HNA Classic pathology system, encompassing all pathology disciplines. Although the current systems are perceived to be robust and comprehensive, they fall short in terms of current requirements and future needs and are not based on a modern technical architecture. The Trust’s current computer systems have been replaced by the supplier with more modern applications and Cerner are encouraging users to migrate to a more modern product, hence support and further development for the existing systems is time-limited. Due to a declining user base and diminishing product development, this support is only guaranteed to satisfy the Trust’s requirements until 2010.

The current system requires that all advances such as links with General Practice and computer-based results reporting have had to be configured separately for each system, and because of the age of the systems, these links continue to present problems in terms of functionality.

The current Pathology system does provide information to a central data store which enables clinicians (with future plans for this to be rolled out to GPs via the Order Communications project) to find and review individual Pathology results. This is an in-house development referred to as Intranet Results Reporting System (iRRS). However, there are intrinsic weaknesses of the current set-up.

The Trust’s pathology service is experiencing growing workload pressures from increased volumes of requests. Activity is forecast to increase generally by 4% per annum across all the pathology disciplines.

There are also pressures for reduced turnaround times for tests, whilst resources and staffing levels are more-or-less static. Furthermore, staff recruitment and retention is a significant problem within Pathology. Application of advanced technology systems, as various national studies have identified, could help further automate and streamline services, addressing this gap between demand and supply.

One of the main drivers for updating functionality in the Trust’s Pathology Computer system, are that different parts of the pathology service need to respond to specific national initiatives beyond the general modernisation and efficiency requirements. For example, improved infection control procedures and new mechanisms for reporting of communicable diseases are required; new barcode standards designed to modernise blood and blood product labelling; full specimen tracking is required and the need to continually audit all aspects for the pathology service.

4. STRATEGIC CONTEXT
The national strategy for information stresses the need for integration, collaboration and sharing of information and IT matters. In relation to electronic communications there are specific targets pathology regarding, especially links to local GP practices, as well as the need to integrate information and functions within a trust-wide Electronic Patient Record (EPR). Some of the Trust’s current systems architecture is now considered outdated and inflexible in relation to the requirement for high levels of integration. This highlights a need for the Trust to ensure that systems are fully compatible to support a move towards electronic communications and the EPR.

Failure to address the above issues will lead to increased risks to service continuity, difficulty in addressing the NHS modernisation agenda and inability to comply with national targets and standards. The prime objectives of the proposed change, therefore, are to:

- Ensure continuity of existing services;
- Improve aspects of direct patient care;
- Enhance service quality;
- Support greater accountability;
- Provide the flexibility to meet service changes, new and future requirements.

National Programme for Information Technology (NPfIT) has been established to facilitate and support the programme of changes to clinical practice, which are currently underway in the NHS. It is a 10-year programme, which will eventually deliver comprehensive and inclusive patient information to clinicians when and where they need it to effectively treat patients. A major part of this programme will be the delivery of the Integrated Care Record Service, which will bring all components (including Pathology data) into a single electronic record. The key to achieving this is strict adherence to standards, which have been set by NPfIT, and to which all future implementations must comply.

Under NPfIT, the Health Service in England has been divided into 5 geographic clusters. Each cluster has contracted with a Local Service Supplier (LSP) to provide a range of IT services. WHHT is part of the East of England cluster. The LSP for this cluster is Computer Sciences Corporation (CSC). Their key supplier of systems and functionality is Isoft. Within each cluster there are ‘core’ Information systems which are specified for future provision within the NHS and these are provided by the LSP under the terms of the contract.

Pathology systems are not part of the core component within the cluster and may be purchased from any source, not necessarily our LSP. However, any purchase must be compliant with NPfIT standards. Each of the 5 clusters in England have their own preferred suppliers with different allies, but all will be required to comply with the national specification for systems.

As Pathology systems do not form part of the core information system requirement, there is less of an imperative to either develop a system, or stipulate the preferred cluster supplier on NHS Trusts. Therefore, providing the selection of a new system ensures that there is either an immediate NPfIT solution or a robust plan to move...
towards appropriate NPfIT integration, it is appropriate to consider solutions other than that offered by the local Cluster provider.

5. REQUIREMENTS

The Trust requires a modern, flexible, fully functional NPfIT, HL7 compliant IT solution, capable of being interfaced both to the current Isoft PAS system, and to Lorenzo, when available, as part of the National Programme. The system should be capable of interfacing seamlessly with other systems such as PMIP, DAWN and IRRS, as well as a wide variety of analysers and equipment. Modules must be fully functional in supporting the work of all clinical laboratories, be intuitive and easy to use, flexibly configurable and capable of results reporting on a variety of stationary forms as well as electronically. Inbuilt quality checking systems are essential. The system must be robust, with full service and 24hr support available, and an assured development pathway for the future.

Hardware Requirements:

- Central Server(s)
- Print Server(s)
- An appropriate numbers of Standard Workstations and Enhanced Management Workstations Networked Report Printers (Laser) to replace Dot Matrix where appropriate.
- Optical scanning of Request forms to enhance usefulness of system.

Software Requirement:

- Appropriate Core Software Licence(s)
- A minimum of 270 User Licences
- Appropriate Management Reporting Module Licence(s)
- Additional software licences (e.g Reflection)

Third party software requirements:

Additional software is required either as functional elements, or to interface with existing analysers and software for interfaces such as:

- Analyser interfaces
- Links for data warehouse
- Interfacing to PAS
- Results reporting links (Revive)
- GPLink (PMIP Nationally Approved Solution - excluding middleware costs)
- Cancer Registry (Uni-directional Results Download)
- Dawn AC interfaces
- Cosurv Interface (Uni-directional)
- FHSA Interface
- Cyres

6. OPTIONS APPRAISAL
Based on the local requirement and the national strategy for IT, a number of options have been considered and these are outlined below.

A. Do Nothing i.e. continue with current systems.

B. “Upgrade” i.e. Upgrade to the Cerner Millennium product.

C. Single i.e. Procure a single replacement solution for all disciplines, from a single supplier.

D. Mixed i.e. Procure separate replacement applications from different suppliers according to their fit with each discipline's requirements (so-called best-of-breed).

Non financial options appraisal

Option A is not feasible, as it cannot meet the requirements associated with modernisation. The hardware, operating system and software will be an unsupported platform in 2010. As defined in the Keele Pathology Benchmarking programme there are only two other sites in the UK running the Cerner Classic system.

Options B is not feasible as this would be the procurement of new system under the Trusts Standing Financial Instructions so would fit into option D.

Options C is and would enable the Trust to market tests commercial systems in both quality and financial terms.

Option D is not feasible as it is considered to bear very high costs and high risks, especially those arising from the integration of different components from different suppliers.

Financial options appraisal overview

Option A is cost neutral however the Trust would not have a supported LIMS system after 2010.

Options B and D have been discounted – see section above.

Option C would require a formal tender process. The work of the now disbanded Bedfordshire and Hertfordshire Pathology Modernisation Board that looked at the cost of replacing the pathology computer system for the whole network in 2006 was reviewed. The cost of a replacement of a pathology system in a comparable multi-site neighbouring Trust was looked at. It is projected that the indicative cost of a new system for WHHT would be in the region of £3.2M. To achieve the successful completion of this project the project manager will be required to spend 9 months to 1 year dedicated to this work. There is a requirement therefore to backfill this post at a cost of £58K. This cost together with the cost of interfaces, laboratory staff backfill and technical support for implementation are included in the indicative cost given above.
The £3.2M is in excess of the £1.4M allowed for in next year’s capital under “Pathology Future Plans” and the forecast of £2.5M stated on the paper presented to the Trust Board in June 2008. This reflects the developments required in the neighbouring Trust’s system. The figure does not take into account the current national economic climate or trends in the computing market in last 3 years. True costs can only be established as part of the Tender exercise.

7. PREFERRED OPTION

It is accepted that there is some considerable clarification required to identify the precise costs. Given that the requirement to replace the current system with a new one, it is imperative that the new system must be clinically viable.

- It must be the preferred clinical solution for the Pathology.
- It must been fully evaluated and has demonstrated positive functionality
- It must deliver an effective compliant system which will minimise the disruption to the service
- It must demonstrate the ability to integrate with the Trust’s current legacy PAS system and new proposed systems.
- It must provide relevant reports and evidence for accreditation purposes and a variety of clinical, management and financial data requirements

The preferred option is Option C.

8. AFFORDABILITY

The replacement of pathology systems across all disciplines in the Trust represents a substantial management challenge. Key issues to address are:

- Affordability and effects on prices
- Project management
- Benefits realisation
- Risk management
- Future Proofing

Affordability is linked to the investment needs supported by the Board at a Trust Board meeting during 2008. It is expected that the costs will be within the envelope of £3.2M.

9. RISKS AND ISSUES
Risk is a major factor to be considered during the management of the Project. Project Management procedures will be designed to control and contain risks and to provide opportunities for risk identification, analysis and management.

The replacement of the computer system has been on the risk register since July 2008 - Datix number 1629 (ref 105682) – with a score of 20.

The major risks are:

1. Support for Current system will cease in 2010
2. Loss of connectivity to other systems
3. Inability to support Trust, PCT and external client clinical work.
4. Inability to achieve rapid reporting and rapid access to results to fulfil the requirements of the Acute Admission Unit and the centralised acute services.
5. Inability to support management and financial systems
6. Affordability
7. Time line sufficient for procurement and implementation process
9. Could compromise Foundation status

Risk will be managed as follows:

Planning - identifying the resources needed to carry out the required risk avoidance/minimisation activities, reflecting the activities in detailed plans and gaining management approval.

Resourcing - planning the resources required to carry out risk avoidance/minimisation activities.

Assigning - ensuring that the responsibility for managing risk, is assigned to appropriate individuals or groups.

Monitoring - checking that planned actions are having the desired effect on risks, watching for the early signs that risks are developing and predicting potential new risks;

Controlling - taking action to ensure that risk avoidance/minimisation activities actually happen.

Specific Risk management activities will be undertaken by the Project Board and the Project Manager. The Project Board's responsibilities will include:

♦ notifying the Project Manager of any external risk exposure to the project;
♦ making decisions on the Project Manager's recommended reactions to risk;
♦ striking a balance between levels of risk and the potential benefits that the project may achieve;
♦ identifying "owners" for individual risks.
The Project Manager will be responsible for ensuring that planning, resourcing, monitoring and controlling activities are undertaken appropriately and that the Project Board is properly apprised of risk status.

Risks are frequently common across projects and benefit from being centralised at programme level. Problems can also result from an inconsistent approach being taken by related projects. For this reason, the Trust will adopt a standard approach to Risk Management across the projects, which form its EPR Programme.

To achieve the successful completion of this project the project manager will be required to spend 9 months to 1 year dedicated to this work. There is a requirement therefore to backfill this post at a cost of £58K.

10. BENEFITS EXPECTED

The main benefits will be:

1. A modern sustainable system for the 21st Century. Supporting all local services.
2. Ability to connect to other application on the National Framework.
3. A system to support the new configuration of pathology with separation of acute and non-acute work at different sites.
4. Allow the introduction of technological advances in pathology
5. Support better turn around times and through put
6. Will allow for service expansion and new business
7. Allows for future proofing
8. Support the acute services of the Trust
9. To sustain CPA accreditation
10. Compliance with current national legislation and regulation in relation to data protection
11. Would support Foundation status

Benefits realisation will be actively managed as a key part of the overall implementation project. This will ensure that responsibility for monitoring and achieving benefits is assigned to appropriate individuals or groups and that progress on benefits realisation is communicated to the Project Board.

11. TIMESCALES

See project plans below.

12. KEY RESPONSIBILITIES

Detail:

a. Executive responsible Russell Harrison – Director of Delivery
b. Divisional Manager  Sally Tucker – Clinical Support

A project board has been established in order to prepare and evaluate options for the production of this business case, together with the intention to steer the project to final implementation through the support of an implementation team, which includes all pathology disciplines within the Trust.

Project Board:

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
</tr>
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<tbody>
<tr>
<td>Chair</td>
<td>Robin Wiggins/Sally Tucker (shared by Clinical Director of Pathology and Clinical Support Divisional Manager)</td>
</tr>
<tr>
<td>Clinical lead</td>
<td>Alan Rubin (Consultant Histopathologist)</td>
</tr>
<tr>
<td>Project Manager</td>
<td>Cathy Ivory (Pathology IT Service Manager)</td>
</tr>
<tr>
<td>Senior. User</td>
<td>Gerard Felix (Pathology Services Manager)</td>
</tr>
<tr>
<td>IT representation</td>
<td>Anne Reilly/Graham Wright (Associate Director of IT / Head of Programme and Technical Design)</td>
</tr>
<tr>
<td>Finance representation</td>
<td>Matt Tattersall</td>
</tr>
<tr>
<td>Clinical (WHHT)</td>
<td>David Gaunt</td>
</tr>
<tr>
<td>Clinical (PCT)</td>
<td>Mike Walton</td>
</tr>
<tr>
<td>HSMC</td>
<td>John Streeton</td>
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Pathology Computer Replacement Working Group consisting of pathology consultants; pathology IT team; laboratory managers and discipline specific database co-ordinators, and scientific staff.

13. PROJECT PLAN

A precise project plan will need to be worked out. An indicative plan is given below:

<table>
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<tr>
<th>Complete by</th>
<th>Activity</th>
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<tbody>
<tr>
<td>28-Jan-09</td>
<td>Present BC to CPG</td>
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<tr>
<td>26-Feb-09</td>
<td>Project Board Approve OBS</td>
</tr>
<tr>
<td>19-Mar-09</td>
<td>BC presented to Trust Board for approval</td>
</tr>
<tr>
<td>23- Mar-09</td>
<td>Invite CfH suppliers to express interest</td>
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<tr>
<td>30-Mar-09</td>
<td>Receipt of Expressions of Interest from Suppliers</td>
</tr>
<tr>
<td>31-Mar-09</td>
<td>Issue of Output Based Specification (OBS) and relevant CfH schedules</td>
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<tr>
<td>12-May-09</td>
<td>Evaluation of supplier responses to OBS and CfH schedules</td>
</tr>
<tr>
<td>12-Jun-09</td>
<td>Completion of Demonstrations and site visits including presentations and interviews</td>
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The formal CPG tracker form will be established, monitored and reported on once the specification has been issued.

14. CONCLUSION AND RECOMMENDATIONS

There is an urgent requirement to upgrade or replace the existing pathology computer system within West Hertfordshire Hospitals NHS Trust with a new system based on the requirement for integration, a robust solution for service provision, the withdrawal of support for the current system, and the need to meet national standards on clinical information provision and management within Pathology Laboratory services generally.

The option to procure a single replacement solution for all disciplines, from a single supplier is recommended.

Authors: Cathy Ivory Pathology IT Services Mgr Date: 09.12.08
Gerard Felix Pathology Services Mgr Date: 09.12.08
Approved: Russell Harrison Director of Delivery Date: 21.01.09
Robin Wiggins Clinical Director of Pathology Date: 21.01.09
Sally Tucker Divisional Manager Date: 21.01.09
Approved: Sarah Wiles CPG Date: Mar 2009
Approved: Trust Board Date: