1. INTRODUCTION

Haematology services contribute to a critical need in the diagnosis, treatment and care of patients in public health and in national screening programmes. The department is constantly under pressure to maintain and improve quality despite increasing workloads and difficulties with staff recruitment and retention. The drive to enhance the patient journey and reduce turnaround times is imperative. Crucial to that is the delivery and reliability of results from the central analytical platform within Haematology. To support the Acute Admissions Unit with a Trust seeking Foundation status and within the broader benefits of centralisation of Haematology services, it is vital that the analytical platform is efficient and cost effective.

WHHT has a need to replace the Haematology analysers because they are reaching their limited shelf life. Support for the current system terminates in January 2010.

2. EXECUTIVE SUMMARY

This Business Case [BC] identifies the need to replace the analytical platform in the Haematology Department. 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.

The current portfolio of analysers has been in the Trust since 2001 and is reaching the end of its life span. The present setup cannot meet the future needs of the service particularly as GP and non-urgent work transferred over to HHGH in March 2009. Full Blood Count [FBC] and Erythrocyte Sedimentation Rate [ESR] analysis is provided using different tubes.

The case for replacing the Haematology analysers is based on a need to ensure that:

A. Haematology can support the re-configuration of clinical services and new ways of working within the Trust to achieve rapid turnaround times to fulfil the requirements of the Acute Assessment Unit and the centralisation of acute services.
B. Analysers continue to function, but high input by Biomedical Scientists is required to maintain consistency and reliability in result generation.
C. Haematology services are responsive to changing demand.
D. Sample provision is kept to a minimum ensuring continuity of care to the patients.
E. To support a modern Haematology Service within the Trust seeking Foundation status.

The Haematology services covered by this BC are based at Watford and Hemel Hempstead.

3. BACKGROUND

The Haematology Services have been operationally dependent on the FBC analysers for over 8 years and these have surpassed their normal life expectancy (normally 7). The Haematology department could not function without analysers, as evidenced by:

- The spread and complexity of functions currently supported by Haematology to users of the service such as:
  - Haematology Clinics
  - AAU and A&E
  - All internal work including Surgical, Medical and Children’s and Women’s Services.
  - GP and Outpatient Services.
- Dependence on automation to support the current high levels of productivity.
- National reports emphasising the key role of analysers into assisting and informing diagnosis.
- Clinical Pathology Accreditation [CPA] requiring minimum levels of standardisation of results particularly:
  - Consistency.
  - Reliability.
  - Reproducibility.
- Requirement for rapid Turnaround Times [TAT] to support Trust targets.

4. STRATEGIC CONTEXT

The Carter report on NHS Pathology Services states that pathology services puts patients first. The replacement of the Haematology analysers addresses concerns raised such as:

- Clinical excellence by adopting innovative technology and practice, where effectiveness is proven.
- Responsiveness by improving access and convenience.
- Cost effectiveness by being resolute on the operating costs and effective deployment of staff.
- Integration by enhancing clinical services through the care pathway.
- Additionally the Haematology has reconfigured its services in keeping with the Delivering a Healthy Future by splitting the internal/urgent work from the external/non-urgent work.
5. REQUIREMENTS

The Haematology Department requires a modern, flexible, fully functional solution that is capable of operating from the two laboratories based at Watford and Hemel Hempstead General Hospitals. The requirements to comply with national guidelines necessitate the need to change the current analytical equipment to improve patient safety and clinical demand on the service. There is a need to choose a solution that offers best value for money, to improve the turnaround times, assuring a consistent quality of results and above all else enhancing patient safety. Additionally:

- To provide a high quality service for the Trust with up-to-date technology.
- To reduce the number of samples required for analysis.
- To deliver the proposed new service and reduce current revenue costs.
- To improve reliability in delivery of the service by engendering a partnership contract through the provision of a detailed technical specification and/or managed service plan.

The Haematology Department has identified a number of aims and objectives that should be addressed in the delivery of this service.

- To promote an effective working relationship the Clinical Service in meeting the national directive to provide a safe and effective Haematology Service to patients.
- To reduce tensions on staffing levels and remove manual intervention as much as possible.
- To minimise the risk of transcription errors as far as is practically possible.
- To reduce turnaround times.
- To provide a more flexible, but consistently reliable service.
- To reduce the number of samples required providing FBC, ESR and HbA1c (processed in Chemical Pathology) analysis from the same tube. This will enable a real-time reduction in the process of Phlebotomy, Specimen Reception and the Laboratory.
- To provide analysis of FBC and ESR tests in a continuous flow process i.e. without manual manipulation in tandem with a robust storage and retrieval facility of samples.
- To ensure a high standard of service that complies with CPA, National Guidelines and European Directives.
6. OPTIONS APPRAISAL

Based on the requirement a number of options have been considered and these are outlined below:

A. Do nothing and continue with current system.
B. “Upgrade” replace analytical base with current supplier.
C. Procure a replacement solution from a supplier.

Non Financial Options Appraisal

Option A is not feasible as the current analytical platform is passed its normal life expectancy and requires high maintenance and service input to keep it going.

Option B is not feasible as this would be a procurement of a new system under the Trusts Standing Financial Instructions and so would fit into option C.

Option C is feasible and would enable the Trust to market test commercial systems in both quality and financial terms.

Financial Options Appraisal Overview

Option A would incur increasing maintenance and servicing costs due to age and fallibility of the analysers. This has been discounted for the reasons given above.

Option B is discounted as above.

Option C would require a formal tender process. The project would not require capital funding, as the tender would be based on 2 other options as below:

1. Reagent Rental – equipment is supplied via the purchase of the reagents.
2. Lease Agreement – equipment is purchased via Leaguard and reagents purchased separately.

The tender would request both options to be presented by the bidders so that the costs associated with them can be considered.

It is projected that cost of the new system would be within the current budget of £210K, which includes the costs for FBC and ESR analysis.

7. PREFERRED OPTION

It is accepted that there is some considerable clarification 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 Haematology.
It must be fully evaluated and has demonstrable positive functionality.
It must deliver an effective compliant system, which minimises the disruption to the service.
It must demonstrate the ability to integrate with the Blood Sciences proposed new systems and ways of working.
It must provide relevant reports and evidence for accreditation purposes and a variety of clinical and operational management requirements.

The preferred option is Option C.

8. AFFORDABILITY

The replacement of the Haematology analysers represents a substantial management challenge. The budget will be aligned with the Cost Centre T6920 using associated account codes 24661, 29181 and 29250, the total budget being £197,366. Key issues are:

- Affordability and the effects on prices
- Project Management
- Benefits realisation
- Risk Management
- Future Proofing
- Support future model for Blood Sciences

Affordability is linked to the investment needs supported by the Haematology Consultant Team.

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 major risks are:

- Current system over expectant lifetime.
- Loss of analytical analysis due to mechanical failure.
- Inability to support Trust, PCT and external client work.
- Inability to achieve rapid reporting and rapid access to results to fulfil the requirements of the Acute Assessment Unit and the centralised acute services.
- Affordability.
- Time line sufficient for procurement and implementation process.
Could compromise application to Foundation status.

The risks will be managed as follows:

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

Resource – planning the resources required to carry out risk avoidance/minimisation activities.

Assign – ensuring that the responsibility for managing risk, is assigned to appropriate individuals.

Monitor – checking that planned actions are having the desired effect on risks, scanning for the early signs that risks are developing and predicting potential new risks.

Control – taking action to ensure that risk avoidance/minimisation activities actually happen.

10. BENEFITS EXPECTED

The main benefits will be:

- A modern sustainable system supporting local requirements.
- Ability to reduce samples taken from patients reducing time taken for phlebotomy and specimen reception procedures.
- A system to support the new configuration of Haematology/Blood Sciences with the separation of acute and non-acute work at the different sites.
- To be aligned to the introduction of technological advances in pathology.
- Support better turnaround times and through put.
- Will allow for service expansion and new business.
- Allows for future proofing.
- Support the acute services of the Trust.
- To sustain CPA accreditation.
- Compliance with national guidelines and European directives.
- Would support Foundation status.
- To reduce costs with the introduction of efficiencies through the implementation of specimen processing units associated with the specification of the business case by:
  - Phlebotomy - reduce number of samples and time spend taking them.
  - Specimen Reception – reduce booking in, labelling and sorting requirements.
Laboratory – the specimen-processing unit will interrogate the LIMS and file samples into specific racks where outstanding test requests are identified.

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 and that progress on benefits realisation is communicated to the Divisional Manager.

11. TIMESCALES

See project plan below.

12. KEY RESPONSIBILITIES

A team 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 the implementation team, which includes Clinical Informatics.

13. PROJECT PLAN

An indicative plan is given below:

<table>
<thead>
<tr>
<th>Complete by</th>
<th>Activity</th>
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<tbody>
<tr>
<td>June 09</td>
<td>Present BC to Pathology Services Manager and Divisional Manager</td>
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<tr>
<td>June 09</td>
<td>Approval Business Case</td>
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<tr>
<td>June 09</td>
<td>OJEC Notice published</td>
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<tr>
<td>July 09</td>
<td>Receipt of Expressions of Interest from Suppliers</td>
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<tr>
<td>Mid August 09</td>
<td>Production of Supplier Short-List</td>
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<tr>
<td>August 09</td>
<td>Technical Specification [TS] to Short-List of Suppliers</td>
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<tr>
<td>Early Oct 09</td>
<td>Evaluation of supplier responses to TS</td>
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<tr>
<td>Oct 09</td>
<td>Completion of Demonstrations and site visits</td>
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<tr>
<td>Late Oct 09</td>
<td>Tender Evaluation</td>
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<tr>
<td>Early Nov 09</td>
<td>Award of Contract</td>
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<tr>
<td>Nov 09</td>
<td>Supplier Feedback</td>
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<tr>
<td>January 10</td>
<td>Analyser implementation Process begins</td>
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14. CONCLUSIONS AND RECOMMENDATIONS

In conclusion the proposal is to replace the current analysers with instruments which have shorter turnaround times, balance workload with capacity and permit continuous testing and storage with minimal staff intervention. This will promote efficient working practices, reduce errors and enable cohesive working practices in Blood Sciences. In addition it is expected to achieve an annual saving in revenue costs of £20,000 to £30,000 depending on the life of the contract. Full costs and financial benefits would become apparent during the procurement procedure.

15. PROJECT ACCEPTANCE SIGN-OFF

Project Manager

Name: Kevin Nulty
Job Title: Haematology Laboratory Manager
Signature: _____________________
Date: _____________________

Divisional Manager

Name: Sally Tucker
Job Title: Divisional Manager
Signature: Sally Tucker
Date: 17.6.09

Executive Director

Name: Russell Harrison
Job Title: Director of Delivery
Signature: _____________________
Date: 18th June 2009