

Trust Board Paper P

To:	Trust Board		
From:	Chief Executive		
Date:	28 August 2014		
CQC regulation:	Not applicable to this paper		
Title:	Blood Transfusion Laboratory Information System (BT-LIMS)		
Author/Responsible Director: Chief Executive			
Purpose of the Report: To seek approval for the procurement of an MHRA compliant Blood Transfusion laboratory computer system.			
The Report is provided to the Board for:			
	Decision	<input checked="" type="checkbox"/>	
	Discussion	<input type="checkbox"/>	
	Assurance	<input type="checkbox"/>	
	Endorsement	<input type="checkbox"/>	
Summary / Key Points: The existing blood transfusion laboratory computer system is outdated and non-compliant with the MHRA regulatory requirements. This paper outlines the case of need for a replacement laboratory information system and presents a summary of option appraisal.			
Recommendations: To procure the Clinisys Winpath laboratory information system for blood transfusion service at UHL.			
Previously considered at another corporate UHL Committee? The business case was approved by the UHL Capital Group on 27 th June 2014.			
Board Assurance Framework: The business case has had the initial approval from the director of finance and the recommended option and procurement route satisfies the requirements of procurement governance.		Performance KPIs year to date: All applicable KPI's will be specified within the service contract with the supplier.	
Resource Implications (eg Financial, HR): The project does not require a capital investment. The revenue cost of £1.6 M (approx.) for a 5-year contract will be offset against the full cost of empath IT procurement plan subject to final approval of the empath business case. There are no HR implications.			
Assurance Implications: The recommended system, Clinisys-Winpath, is fully compliant with the MHRA regulatory requirements.			
Patient and Public Involvement (PPI) Implications: None. The system is clinically and technically evaluated.			
Stakeholder Engagement Implications: All stakeholders including emPath board, emPath executive team and IT procurement team, CSI CMG, UHL IM&T / IBM, UHL procurement team and UHL capital group have been fully involved.			
Equality Impact: Not applicable to this paper.			
Information exempt from Disclosure: No exemption.			
Requirement for further review? None			

1. Project Background

Blood Transfusion Services in the UK must comply with Blood Safety and Quality Regulations 2005 (*BSQR 2005, Statutory Instrument 50*). In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) enforce full compliance with this legislation through regular inspections. The MHRA have the authority, under *articles 11,14,18 and 19 of BSQR 2005, SI 50*, to prosecute individuals responsible for failure to comply, as well as serve hospitals / blood transfusion services with legal enforcement notices, including an eventual 'cease and desist' notice.

At their last inspection of UHL blood transfusion service in February 2014, the MHRA highlighted a number of non-conformities, including the current blood transfusion laboratory system being non-compliant with regulatory requirements.

Following the inspection, a comprehensive action plan was drawn up, including the procurement of a fully compliant Blood Transfusion Laboratory Information system (BT-LIMS).

2. Project outline

The project will require a maximum revenue expenditure of approximately £1.6m over 5 years, as detailed below.

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Total Cost	240,921,83	333,477.17	333,624.88	333,780.35	333,947.82	1,575,752.04

No capital is requested and there is no impact on estates. IM&T support would be required to implement the hosted service and to maintain desktop support as currently provided. Implementation support will be required from empath (Nottingham University Hospital and University Hospitals of Leicester Pathology IT teams).

The revenue will purchase a stand-alone, hosted, LIMS service for Blood Transfusion. The supplier of this solution will be emPath's preferred supplier for a definitive pan-pathology LIMS solution. The strategic Outline Business Case (OBC) for the pan-pathology solution has already been approved by the Trust and the Full Business Case (FBC) is scheduled to go through the approvals process shortly. In the event of the FBC being approved by October 2014, the full cost of this stand-alone BT solution will be offset by the main contract. The additional cost (over and above the strategic solution) and financial risk is therefore very likely to be only that arising from an extended period of double running of systems rather than any substantial additional committed expenditure.

In the unlikely event of Full Business Case approval for the strategic solution not being achieved, then a compliant LIMS would still be required by the Trust and similar expenditure would still incur.

<p>3. Summary of Option Appraisal</p>	<p>The option appraisal involved full consideration of six possible options, as it is not possible to “do nothing” and continue to operate as a licensed blood establishment. The options are:</p> <ol style="list-style-type: none"> 1) Present MHRA with a plan to carry on with present manual checking solution. 2) Revert to Serological matching for all patients. 3) Modification of Existing BAPEX system for compliance. 4) Roll out v5 of the preferred LIMS from Nottingham University Hospital 5) Introduce a stand-alone BT solution 6) Proceed with the original plan of early roll out of blood transfusion component of the empath pan-pathology IT solution. <p>Options 1 to 5 are discounted as inappropriate, not cost effective or not deliverable.</p> <p>Option 6 is being presented as the preferred solution, which would be fully compliant with the MHRA, and in line with the overall emPath IT strategy.</p>
<p>4. Recommendation & Benefits of Decision</p>	<p><i>4.1: Preferred Option (No 6).</i> Option 6 offers an MHRA compliant solution that could be procured and implemented in the required timeframe. However, the contract period would only make it financially viable if the procurement of a stand-alone system could be linked to the strategic direction i.e., bringing forward components of full emPath IT programme, with reuse of the resource such that much of the cost of initial implementation would be offset when full emPath IT solution is subsequently implemented.</p> <p><i>4.2: Recommendation:</i> Based on the above, on behalf of the project steering group, I make the following recommendations to the board:</p> <ul style="list-style-type: none"> • <i>Proceed with the procurement of Clinisys-Winpath LIMS for blood transfusion service at UHL.</i> <p><i>4.2: Benefits of Decision:</i></p> <ul style="list-style-type: none"> • The preferred solution will achieve compliance with the MHRA regulations (BSQR 2005). • This solution is deliverable within the tight timeframe required by the MHRA. • Since this option essentially brings forward a component of the preferred empath IT solution, the initial revenue cost will be subsequently offset against the cost of full emPath IT project.