

PWYLLGOR DIGIDOL, DATA AC ARLOESI
DIGITAL, DATA AND INNOVATION COMMITTEE

DYDDIAD Y CYFARFOD: DATE OF MEETING:	22 July 2025
TEITL YR ADRODDIAD: TITLE OF REPORT:	Laboratory Information Management System (LIMS)
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Huw Thomas, Executive Director of Finance
SWYDDOG ADRODD: REPORTING OFFICER:	Anthony Tracey, Digital Director

Pwrpas yr Adroddiad (dewiswch fel yn addas)
Purpose of the Report (select as appropriate)

Ar Gyfer Penderfyniad/For Decision

ADRODDIAD SCAA
SBAR REPORT

Sefyllfa / Situation

This report provides an update to the Committee on a critical risk within Pathology related to the Laboratory Information Management System (LIMS), which is fundamental to the delivery of safe and effective services.

There is a significant concern that delays in the implementation of the new LIMS solution (TCLe) may extend beyond the end-of-life date of the current system. Should this occur, it could lead to a complete failure of the pathology service. Such an outcome would have a catastrophic impact across acute, primary, and secondary care within Hywel Dda University Health Board (HDdUHB), and potentially affect services across Wales. Urgent attention and mitigation planning are required to address this risk and ensure continuity of service.

Cefndir / Background

The LIMS is a critical digital system used by Pathology to manage patient samples from receipt and registration through to the reporting of results. It underpins the safe and effective delivery of diagnostic services. As highlighted in the Department of Health's 2006 review of NHS Pathology Services, an estimated 70–80% of healthcare decisions affecting diagnosis or treatment involve a pathology investigation, making LIMS essential to clinical decision-making and patient care.

HDdUHB currently uses TCL2016, provided by InterSystems, with Blood Transfusion services operating on the legacy Telepath system. With TCL2016 approaching end-of-life in late 2025, a procurement process was initiated in 2021. Citadel Health was appointed to deliver a replacement system by July 2025. However, the contract was terminated during FY2022/23. As a contingency, the current supplier agreed to provide a five-year extension from the end of the existing contract, allowing for a new procurement to be completed by 2030. This has necessitated a revised implementation approach, with many build and testing activities now occurring in parallel and at reduced scope to deliver a minimum viable product for Wales.

The national LIMS programme is led by Digital Health and Care Wales (DHCW) in collaboration with Health Boards, Public Health Wales (PHW), the Welsh Blood Service, and Velindre University NHS Trust. Initially, a sequential rollout by Health Boards was planned, with HDdUHB and Swansea Bay scheduled to go live in February 2025 as part of a regional deployment. However, significant challenges with system build and User Acceptance Testing (UAT) prompted a comprehensive review.

Asesiad / Assessment

Due to the complexity of the programme and the compressed delivery timelines, several challenges have emerged. These include delays in delivering key functionality, an extended period of UAT, a high volume of identified defects, and limited availability of specialist resources. As a result, key milestones have been delayed, and it is now evident that the overall programme timelines will not be met.

In response, a mitigation plan was developed collaboratively with Health Boards to address the delays and ensure all organisations transition off TCL2016 by the end of December 2025. This revised approach shifts from a Health Board-by-Health Board rollout to a **national, discipline-based implementation model**. Additionally, the deployment of Blood Transfusion services has been decoupled for Health Boards still using legacy LIMS systems. These deployments are now scheduled between January and March 2026, allowing the programme to prioritise the transition of Swansea Bay University Health Board off TCL2016 by the end of 2025.

However, delays in adoption will defer the realisation of anticipated benefits and result in significant additional costs for NHS Wales. Prolonged reliance on obsolete LIMS platforms — many of which are approaching or beyond end-of-life. This will increase operational risks due to limited vendor support and heightened potential for system failure.

Given ongoing concerns about the achievability of the revised timelines, the programme is now exploring a contingency or "backup" plan in the event that delivery extends into 2026. While this would provide a safety net, extending the use of legacy systems would incur substantial further costs and introduce additional risks, particularly as resources are diverted to re-planning efforts.

In response to a number of risks, a request for a new risk for inclusion on the corporate risk register was presented to the Executive Team in April 2025. Additionally, the national programme's Senior Responsible Owner (SRO) raised the issue at the All-Wales Chief Executive meeting in May 2025, ensuring that senior leadership across Wales is fully aware of the potential impact and urgency of the situation.

Following a comprehensive review of readiness across Health Boards, Trusts, and individual disciplines, it was agreed that the most effective approach to transition from TCL2016 by December 2025 would be to proceed with **Option 2: deployment by discipline**.

A key caveat to this plan is the recent confirmation from Microbiology that they will proceed with a **reduced scope go-live in July 2025**, limited to the PenGU laboratory. As a result, further discussions will be required with PHW to explore an **incremental deployment model** for Microbiology before the end of the calendar year. Although the full system, including national integrations, will technically be operational, the initial access will be restricted to a limited user group.

InterSystems has expressed concerns regarding the reduced scope of the Microbiology deployment and has requested that the decision be revisited. In response, we have proposed a

revised approach that includes **dedicated task-and-finish sessions** to complete the remaining technical delivery, address outstanding defects, and finalise data migration and UAT activities.

These proposals have been discussed with the Microbiology team, who are now considering the possibility of expanding the deployment scope.

Key Rationale for the Deployment Change

The decision to shift from a Health Board/Trust-based deployment to a discipline-led approach is based on several critical factors:

- **Testing Readiness and Resource Constraints:**
The majority of remaining activity involves UAT within laboratories, alongside defect resolution by the supplier and configuration changes led by DHCW. Releasing staff to support testing has proven challenging, and disciplines are progressing at different rates. Public Health Wales Microbiology and Cervical Screening are closest to go-live (targeting July), while Blood Sciences and Blood Transfusion are aiming for October/November 2025.
- **Discipline-Led Workshop Findings:**
In-depth workshops led by discipline leads concluded that the original testing milestones were unachievable. The option to bring in external testers was considered but ultimately rejected due to concerns around the need for local expertise and ownership of the testing process.
- **Risks of Continuing with the Original Deployment Model:**
Maintaining the original Health Board/Trust-based rollout would likely delay the earliest possible go-live to the end of 2025 and extend remaining deployments into 2026. This would significantly increase programme costs and prolong reliance on legacy systems.
- **Benefits of a Discipline-Based Approach:**
Deploying by discipline allows for earlier implementation of TCLe, reducing the risk of cost overruns extending into FY2026–27. It also enables more focused support and coordination within each specialty.
- **Simplified Dual Running:**
A discipline-led rollout reduces the complexity of dual running TCL2016 and TCLe. Under this model, the overlap period for each discipline is limited to a few days, compared to several months under a Health Board/Trust-based approach.

Financial Impact

As part of the revised discipline-based delivery model for the LIMS programme, each Health Board is required to contribute additional resources to support implementation activities. Digital Health and Care Wales (DHCW) is currently seeking **£1.6 million in additional funding** from Welsh Government to offset these costs across NHS Wales.

Should this funding not be secured, the financial burden will fall to individual Health Boards. For **HDdUHB**, this would result in an **additional cost of approximately £176,000 in the 2025/26 financial year**. This figure reflects the increased demand for staffing, testing, and programme support required under the new delivery approach.

The financial risk associated with this potential shortfall should be considered in the context of broader programme delays and the ongoing need to maintain legacy systems, which may also incur further unplanned costs.

The plan is both challenging and ambitious, with several key dependencies that must be met to achieve the outlined timelines. These include the resolution of defects within each tranche, successful delivery of data migration, and completion of user acceptance testing. Without the

establishment of a firm deadline, there is significant risk that ongoing pressures within the NHS would lead to the use of any additional time — and potentially more — if it were available. As such it is critical that resources across Health Boards and DHCW are prioritised accordingly.

Argymhelliad / Recommendation

The Committee are requested to:

- **RECOMMENDED FOR APPROVAL BY THE BOARD** that the LIMS2.0 programme adopts a deployment approach based on discipline as this strategy will enable the earliest transition away from the current TCL system.
- **SUPPORT** the collective approach to Welsh Government, requesting that this funding be prioritised for slippage allocation from the 2025/26 Digital Priorities Investment Fund (DPIF).
- **NOTE** that if the funding request is unsuccessful, Hywel Dda University Health Board will be required to allocate **£176,000 in 2025/26** to support the revised discipline-based deployment model.

Amcanion: (rhaid cwblhau) Objectives: (must be completed)	
Committee ToR Reference: Cyfeirnod Cylch Gorchwyl y Pwyllgor:	3.1.5 Review and scrutinise business cases, and associated revenue implications, and associated revenue implications, relating to digital and research and innovation activities, and ensuring there are robust contracting processes and procedures are in place, prior to Board approval.
Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol: Datix Risk Register Reference and Score:	DATIX 2079 Risk of loss of Pathology service across the Health Board due to delayed implementation of LIMS. Score: 20
Parthau Ansawdd: Domains of Quality Quality and Engagement Act (sharepoint.com)	7. All apply
Galluogwyr Ansawdd: Enablers of Quality: Quality and Engagement Act (sharepoint.com)	6. All Apply
Amcanion Strategol y BIP: UHB Strategic Objectives:	All Strategic Objectives are applicable
Amcanion Cynllunio Planning Objectives	9 Digital plan All Planning Objectives Apply

Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2021-2022	9. All HDdUHB Well-being Objectives apply
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Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	Not applicable
Rhestr Termiau: Glossary of Terms:	Included within the main body of the report
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Digidol, Data ac Arloesi Parties / Committees consulted prior to Digital, Data and Innovation Committee:	Pathology Operational Team

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: Financial / Service:	Not implementing LIMS would lead to increased financial burdens, service inefficiencies, and compromised patient care, ultimately hindering the health board's ability to deliver high-quality radiology services.
Ansawdd / Gofal Claf: Quality / Patient Care:	Loss of service would have catastrophic impact on patient outcomes
Gweithlu: Workforce:	Staff would be unable to perform their duties
Risg: Risk:	No service provision, mitigated by a robust contingency plan and additional resource or time to complete User Acceptance Testing within timeframes.
Cyfreithiol: Legal:	Regulatory Compliance through MHRA would be unachievable
Enw Da: Reputational:	Inability to provide a pathology service would have a significant detrimental effect at health board and national level.
Gyfrinachedd: Privacy:	An unsupported application could lead to risk of cyber-attack.
Cydraddoldeb: Equality:	All patients would be affected equally.