



## CYFARFOD BWRDD PRIFYSGOL IECHYD UNIVERSITY HEALTH BOARD MEETING

<b>DYDDIAD Y CYFARFOD: DATE OF MEETING:</b>	30 May 2024
<b>TEITL YR ADRODDIAD: TITLE OF REPORT:</b>	Regional Pathology Operational Delivery Network (ODN) Transitional Memorandum of Understanding (MOU)
<b>CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:</b>	Andrew Carruthers, Director of Operations
<b>SWYDDOG ADRODD: REPORTING OFFICER:</b>	Neil Miles, A Regional Collaboration for Health (ARCH) Pathology Programme 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 is provided to update the Board on the development of the Regional Pathology Operational Delivery Network (ODN) between Hywel Dda and Swansea Bay University Health Boards.

The Board is being asked to review and agree the Transitional Memorandum of Understanding (MoU) between the two organisations. The Transitional MOU will terminate on 31 March 2025, or when the Project is completed, whichever is the latest, and facilitate closer working between the organisations corporate and operational teams to develop the detail required to form the ODN.

The ODN Delivery Board will be responsible for developing the detailed implementation arrangements and agreement between the organisation and representing the final MOU, service specification and finance and commissioning approach to a future Board, prior to full formation of the Network arrangements in 2025/26.

At that time, it is anticipated that a further MoU will be in place that will set out the operational arrangements for the Regional Pathology ODN.

##### Cefndir / Background

Pathology services across South West Wales have been severely challenged due to a number of factors, including critical workforce shortages, poor estates and health and safety concerns.

In 2012 to meet these challenges, a Regional Cellular Pathology Board was set up to discuss and progress a plan for regional working. However, this was superseded in 2014 due to a recognition nationally of the crisis faced and that the consolidation of pathology services was considered essential. An all Wales Cellular Pathology Project was launched and tasked with considering options and delivering change; in 2015, an option appraisal was completed and recommended that two sites in South Wales were needed and these should be at Morriston and Cardiff. A similar work stream recommended consolidation of Immunology services into two regional services.

This recommendation was then passed back to Health Boards with the additional expectation that all laboratories in Wales should be externally accredited. This led to the regional development of the Strategic Outline Case for Pathology services in South West Wales being submitted and approved by Welsh Government in November 2022.

The report provides an update on the development of the South West Wales Regional Pathology Operational Delivery Network (ODN). The programme has two key components:

1. The development of a single Regional Pathology service via an Operational Delivery Network (ODN) approach, with Swansea Bay University Health Board (SBUHB) as the host organisation.
2. The development of a Hub Laboratory Centre of Excellence on the Morriston Hospital site to provide fit for purpose modern laboratory service for the region and local laboratory refurbishments via Welsh Government Capital investment processes.

## **1. Regional Pathology ODN**

This report focuses on the proposed establishment of formal arrangements to support the development of the Transitional ODN via the adoption of a shared MOU covering the period up to 31 March 2025 or until the end of the Project, whichever is the latest.

To progress the transformation plan for Pathology services in South West Wales, Hywel Dda and Swansea Bay University Health Boards agreed, in November 2022, the need to create a Regional Pathology service model.

This approach, new for NHS Wales but not across the United Kingdom, would enable joint recruitment, collaborative development of service plans, standardisation of approach, equipment and facilities and the benefits of consolidation. A number of possible options of how a regional management model could operate, underpinned by a strong governance framework and an agreed set of principles, were considered.

A Joint Executive meeting between SBUHB and Hywel Dda University Health Board (HDdUHB) was held on 24 November 2021; these points were discussed and a subsequent visioning workshop was held on 29 November 2021, chaired by the then CEO of SBUHB.

A Regional Pathology Task and Finish (T&F) Group convened in 2022, chaired by Andrew Carruthers (Director of Operations HDdUHB), and supported by Christine Morrell (Director of Therapies and Health Science SBUHB) as SRO for the A Regional Collaboration for Health (ARCH) Regional Pathology Transformation Programme. The group considered their options for the management model and undertook an appraisal and sought advice from NHS Wales Legal and Risk services. The detail of the decision making process is provided in the [November 2022](#) paper considered by both Health Boards. The conclusion was the development of an Operational Delivery Network (ODN) for Regional Pathology services, with an aim to be operational by Q4 2022/23.

Following the establishment of the ARCH Pathology team in early 2023/24, the task of delivering the ODN model moved forward at pace. The terms of reference of the Task & Finish group were revised to form an ODN Transition Board and sub groups established to consider implications for Finance and Commissioning, Workforce and Digital services. In addition, Legal & Risk advice has been retained to work with both HB governance teams on the MoU and legal agreements required to deliver the network.

To date, the following developments have been agreed:

1. Development and agreement of a Mortuary MOU for the Region. This has facilitated closer working between the mortuaries and the appointment of a regional mortuary team, joint training processes and rotations.
2. Development and agreement of joint regional management structure and job descriptions and person specifications for those roles.
3. Baseline assessment of performance, resources, quality/accreditation, compliance and workforce for the region.
4. Review of existing logistics and transport arrangements.
5. Continued development of regional Digital Cellular Pathology pilot in the region.
6. Appointment of a single Designated Individual (DI) for the regional mortuary service following the retirement of the current HDdUHB post holder. This has been achieved by appointment of the same individual to take responsibility for both Health Board licences, although licences still remain separate.
7. Development of staff and staff side communication processes. To date two rounds of face to face engagement (backed up by Teams access) has taken place in all laboratories in the region. This included the launch of the Pathology ODN SharePoint site and the development of the Frequently Asked Questions (FAQs) which captures the conversation and feedback with staff on all sites. The Sharepoint site [West Wales Regional Pathology Programme – RESEARCH & DESIGN \(sharepoint.com\)](#) also includes copies of the materials shared at the engagement events along with the FAQs. Two updates have been shared with staff side representatives from both organisation following those events. Further engagement is planned, following the consideration of this Transitional MOU and there is a commitment to onward engagement on at least a quarterly basis as the ODN forms.

Current work is focusing on:

1. Development of a regional 'compliance' team structure to combine functions in both organisations in pathology, IT, Quality, Health and Safety and Training.
2. LIMS 2.0 roll out regionally by February 2025. To ensure that the region has a consistent pathology digital system with replicable supporting processes in both health boards.
3. Consideration of the regional recruitment and training of non-consultant medical staff to histopathology.
4. Development of a Transitional Pathology Regional MOU for consideration by both Boards to support the development of the regional management team and integrated service change.
5. Development of the Service Specification and commissioning arrangements for the Pathology service for consideration by both organisations.

The proposal, therefore, is to continue to regionalise the service via the Transition Board but also move into the territory over the next 12 months of harmonising workforce arrangements. Once the commencement date of the Network is agreed by both Boards, the process of appointing into the senior leadership team, and subsequent TUPE transfer of staff into the new service model, will commence.

### **Transitional MOU**

In order to deliver the ODN, a Memorandum of Understanding (MOU) is required between the two organisations. This will set out roles and responsibilities for both organisations and legal and risk accountabilities, along with operational management and monitoring arrangements. The MOU will be complimentary to the service specification and commissioning arrangements, which will also require agreement. This will detail the service to be delivered and the financial

and workforce implications. In order to develop the above, it has been suggested to develop a Transitional MOU. This will facilitate in a fixed time period the closer collaboration between the organisations to enable them to:

- Share information
- Develop a joint management structure
- Outline considerations for staff working across the region
- Joint procurement
- Regional leadership arrangements and governance

To develop the Transitional MOU, a task and finish group has been established under the leadership of the ARCH Programme Director, with input from NHS Wales Shared Services – Legal and Risk, and SBUHB and HDdUHB Governance Teams. The group has met monthly to develop the attached draft MOU for the Transition period.

The Transitional MOU takes the same form as the proposed final MOU but with the following differences:

- The Transitional MOU shall commence when the MoU is signed by both SBUHB and HDdUHB and will continue until 31 March 2025 or on completion of the Project, whichever is the latest. If the Project is not completed by 31 March 2025, the ODN Delivery Board shall propose the time period of extension for the Transitional MOU for decision by both Health Boards in their March 2025 meetings.
- It has no permanence as the organisations will need to agree to the formal MOU once developed for the recurrent networked service.
- The ToR for the ODN will be developed during the Transition period and therefore this annex and others are under development through the Transition period.

The Transitional MOU seeks to support:

- Development of the Service Specification for the Pathology ODN.
- Development of Commissioning arrangements, including quality management and assurance.
- Support to start implementing the leadership team for the regional service.
- Information and data sharing of staff information and clinical service information.

## **2. Hub Laboratory Centre of Excellence - Outline Business Case**

In November 2020, a Strategic Outline Case (SOC) was approved by Welsh Government (£77m capital) to support the development of A Regional Collaboration for Health (ARCH) Mid and South West Wales Regional Centre of Excellence Cellular Pathology Laboratory, Regional Diagnostic Immunology Laboratory Facility and local SBUHB Regional Medical Microbiology facility, was submitted to Welsh Government and approved. Morriston Hospital has been identified as the location for the new regional build and the organisations (SBUHB and HDdUHB) are jointly developing an Outline Business Case (OBC). along with Public Health Wales (PHW) who provide Microbiology Services (excluding WGH), for the Health Board populations.

There was significant delay in progress of SOC approval due to the pandemic and lack of project resource, but in late 2021/22 work recommenced to deliver:

- The resource schedule for the programme was agreed with Welsh Government for external partners and internal resource.
- Formal agreement by Health Boards that the laboratory will be located on the Morrison Hospital site.
- Supply chain partners appointed and a launch event took place on 6 October 2022.
- Recommendations from the Gateway Review have been actioned and completed including the appointment of a Programme Director and supporting team to deliver the OBC and ODN.

In addition to the appointment of the Supply Chain Partner (SCP), Kier Construction, the Welsh Government capital funding supported fees for internal Health Board staff to contribute to the business case and ODN development. Resources were available for Digital, Capital Planning, Workforce and Clinical and Service leadership resources from within the organisations. Additional funding was agreed for the direct appointment of roles to lead the Pathology Programme under the ARCH partnership between the organisations.

The Outline Business Case for Pathology in South West Wales proposes the development of a new Centre for Excellence Laboratory on the Morrison Hospital site and local laboratory refurbishments across the region:

- The proposed option in Morrison will provide new facilities for cellular pathology, blood sciences, microbiology services and a precision medicine area. The latter will host Swansea University and Genomics services.
- The Precision Medicine unit will work in collaboration with the soon to be developed Institute of Life Sciences building on the Morrison site (separate funding) to provide laboratory space for innovation and research.
- The new building will replace services in Singleton hospital (microbiology and cellular pathology), Morrison (blood sciences) and Glangwili (cellular pathology).
- Singleton and Glangwili spaces will be refurbished to provide local laboratory services for those sites, networked to the Morrison site.
- The Glangwili vacated Cellular Pathology space will be repurposed to provide additional Blood Sciences space.
- The business case will also propose local refurbishments based on estate condition and service change to Prince Phillip and Withybush Hospitals. Refurbishment of the laboratories at Bronlais is not considered required at this stage.
- The existing pathology building in Morrison will be refurbished to extend the Mortuary facilities serving SBUHB and to accommodate some functions that are not required to be collocated in the new building (to reduce the cost of the new build and focus that investment on the modern laboratory service requirements).
- The expanded Mortuary service will continue to work as a networked service with the Mortuary service in Glangwili with integrated clinical leadership and regional management support.

The ARCH Pathology team and Design team worked with the service in early 2023 to develop the detailed proposals for the hub laboratory building, in line with Welsh Government capital guidelines and also changes and developments in pathology services since the initial SOC proposals were developed in 2018/19.

This included visits and MS Teams contacts with other laboratories and networks across the UK, including Liverpool, Wolverhampton, Bristol, Leeds, Manchester and North Wales.

The design proposals for the OBC were taken to RIBA Stage 2 (1:200) stage with detailed building massing, schedule of accommodation development and design. This enabled accurate costing of the proposals to be undertaken by the cost advisers. This cost was significantly higher than that approved at SOC stage and whilst there are global inflation pressures impacting on construction costs post the pandemic and other global events, the proposed scheme was in excess of the tolerance advised by Welsh Government between SOC, OBC and following FBC stage.

Therefore, the intended submission of the OBC to Welsh Government in March 2024 has had to be reviewed. This review has taken three forms:

- Review of physical location of the proposed building on the Morriston site to reduce significant groundworks and car parking requirements that added cost to the proposals.
- Review of the schedule of accommodation for the proposed laboratory building to value engineer the space and for the size and design to be closer to the original SOC concept (pre Design team input).
- Review of inflation costs and the impact on building the SOC proposal at 'current' prices.

This exercise has resulted in the following outcomes:

- Relocation of proposed building to the lower area of the demolition land in Morriston, reducing impact on existing car parking spaces and therefore removing the need for re-provision and reducing ground works costs.
- Reduction in SOA from 14,000 sqm to 9,000 sqm. This was achieved by continuing to utilise the existing pathology building in Morriston for mortuary services rather than moving to the new build and the rest of the building for office accommodation not directly linked to the new build. This review did conclude that the blood sciences laboratory should be located in the new build and not remain in situ as per the SOC. This will provide greater value than the cost of refurbishing the existing space and also greater opportunity and future proofing for the network and possibility of service change in the future.
- Application of inflation factors to the SOC and accounting for changes in capital guidance on decarbonisation measures, to provide a 'current' cost of the SOC and proposed building to deliver a scheme cost within the 10% variance from SOC, as per Welsh Government recently issued guidance.

A revised programme for OBC completion, Health Board approval and submission to Welsh Government has been developed. This will take Health Board approval to March 2025 (based on an April 2024 recommencement of design). A fee proposal has been developed and submitted to Welsh Government for consideration and a response is awaited.

The requirement to seek further fee support from Welsh Government for 2024/25 puts at risk the internal resource to support the work as the team, who are on secondment and fixed term contracts, are subject to redeployment or return to substantive posts before the confirmation of funding is received. This will not only impact on the OBC but on the ODN development also, as the ARCH Pathology team is supporting both aspects of the programme.

In addition, the team has completed the recently issued Welsh Government capital prioritisation form for consideration as part of the 2024/25 IMTP process. SBUHB submitted this document on behalf of the region in line with the guidance issues as the 'host location' for the facility. The SBUHB ranked the Pathology capital scheme as eighth amongst their priorities.

## Asesiad / Assessment

The reasons for the originations seeking to develop a Pathology Network remain, or have increased in severity, since November 2022.

Both organisations have increasing vacancy challenges in key roles and professions. Most notably, in Consultant Pathology roles and clinical leadership across pathology services. Non-medical scientist roles are also in short supply in certain sites, causing challenges in sustaining 24/7 rota cover.

In addition, estate condition and backlog maintenance, and the suitability of that estate to provide modern, innovative laboratory services, is significantly challenged.

Further, increasing demand both in volume and turn-around times to support health diagnostics in the region is putting poor pressure on the existing physical and workforce infrastructure and resilience. Not all laboratories in the region are accredited and some activity is required to be outsourced to meet demand.

### **1. Regional Pathology ODN**

The development of the ODN requires legal agreements between the organisations and significant workforce change (new leadership structures and transfer of staff between employers).

The development of the network requires a commissioning specification and approach to be developed and agreed between the organisation with contracting, finance and risk agreements to be in place.

A single Pathology digital system is required to optimise the delivery of services across the network.

Therefore, 'go live' for the final network form is targeted at 1 April 2025.

To move towards the April 2025 implementation, a number of measures are required to strengthen current arrangements between the organisations, namely:

- Formalisation of an ODN Board with ToRs that details reporting arrangements.
- Formal Quality governance system.
- Service Specification and Commissioning Approach (and agreement of what services form the Pathology ODN).
- Appointment of Pathology ODN Leadership team.

The below table outlines the current variance between what constitutes pathology in the two organisations:

	<b>HDdUHB</b>	<b>SBUHB</b>
<b>Phlebotomy</b>	Carmarthenshire – all in pathology Pembrokeshire – only ward based Ceredigion – hospital (ward and outpatient) not primary care	Morrison, NPT and Singleton – inpatient and outpatient (limited) Community pathology hubs serving primary care POW – Inpatient only Small specialist clinic for 'difficult to bleed' in primary care



<b>Clinical Haematology</b>	Consultant and admin staff – pathology Nursing – pathology (OPD and specialist) No ward environment, patients located on medical wards in various sites	Part of cancer services. Internal SLA with C Services for Lab cover (medical consultant session)
<b>Anticoagulation</b>	Nursing – not pathology Support team is pathology	Under Clinical Haematology (Cancer Services)
<b>Bereavement services</b>	Carmarthenshire – in path Pembrokeshire – nursing Ceredigion – directorate/hospital	Care After Death team part of Morriston Service Group. But plans to bring into Pathology budget

The ODN Board will need consider the options for the above through the development of the service specification and commissioning arrangements.

The MOU therefore outlines how the organisations will collaborate during the transitional period (present up to April 2025 or when the Project is completed, whichever is the latest) to develop the final MOU for the Pathology ODN for approval.

## 2. Hub Laboratory Centre of Excellence - Outline Business Case

In regard to the Outline Business Case, limited further work has taken place during April 2024 due to the fee position. Currently a response is awaited from Welsh Government to support the fees for the supply chain partner for 2024/25. Without this, the business case process is 'on hold' and the subsequent impact will be a delay on the revised OBC being ready for Health Board approval and submission.

Dialogue continues between SBUHB Capital and Finance teams and Welsh Government. It is not yet known when an outcome to the capital prioritisation process will be received by Health Boards. There are risk to the sustainability of the ARCH Pathology team (funded through capital monies) as fixed term contracts come to an end and the team look for alternative roles.

### Argymhelliad / Recommendation

The Board is requested to:

- **NOTE** the development progress of the ODN and onward timescales; transition from May 2024 to a proposed launch on 1 April 2025.
- **NOTE** the development of the Hub Laboratory and local refurbishment capital case and the current position ('on hold') with regard to Welsh Government fee funding to further advance the OBC to completion, approval and submission.
- **SUPPORT** the adoption of the Transitional ODN Memorandum of Understanding (MOU) (**Appendix A**) to enable the Regional Pathology Network to take the next step towards formation.
- Await the Regional Pathology ODN Board presentation of the final MOU, Service Specification and Commissioning arrangement for the Network later in 2024/25 for final decision to adopt a Network approach to Pathology services across the region.



<b>Amcanion: (rhaid cwblhau)</b> <b>Objectives: (must be completed)</b>	
Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol: Datix Risk Register Reference and Score:	
Parthau Ansawdd: Domains of Quality <a href="#">Quality and Engagement Act (sharepoint.com)</a>	7. All apply
Galluogwyr Ansawdd: Enablers of Quality: <a href="#">Quality and Engagement Act (sharepoint.com)</a>	6. All Apply
Amcanion Strategol y BIP: UHB Strategic Objectives:	All Strategic Objectives are applicable
Amcanion Cynllunio Planning Objectives	All Planning Objectives Apply
Amcanion Llesiant BIP: UHB Well-being Objectives: <a href="#">Hyperlink to HDdUHB Well-being Objectives Annual Report 2021-2022</a>	9. All HDdUHB Well-being Objectives apply

<b>Gwybodaeth Ychwanegol:</b> <b>Further Information:</b>	
Ar sail tystiolaeth: Evidence Base:	Contained within the report
Rhestr Termiau: Glossary of Terms:	Contained within the body of the report
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol: Parties / Committees consulted prior to University Health Board:	HDdUHB Executive Team SBUHB Management Board Regional Pathology Task and Finish (T&F) Group

<b>Effaith: (rhaid cwblhau)</b> <b>Impact: (must be completed)</b>	
<b>Ariannol / Gwerth am Arian:</b> <b>Financial / Service:</b>	The financial implications of developing the Transitional MOU relate to the fees associated with the advice and input from NHS Wales Shared Services Legal and Risk teams. This is estimated to be in the region of £2500 (final figure dependent on hours on input required from the legal

	<p>team). SBUHB and HDdUHB Legal and Risk teams have agreed to a 50/50 split of these costs.</p> <p>All other resources are provided from within existing resources from Health Board Teams and the ARCH Pathology team without financial recharge.</p>
<p><b>Ansawdd / Gofal Claf: Quality / Patient Care:</b></p>	<p>One of the key aims of the network is to ensure consistency of service delivery to the regional population regardless of their location. This will be achieved through the implementation of digital pathology solutions where possible, the development of a robust regional transport and logistics network and the timely analysis and reporting of investigations. Developing consistent service models and equipment and processes in all laboratories will also shore up business continuity through the movement of samples in the event of any laboratory down time in any site.</p>
<p><b>Gweithlu: Workforce:</b></p>	<p>The ODN will involve the creation of a single management team for Pathology across the region. Work is underway to determine the extent by which existing staff are eligible for consideration to appointment to these roles or they will be 'new'. Development of these roles will continue through the ODN Transition phase with appointments to be made towards the conclusion of the phase as the Network prepares to go live in April 2025.</p> <p>The ODN will be hosted by SBUHB and all staff will work for the Pathology Network regardless of the location of their role. Therefore the Transitional ODN Board will oversee the transfer of existing Hywel Dda staff and vacancies into Swansea Bay employment. Initial engagement has taken place to this effect with staff side groups in both organisations.</p> <p>Additionally, the Pathology team have completed two rounds of face to face engagement with pathology staff on all 8 laboratory sites in the network, to share the detail and progress of the ODN and OBC and to develop a strengths and challenges matrix for the existing service model and provision. This engagement is being extended to 'users' of the pathology service in secondary and primary care in coming months.</p>
<p><b>Risg: Risk:</b></p>	<p>The development of the ODN aims to provide stability and sustainability to pathology service across the region. Developing critical mass of service delivery, joint training and quality management systems, single digital information systems and collective recruitment for hard to recruit to roles will all contribute to decreasing risk with current service delivery methods. The balance of risk between the organisations does need to be considered as part of the establishment of the network and arrangements with regard for example capital investment in retained local laboratory services outside of any investment</p>

	<p>secured by the capital process will need to be considered i.e. significant backlog maintenance to existing buildings.</p> <p>One of the key aims of the network is to ensure consistency of service delivery to the regional population regardless of their location. This will be achieved through the implementation of digital pathology solutions where possible, the development of a robust regional transport and logistics network and the timely analysis and reporting of investigations. Developing consistent service models and equipment and processes in all laboratories will also shore up business continuity through the movement of samples in the event of any laboratory down time in any site.</p>
<p><b>Cyfreithiol: Legal:</b></p>	<p>The development of the ODN will require due consideration and legal sign off by both Health Boards prior to commencement. This will be a key activity of the ODN Board during the Transition period. The work of the Transition Board will be supported by a Memorandum of Understanding that will require approval by both Boards. This will consider the structure of the ODN Board and the use of delegated responsibilities of Executive Directors of both Boards.</p> <p>The development of the Transitional ODN MOU and final ODN MOU is being developed by legal and governance representatives from both Health Boards and legal advisors from NHS Wales Shared Services.</p> <p>The Transitional MOU proposes Quality reporting mechanisms through Health Board committee's during the transitional period (every other month) and that a view will need to be taken by those committee's in advance of the formal launch of the Network in April 2025 or how assurance should be provided on a recurrent basis.</p> <p>It is also proposed that an update be provided through the Transitional period to committee's focussed on Finance and Performance issues and approval is sought for commissioning and contracting issues through these mechanisms in the transition period.</p>
<p><b>Enw Da: Reputational:</b></p>	<p>The Pathology network and capital improvements to laboratories in the region will improve and sustain pathology as a modern, flexible, high quality diagnostics service for the region. This will ensure equity of access, performance improvements in turnaround times, recruitment and retention of staff and integration of pathology services with other parts of the clinical pathway to optimise patient care.</p>

<p><b>Gyfrinachedd: Privacy:</b></p>	<p>The Transitional MOU includes the development of Information Governance and Data Sharing agreements between both Health Boards. This will be essential to workforce change and the sharing of activity information for pathology services to assist in the planning of the delivery of the networked service.</p>
<p><b>Cydraddoldeb: Equality:</b></p>	<p>Equality Impact Assessments (EIAs) could be developed to help promote fair and equal treatment in the delivery of the Pathology Services. EIAs would aim to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender reassignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).</p> <p>Obligations on SBUHB, HDdUHB and PHW in respect of the well-being goal of 'A more equal Wales' under WBFGA could also assist in addressing social injustice and inequalities.</p>

**DATED** \_\_\_\_\_

**TRANSITIONAL**  
**MEMORANDUM OF UNDERSTANDING**

BETWEEN

SWANSEA BAY UNIVERSITY LOCAL HEALTH BOARD

AND

HYWEL DDA UNIVERSITY LOCAL HEALTH BOARD

**OPERATIONAL DELIVERY NETWORK SOUTH-WEST WALES REGIONAL PATHOLOGY**  
**2024/2025**

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This Transitional MoU is dated \_\_\_\_\_

## Parties

- (1) SWANSEA BAY UNIVERSITY LOCAL HEALTH BOARD of One Talbot Gateway, Baglan Energy Park, Baglan, Port Talbot, SA12 7BR (**SBUHB**)
- (2) HYWEL DDA UNIVERSITY LOCAL HEALTH BOARD of Corporate Offices, Ystwyth Building, Hafan Derwen, St David's Park, Jobswell Road, Carmarthen, SA31 3BB (**HDUHB**)

Each a **Health Board** and together the **Health Boards** as the context requires.

## 1. BACKGROUND

- 1.1 On 22<sup>nd</sup> November 2022, SBUHB and HDUHB submitted a Report to their respective Boards to take forward the development of an Operational Delivery Network (ODN) as the management model for South-West Regional Pathology Services ("**Service**"). The Report recommendations were approved in both public Board meetings, confirmed in minutes. HDUHB agreed to collaborate with SBUHB to establish the ODN. The re-designed regional pathology service ("**Project**") will bring together two organisations; SBUHB and HDUHB laboratory-based services under one umbrella. The ODN will also lead on behalf of the organisation in the commissioning of microbiology services for the region. Currently, these are provided in the majority of instances by Public Health Wales (PHW). This change will facilitate delivery of a new regionalised and co-located service model, supported by integrated management and a joint Health Board workforce. It is planned that a regional pathology hub laboratory will be created at Morriston Hospital via Welsh Government investment through the capital business case process. This investment case will also propose refurbishment of existing laboratories not on the Morriston site to provide fit for purpose local services to meet relevant service models. This hub and spoke network will work consistently across the region. The proposed hub laboratory will incorporate regional services for cellular pathology, laboratory medicine, microbiology, immunology and specialist reference units and precision medicine laboratories.

The term "Laboratory Medicine" is used throughout the document to refer to the discipline known as Blood Sciences in Hywel Dda, as well as any equivalent service created by the amalgamation of SBUHBs Laboratory Medicine and HDUHB's Blood Sciences services.

- 1.2 Major aspects of the case for change to develop the Project are based on workforce fragility (which has now reached a critical phase), future proofing for demand and developments in service delivery, financial efficiencies and estates with significant backlog maintenance and of a design that is not fit for purpose to deliver modern laboratory services in the majority of cases. The pathology service must be developed to meet service user's changing expectations in respect of high quality, safe and efficient health care services and the delivery of these services as close to home as possible. The pathology service must embrace competitiveness and a commissioner-led focus. It requires strong local clinical leadership and a business orientated management infrastructure, focusing on productivity by matching the workforce to activity, workflow and the roles and functions that are needed to deliver the ODN, through improving systems and processes and realising the benefits of new technology. The ODN will be a partnership between

participating organisations, working collaboratively to achieve its common goals and purpose.

- 1.3 This is a transitional Memorandum of Understanding (“**Transitional MoU**”) and its purpose is to outline the accountability arrangements and resulting responsibilities of the Health Boards in respect of the transitional ODN model, to act as the (transitional) hosting agreement between the Health Boards and to bridge the gap before the Health Boards enter into the MoU for the ODN which will come into effect after the transitional phase has completed, when the final details of the ODN have been agreed. This Transitional MoU should be read in conjunction with the Report to SBUHB’s Board dated 22<sup>nd</sup> November 2022. This Transitional MoU is between SBUHB and HDUHB only. There will be a separate agreement with PHW regarding PHW’s role in respect of the Microbiology Services that PHW will be providing in connection with the ODN. It is envisaged that other MoUs will be required in respect of the ODN.
- 1.4 The ODN will be hosted and managed by SBUHB. This hosting role is entirely separate from the role of SBUHB as a provider of pathology services and all references to SBUHB throughout this Transitional MoU (unless otherwise stated) refer to SBUHB’s role as host of the ODN. SBUHB will ensure a clear distinction between its day-to-day operational responsibilities, as a health care provider for its local population and its responsibilities as the host of the ODN.
- 1.5 The Health Boards have agreed to work together on the Project detailed in ANNEX A.
- 1.6 The Health Boards wish to record the basis on which they will collaborate with each other on the Project. This Transitional MoU sets out:
  - (a) the key objectives of the Project;
  - (b) the principles of collaboration;
  - (c) the governance structures the Health Boards will put in place; and
  - (d) the respective roles and responsibilities the Health Boards will have during the Project.

## 2. DEFINITIONS

“Data Protection Legislation” means all applicable data protection and privacy legislation in force from time to time in the UK including the retained EU law version of the General Data Protection Regulation ((EU) 2016/679) (UK GDPR); the Data Protection Act 2018 (DPA 2018) (and regulations made thereunder) and the Privacy and Electronic Communications Regulations 2003 (SI 2003/2426) as amended; and

“**Intellectual Property Rights**” means any and all patents, trade marks, service marks copyright, moral rights, rights in design, know-how, confidential information and all or any other intellectual or industrial property rights whether or not registered or capable of registration and whether now or in the future subsisting in the United Kingdom or any other part of the world together with all or any good will and accrued rights of action;

“Programme of Work” means the development of the Pathology ODN in its Transition period (up to March 31<sup>st</sup> 2025). This includes;

- (i) The development of the leadership team and any associate staff changes to existing pathology leadership structures.
- (ii) The process by which pathology staff transfer from existing employers to the ODN under the hosted arrangements.
- (iii) The programme management of the development of the network via the existing programme management arrangements and resources.
- (iv) Develop and agree a commissioning arrangement to include a service specification, commissioning method and financial consideration of investment and risk approach
- (v) Ensuring the parallel production of the capital business case for the Hub Laboratory and spoke refurbishments continues to reflect the changing regional nature of pathology service provision and that the regional management team fully engage with the capital business case process to produce a robust, region OBC for the capital infrastructure to support the network in future years.

### **3. KEY OBJECTIVES FOR THE PROJECT**

- The Health Boards shall undertake the Project to achieve the following Key Objectives:
- The Project will deliver high quality pathology services to SBUHB and HDUHB. The Project will take a whole system collaborative approach to ensuring the delivery of safe and effective services across the patient pathway, adding value stakeholders. There will be improved cross-organisational multi-professional clinical engagement to improve clinical care.
- The Project will provide equity of access to pathology services for patients within SBUHB and HDUHB Health Board areas (and those served from neighbouring Health Boards)
- The Project will cover Cellular Pathology, Mortuary, Immunology and Laboratory Medicine.
- The Project will have a single management team (the Pathology ODN Operational Group), a single consultant lead (Network Clinical Director) and laboratory service staffing hosted by SBUHB.
- The management team will be established with clear accountability arrangements for the operational delivery of services.

- There will be a joint mechanism in place to oversee the strategic direction, annual planning and performance delivery of the Project, via the Pathology ODN Board and the Pathology ODN Operational Group.
- The Project will have a single budget set against specifications agreed by the Health Boards.
- There will be investment in the Project by the Health Boards and joint investment in the capital infrastructure where necessary.
- The assets for the Project will remain on each Health Board's balance sheet.
- The provision of service support facilities across the ODN laboratory network will be determined via the Service Specification for the Pathology ODN. This will include responsibility and accountability for estates and facilities management, financial management, IT equipment and support and Human Resources support including Occupational Health
- The quality and safety and finance and performance committees of each Health Board will review, at least annually, a report for the joint service on its quality and safety performance and its operational and financial performance. Escalation of this reporting will be more frequent should it be necessary.
- Services will be accredited to meet regulatory standards. In particular, the Human Tissue Authority (HTA) regulations to ensure human tissue is used safely and ethically, and with proper consent.
- The Lead Director (named Executive of Host Organisation) will be responsible for the quality governance for the Service across the region.
- A digital first approach will be taken to the development of the regional service delivery model.
- The service model will enhance the resilience and sustainability of the Service.

#### **4. CONTRIBUTIONS**

- 4.1 The Health Boards acknowledge that the current position with regard to the Project and the contributions already made or to be made (financial and otherwise) are as detailed in Annex D to this Transitional MoU.

#### **5. PRINCIPLES OF COLLABORATION**

- 5.1 The Health Boards agree to adopt the following principles when carrying out the Project (**Principles**):
- (a) collaborate and co-operate. Establish and adhere to the governance structure set out in this Transitional MoU to ensure that activities are delivered and actions taken as required;

- (b) be accountable. Take on, manage and account to each other for performance of their respective roles and responsibilities set out in this Transitional MoU;
- (c) be open and transparent. Communicate openly about major concerns, issues or opportunities relating to the Project to inform good decision-making and to minimise risk;
- (d) learn, develop and seek to achieve full potential. Share information, experience, materials and skills to learn from each other and develop effective working practices, work collaboratively to identify solutions, eliminate duplication of effort, mitigate risk and reduce cost;
- (e) adopt a positive outlook. Behave in a positive, proactive manner;
- (f) adhere to statutory requirements and best practice. Comply with applicable laws and standards including public procurement rules, data protection and freedom of information legislation. In particular, the Health Boards agree to comply with the requirements of the Information Sharing Protocol attached to this Transitional MoU in ANNEX B;
- (g) act in a timely manner. Recognise the time-critical nature of the Project and respond accordingly to requests for support;
- (h) manage stakeholders effectively;
- (i) deploy appropriate resources. Ensure sufficient and appropriately qualified resources are available and authorised to fulfil the responsibilities set out in this Transitional MoU. In particular the parties agree to make the contributions detailed in ANNEX D to this Transitional MoU;
- (j) act in good faith to support achievement of the Key Objectives and compliance with these Principles;
- (k) be mutually supportive, respecting the statutory status and independence of all participating organisations; and
- (l) be valued at the highest levels within the ODN, with visible leadership, clear lines of accountability and a coherent collaborative approach.

## **6. PROJECT GOVERNANCE**

### **6.1 Overview**

As a non-statutory organisation without legal identity, the ODN does not in itself possess constitutional rights, but rather it will fall under the governance arrangements of its host organisation, SBUHB. Commissioners will continue to be accountable for the commissioning of services and providers will continue to be accountable for the delivery of services. Each Health Board would either be separately or collectively accountable for the commissioning of services.

The Health Boards will have in place appropriate governance arrangements and Schemes of Delegation as may be necessary and required in order to carry out their respective functions within the ODN.

The ODN will be accountable to SBUHB for all arrangements pertaining to the running of the ODN. This will include, but not be limited to, employment of staff to work within the

ODN, provision of all employment HR and corporate services, accommodation and training.

The governance structure defined below provides a structure for the development and delivery of the Project.

## 6.2 Guiding Principles

The following guiding principles are agreed. The Project's governance will:

- (a) provide strategic oversight and direction;
- (b) be based on clearly defined roles and responsibilities at organisation, group and, where necessary, individual level;
- (c) align decision-making authority with the criticality of the decisions required;
- (d) be aligned with Project scope (and may therefore require changes over time);
- (e) leverage existing organisational, group and user interfaces;
- (f) provide coherent, timely and efficient decision-making; and
- (g) correspond with the key features of the Project governance arrangements set out in this Transitional MoU.

## 6.3 Recruitment of ODN Leadership Team in connection with the Transitional ODN

The ODN Leadership Team acts as a resource, co-ordinator and facilitator for all its stakeholders to achieve a collaborative approach to safe and equitable and effective specialised pathology services. It consists of the following membership:

ODN Post	Roles and Responsibilities
Regional Pathology Network Director	To be operationally responsible for the delivery of the Pathology ODN and all of its associated services.
Regional Pathology Network Clinical Director	To be the Consultant level Clinical Director of the Pathology Network. To work alongside the Network Director to provide senior leadership, operational accountability and resource management. To lead on Quality and Safety for the Network.
Pathology Transformation Programme Director	A fixed term post linked to the establishment of the Network and not required for recurrent running of the service once established and senior leadership team in place.

Designated Individual for Mortuary Services (i.e. the individual designated in a licence under the Human Tissue Act 2004)	Responsible for the duties set out in Section 18 (Duty of the designated individual) of the Human Tissue Act 2004.
Regional Mortuary Manager	Responsible for the operational running of Mortuary services in both Health Boards under the direction of the Mortuary services MOU

#### 6.4 Provider Organisations within the Transitional ODN

The following organisations shall perform the following ODN functions:

Organisation	Function
Swansea Bay University Health Board	ODN host organisation and commissioner of the ODN
Hywel Dda University Health Board	Commissioner of the ODN
Public Health Wales	Provider of majority microbiology services in region. Commissioned by HDUHB and SBUHB
A Regional Collaboration for Health (ARCH)	Joint Health Board and Swansea University programme supporting change in service delivery i.e. the formation of the ODN

#### 6.5 Governance Structure

##### Pathology ODN Delivery Board

- (a) The Pathology ODN Delivery Board provides overall strategic oversight and direction to the Project. The Board meets on a monthly basis and is the main decision-making body, being responsible for leading the ODN, considering current and future strategy, ratifying ODN guidelines and overseeing the work needed to deliver its annual programme of work and meet its agreed aims and objectives. This group will consist of:

**SBUHB:**

Chief Operating Officer (Lead Director)

Director of Therapies and Health Sciences



Director of Finance

Medical Director's Office representative

Workforce Director representative

Network Director, Pathology ODN

Network Clinical Director, Pathology ODN

Programme Director, ARCH Pathology (Transitional ODN only)

**HDUHB:**

Director of Therapies and Health Sciences

Director of Operations

Director of Finance

Medical Director's Office representative

Workforce Director representative

- (b) The Pathology ODN Delivery Board shall be managed in accordance with the terms of reference set out in ANNEX C to this Transitional MoU.

Pathology ODN Operational Group

- (a) The Pathology ODN Operational Group will provide strategic management at Project and workstream level. The Pathology ODN Operational Group shall meet monthly. It will provide assurance to the Pathology ODN Board that the Key Objectives are being met and that the Project is performing within the boundaries set by the Pathology ODN Board.
- (b) The Pathology ODN Operational Group consists of representatives from each of the Parties. The Pathology ODN Operational Group shall have responsibility for the creation and execution of the programme of work and deliverables, and therefore it can draw technical, commercial, legal and communications resources as appropriate into the Pathology ODN Operational Group. The core Pathology ODN Operational Group members are:

Network Director, Pathology ODN

Network Clinical Director, Pathology ODN

Service Manager, Cellular Pathology, Pathology ODN

Clinical Director, Cellular Pathology, Pathology ODN

Service Manager, Laboratory Medicine, Pathology ODN

Clinical Director, Laboratory Medicine, Pathology ODN

Quality and Safety Lead, Pathology ODN

Training Lead, Pathology ODN

Service Group Director, Morriston Hospital

Pathology Workforce Manager

Pathology Finance Manager

- (c) The Pathology ODN Operational Group shall be managed in accordance with the terms of reference set out in ANNEX C to this Transitional MoU.

## 7. REPORTING

Project reporting shall be undertaken at three levels:

- i) **Pathology ODN Operational Group:** minutes and actions will be recorded for each Pathology ODN Operational Group meeting. Meetings will be held on a monthly basis. Any additional reporting requirement shall be at the discretion of the Pathology ODN Operational Group.
- ii) **Pathology ODN Delivery Board:** Reporting shall be monthly, based on the minutes from the Pathology ODN Operational Group highlighting: Progress within the current period; issues being managed; issues requiring help (that is, escalations to the Pathology ODN Board) and progress planned next period and/or aligned with the frequency of the Pathology ODN Board meetings.
- iii) **Organisational:** the Pathology ODN Delivery Board should report every 2 months via an agreed standardised format to both Health Boards Management Board/Executive Team and committees. A Quarterly report should be prepared for each organisations Quality and Safety committee highlighting any issues within the period. The ODN Delivery Board should prepare an annual review covering the previous 12 month period, highlighting activity, performance, quality and safety and workforce issues should be shared with SBUHB and HDUHB Management Board/Executive Team and to the appropriate committee before public board reporting.

This Transitional MoU does not affect any existing reporting arrangements currently in place.

## 8. QUALITY GOVERNANCE ARRANGEMENTS

- 8.1 The ODN will not have statutory responsibility for clinical governance arrangements within each Health Board. The ODN will be responsible for ensuring regular and complete reporting into the Pathology ODN Operational Group on clinical governance matters relating to the ODN.

- 8.2 Both Health Boards will provide the information requirement outlined in the [name of document], thus enabling the ODN to be compliant with reporting requirements.

Both Health Boards will provide confirmation to the ODN that Quality governance information and incidents have been reported to their respective Health Board's Quality and Safety Committee.

## **9. ODN POLICIES**

- 9.1 During the Transition period the ODN will develop and seek agreement on policies relating to the operational running of the network and clinical and organisational governance. These include (but are not limited to) the following:

- (a) Quality Governance Policy
- (b) Information Sharing Protocol / Data Sharing Agreement (Annex B)
- (c) Quality statement and reporting matrix
- (d) Activity and performance matrix
- (e) Service specification
- (f) Commissioning specification and process

Development and approval of the above will be required prior to the Transnational ODN moving to the permanent MOU agreement.

- 9.2 The policies will be accessible on the SharePoint website of each Health Board. New policies and updates to existing policies will be developed and approved through the ODN governance structure. Each Health Board will be responsible for ensuring it has a process in place for receiving and implementing notifications of new policies and updates to existing policies.

## **10. CLINICAL GUIDELINES**

- 10.1 All clinical guidelines have been developed collaboratively with the process of development having been approved by the Pathology ODN Operational Group. Each Health Board should acknowledge access to the guidelines.

- 10.2 The ODN will update the clinical guidelines as required and provide notification to the Health Boards. Both Health Boards are responsible for having in place a system of receiving updates to clinical guidelines.

## **11. ROLES AND RESPONSIBILITIES**

- 11.1 The Health Boards shall undertake the following roles and responsibilities to deliver the Project:

<b>ACTIVITY</b>	<b>SBUHB</b>	<b>HUHB</b>
<b>Governance and Finance</b>		
Host organisation	Lead	Assure
To have in place appropriate governance arrangements and a Scheme of Delegation as necessary and required to enable the ODN to carry out its functions	Mutual	Mutual
To hold and manage the budget for the ODN making payments and receiving income as necessary	Lead	Assure
To be the legal entity which enters into agreed procurement arrangements to include, but not restricted to, procurement contracts, quotations, terms of engagement etc. commissioned by the ODN for example, in respect of the refurbishment of laboratories in satellite hospitals to modernise and create fit for purpose pathology services.  It is anticipated (although not yet decided) that the ODN may procure as a network during the transitional form, in order to improve purchaser power and to provide consistent equipment in all sites over time (existing contracts pending/ending in the next financial year will be reviewed)	Lead	Assure
To be authorised to appoint lawyers and other professional advisors and to agree the terms and conditions from time to time on behalf of the ODN	Lead	Assure
In fulfilling its obligations and responsibilities under this Transitional MoU, the Health Boards shall not be required to act contrary to their statutory powers and duties, Standing Orders and Standing Financial Instructions, Welsh Government approval requirements, corporate governance requirements generally, procurement requirements (for example, the Public Contracts Regulations 2015 or the Procurement Act 2023) or any legal obligations not covered elsewhere under this clause 11	Mutual	Mutual
Responsibility for ensuring that the Pathology ODN Board is accountable to the organisations represented on its board	Lead	Assure
Accountability for the commissioning of providers for the delivery of services	Mutual	Mutual
<b>Service Specification</b>		
Draft the Service Specifications for Cellular Pathology, Mortuary, Immunology and Laboratory Medicine, prior to the operational date of the ODN and develop the Service Specifications as required	Mutual	Mutual
<b>Strategic Planning</b>		
Provide professional and clinical leadership across the ODN	Lead	Assure
Host a risk register and undertake risk management across the ODN	Lead	Assure
Develop an annual working plan for an approved programme of work for the ODN to deliver against the quality and delivery framework and	Lead	Assure

report through the governance structure progress against the programme of work		
Contribute towards evaluation of the ODN	Lead	Assure
To provide effective linkage into commissioning groups	Lead	Assure
Produce quarterly and annual reports	Lead	Assure
Undertake comparative benchmarking and audit across the ODN for quality control purposes	Lead	Assure
Procurement of Service Providers for the delivery of Services – eg appointment of a Supply Chain Partner to support capital planning	Lead	Assure
Outsourcing of activity – regional basis	Lead	Assure
<b>Operational Delivery</b>		
Implementation of ODN wide digital systems to support pathology i.e. LIMS 2.0 national roll out of new pathology system as a region scheduled for completion in February 2025	Lead	Assure
Develop coordinated patient clinical pathways throughout the Service over a wide area (as a minimum, the geographic areas of both Health Boards) to ensure access to high quality, safe and efficient pathology services	Lead	Assure
Ensure improved access and equity of access to pathology services	Lead	Assure
Responsibility for monitoring of day-to-day capacity across the ODN, agreeing and working to an escalation plan (with agreed thresholds for escalation triggers) both within and across the ODN to monitor and manage surges in demand for pathology services	Lead	Assure
Support capacity planning and activity monitoring for collaborative matching or demand and supply	Lead	Assure
Ensure the quality of the ODN is monitored and subject to a process of continuous quality improvement through clinical audit	Lead	Assure
Responsibility for performance management of the ODN in line with the Services Specification(s)	Lead	Assure
Develop and implement ODN standardised operating policies and procedures	Lead	Assure
Joint recruitment i.e. medical workforce and generally to posts	Lead	Assure
Advanced Practice BMS development	Lead	Assure
Training – standardisation and movement of trainees and trainers between sites where relevant	Lead	Assure
Development of single quality systems	Lead	Assure
<b>Tactical (local) Advice and Support to Commissioners</b>		
Provide local information, data and intelligence to support performance monitoring of the ODN (i.e. clinical reports, process measures, key performance and quality indicators, case-mix standardised outcomes, workforce data etc.)	Lead	Assure

To provide ongoing programme management of a phased implementation across the ODN	Lead	Assure
Develop, through the Digital Sub-group, a shared IT system that can 'communicate' or 'interface'? between Health Boards	Mutual	Mutual
<b>Improved Quality and Standards of Care</b>		
Deliver a clinical governance framework including a process for incident reporting with follow up action plans and network morbidity and mortality review. This includes collaborative serious incident investigation.	Lead	Assure
Deliver an ODN-wide training and education programme encompassing the whole patient pathway prioritising key areas	Lead	Assure
Implement a clinical informatics system for the ODN	Lead	Assure
Ensure on-going service improvements and best practice models are embedded and contribute to improved quality performance	Lead	Assure
Monitor and provide advice on improvements to clinical services and commissioners	Lead	Assure
Use clinical process and clinical outcome measures to compare and benchmark providers	Lead	Assure
Deliver an annual quality improvement and audit programme	Lead	Assure
<b>Partnership Development</b>		
Engage with staff during the Transitional MOU period to ensure staff are full informed and engaged on the development of the Pathology ODN and where appropriate consulted upon any formal changes that might arise. This will include regular briefing to and attendance of Staff Side Partnership meetings in both organisations from the Pathology team in liaison with local Workforce representatives.	Mutual	Mutual
Engagement with third sector organisations	Lead	Assure
Linkage with any other relevant ODNs (national/local level)	Lead	Assure
Enhance relationships with other health boards in Wales to ensure the ODN reaches optimal effectiveness	Lead	Assure
Embed communication strategy and key communication deliverables	Lead	Assure
Monitoring and performance management of active engagement by members in the ODN to improve performance against agreed outputs	Lead	Assure
Participation in relevant national policy or guideline development	Lead	Assure

For the purpose of the table above:

- (a) **Lead:** the Health Board that has principal responsibility for undertaking the particular activity, and that will be authorised to determine how to undertake the activity. The Lead must act in compliance with the Objectives and Principles at all times, and consult with the other Health Board in advance if they are identified as having a role to Assure the relevant activity;

- (b) **Assure:** the Health Board that will defer to the Lead on a particular activity, but will have the opportunity to review and provide input to the Lead before they take a final decision on any activity. All assurance must be provided in a timely manner. Any derogations raised must be limited to raising issues that relate to specific needs that have not been adequately addressed by the Lead and/or concerns regarding compliance with the Key Objectives and Principles.
  - (c) **Mutual:** both Health Boards share equal responsibility for undertaking the activity.
- 11.2 Within 3 months of the date of this Transitional MoU the Health Board with the Lead role for any aspect of the Project shall develop a delivery plan for that part of the Project which shall identify the following:
- (a) the key milestones for the delivery of the Key Objectives;
  - (b) what employees (other than employees identified in this Transitional MoU) will be required to work on the Project;
  - (c) whether any staff will need to be seconded from one Health Board to the other;
  - (d) what staff will require access to the premises of the other Health Board;
  - (e) TUPE implications; and

Each delivery plan must be approved by the Pathology ODN Operational Group prior to being implemented.

## 12. EMPLOYMENT OF STAFF

- 12.1 The working assumption is that when the ODN takes effect (and not during the phase of this Transitional MoU) it is anticipated that there will be a “relevant transfer” for the purposes of the Transfer of Undertakings (Protection of Employment) Regulations 2006 (as amended) (“TUPE”) i.e. the ODN function for pathology services is formed by transferring existing staff into the ODN host organisation (SBUHB) and the assumption is that TUPE will apply to staff who are in scope to transfer under TUPE at the commencement of the provision of the pathology services. Any new posts are appointed to SBUHB as ODN posts and therefore, TUPE on commencement of services will not apply to these new posts.

In the event that the Transitional MoU proceeds to the MoU for the ODN, the existing employer, will be responsible for any TUPE arrangements (e.g. the obligation to inform and consult with appropriate representatives (where appropriate) and provide Employee Liability Information under regulation 11, TUPE) and in respect of re-tendering and the handover of services. . If and when the provision of pathology services under the ODN expires or terminates pursuant to applicable contracts, SBUHB, as the employer under the ODN, will be responsible for the application of TUPE (e.g. the obligation to inform and consult with appropriate representatives (where appropriate) and provide Employee Liability Information under regulation 11, TUPE) and in respect of re-tendering and the handover of services.



As part of the transitional phase/this Transitional MoU, the Health Boards shall agree which services are to be transferred to the ODN and consequently, which staff are in scope to TUPE transfer. This information will be used to inform the MoU for the ODN and will be captured in the ODN Service Specification as and when developed.

- 12.2 SBUHB shall be responsible for the appointment of staff in line with the posts agreed through the Pathology ODN Operational Group.
- 12.3 New staff appointed to work within the ODN will be employed by SBUHB, they will be entitled to be treated as any other SBUHB employee. They will be expected to abide by all SBUHB policies, procedures and guidance including, but not limited to, fire safety and health and safety procedures. ODN staff will benefit from access to all applicable policies and procedures including training and development.
- 12.4 The ODN staff will be accountable for their performance to the Service Group Director, Morriston Hospital who, for this role, is accountable to the ODN Senior Responsible Officer Director in SBUHB.
- 12.5 The ODN core team will be situated in Morriston Hospital but with the expectation that they work across the Network flexibly to meet the needs of the service and provide a visible presence in all sites. Some posts in the Network will be Regional roles, i.e. working across or being responsible for services across multiple sites. ODN staff will require practice rights in both Health Board organisations regardless of their normal 'base' site as they could be required to work across the network as part of their roles. In the transitional phase and prior to any TUPE transfer, those staff who have been identified as working across both Health Board sites will be given practice rights to practice within both sites. Such rights will be supplemental to the staffs' existing contracts (via a collateral contract or "side letter"), which will bridge the gap prior to implementation of the MoU for the ODN and the TUPE transfer. On the relevant TUPE transfer date, the side letter will remain in force (for the duration of the contract or for as long as cross-site practice rights are necessary), to provide for cross-site practice rights where applicable to those staff who are required to practice within both Health Board sites.
- 12.6 ODN staff members will be expected to maintain professional CPD, complete all mandatory training and uphold competencies in line with the requirements of the role. ODN staff will be subject to all SBUHB HR policies including annual appraisals/PADR and disciplinary processes ODN staff in training will be expected to work in the geographic areas of both Health Boards, as part of their training.

### **13. ESCALATION**

- 13.1 If either Health Board has any issues, concerns or complaints about the Project, or any matter in this Transitional MoU, that Health Board shall notify the other Health Board and the Health Boards shall then seek to resolve the issue by a process of consultation. If the issue cannot be resolved within a reasonable time, the matter shall be escalated to the Pathology ODN Operational Group, which shall decide on the appropriate course of action to take. If the matter cannot be resolved by the Pathology ODN Operational Group within [28] days, the matter may be escalated to the Pathology ODN Board for resolution. At this stage of escalation, the CEOs of both organisations should be notified of the dispute with a view to resolution. If the CEOs cannot resolve the dispute, it will be escalated to Welsh Ministers for resolution.

#### **14. RISK MANAGEMENT**

- 14.1 A risk management arrangement and process will be established in the event of closure of the ODN. This will include an assurance process to ensure risks are identified, analysed, evaluated, controlled, monitored and communicated appropriately.
- 14.2 A quality assurance process will be undertaken to ensure consistency of standards and quality of care across the ODN. This will include ODN facilitated external/internal peer review undertaken as appropriate.
- 14.3 There will be an ODN escalation plan and structures established in the event of a major incident / surge with links to appropriate organisations for effective emergency preparedness, resilience and response arrangements.

#### **15. INTELLECTUAL PROPERTY**

- 15.1 The Health Boards intend that notwithstanding any secondment any Intellectual Property Rights created in the course of the Project shall vest in the Health Board whose employee created them (or in the case of any Intellectual Property Rights created jointly by employees of both Health Boards in the Health Board that is Lead Health Board noted in clause 11 above for the part of the Project that the Intellectual Property Right relates to).
- 15.2 Where any Intellectual Property Right vests in either Health Board in accordance with the intention set out in clause 15.1 above, that Health Board shall grant an irrevocable licence free of charge to the other Health Board to use the Intellectual Property Rights for the purposes of the Project.
- 15.3 Each Health Board shall retain all title, right and interest in and to its respective Intellectual Property Rights.
- 15.4 Property Rights created prior to the effective date of, or outside the scope of, this Transitional MoU ("Background IP"). Save as expressly granted under this clause 15 or as otherwise agreed herein, nothing in this Transitional MoU shall be construed as a transfer, licence and/or assignment from one Health Board to the other of ownership of, title, right or interest in and to its respective Background IP.

#### **16. DATA PROTECTION AND INFORMATION GOVERNANCE**

- 16.1 The Health Boards agree to comply with the requirements of the Information Sharing Protocol and to enter into a Data Sharing Agreement as applicable, as attached to this Transitional MoU in Annex B.

#### **17. TERM AND TERMINATION**

- 17.1 This Transitional MoU shall commence on the date of signature by both Health Boards, and subject to clause 17.3, shall expire on 31 March 2025 or on completion of the Project, whichever is the latest.
- 17.2 If the Project is not completed by 31 March 2025, the ODN Delivery Board shall propose the time period of extension for the Transitional MOU for decision by both Health Boards in their March 2025 meetings.

17.3 Either Health Board may terminate this Transitional MoU by giving at least six months' notice in writing to the other Health Board at any time.

## **18. VARIATION**

18.1 This Transitional MoU, including the Annexes, may only be varied by written agreement of the Pathology ODN Board.

## **19. CHARGES AND LIABILITIES**

19.1 Except as otherwise provided, the Health Boards shall each bear their own costs and expenses incurred in complying with their obligations under this Transitional MoU.

19.2 The Health Boards agree to share the costs and expenses arising in respect of the Project between them in accordance with the Contributions Schedule set out in ANNEX D to this Transitional MoU to be developed by the Pathology ODN Operational Group and approved by the Pathology ODN Board within three months of the date of this Transitional MoU.

19.3 Both Health Boards shall remain liable for any losses or liabilities incurred due to their own or their employee's actions and neither Health Board intends that the other Health Board shall be liable for any loss it suffers as a result of this Transitional MoU.

## **20. OWNERSHIP OF ASSETS**

20.1 All assets (including intellectual property rights) acquired by SBUHB in connection with the ODN shall belong to SBUHB but be held upon trust for the ODN.

20.2 SBUHB shall, to the extent it is legally entitled to do so, transfer ownership and any other rights in such assets to such party or body as a commissioner shall require and within such timescales as are reasonably required.

20.3 In the event that any income is derived from such assets or from their disposal, such revenues shall be regarded as part of the ODN income and accounted for accordingly.

## **21. PROCUREMENT**

21.1 When existing contracts, which have been entered into separately by each Health Board, have expired, it is envisaged that new contracts will be entered into for the benefit of the ODN by adopting a joint approach, for example, SBUHB will act as the lead procurer for goods, services and works that are required by the Health Boards.

21.2 Existing (separate) contracts entered into by the Health Boards will remain in force until their expiry date (unless such contracts may be lawfully terminated, for example, because of contractor default, insolvency etc. or where the Health Boards have a right to terminate at will on written notice). Upon expiry, the approach in clause 21.1 above will be adopted.

21.3 Where contract terms permit and subject to the public procurement rules in force at the time, in order to be in a position to re-procure jointly, a Health Board may extend (or not, as the case may be) any existing contract to align its expiry date with a corresponding contract entered into by the other Health Board.

## **22. HOST HEALTH BOARD - DUTY OF CARE**

22.1 SBUHB shall be responsible for ensuring that all reasonable skill, care and diligence are exercised in carrying out those services which it is required to perform under the ODN as the host Health Board, properly and efficiently in accordance with this Transitional MoU and its overall responsibilities under the National Health Service (Wales) Act 2006 and all other appropriate legislation.

22.2 SBUHB shall keep the ODN informed of any reasonably foreseeable or actual changes in circumstances which are likely to affect its ability to comply with the terms of this Transitional MoU as the Host Health Board.

## **23. MANAGEMENT OF CONCERNS**

23.1 Where a matter is received into the ODN and is regarded as an individual concern (as defined in The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ("Redress Regulations")), SBUHB will only be responsible for the management of those concerns where qualifying liability (as defined in the Redress Regulations) in tort is established, which relates to its geographical area of responsibility and arises from its own resident population. In such circumstances, the Chief Executive of SBUHB will be responsible for investigating and responding to the concern in accordance with the Redress Regulations. For the avoidance of doubt, complaints or matters which are not Concerns or Complaints (as defined in the Redress Regulations) but which otherwise relate to the performance of this Transitional MoU, are dealt with under clauses 23.5 and 23.6 of this Transitional MoU.

23.2 Individual Concerns or Complaints received into the ODN and relating to patients resident outside SBUHB's geographical area of responsibility will be referred to the Chief Executive of the health board in the appropriate geographical area no later than two (2) Working Days of becoming aware of that Concern or Complaint.

23.3 Where a Concern or Complaint involves the exercise of functions by both SBUHB and HDUHB, the Health Boards shall co-operate for the purposes of co-ordinating the handling and consideration of the Concern or Complaint in accordance with the Redress Regulations and shall ensure that the person who notified the Concern or Complaint receives a co-ordinated response to the Concern or Complaint that he or she has notified. This duty to cooperate includes a duty for each Health Board to:

- (a) agree which Health Board shall take the lead in:
  - (i) co-ordinating the handling and consideration of the Concern or Complaint; and
  - (ii) communicating with the person who notified the Concern or Complaint;
- (b) provide information relevant to the handling and consideration of the Concern or Complaint which is reasonably requested by the other Health Board; and
- (c) to ensure that it is represented at any meeting reasonably required in connection with the handling and consideration of the Concern or Complaint.

- 23.4 In respect of the performance of this Transitional MoU, both Health Boards shall and shall procure that their staff shall be required to comply with the duty of candour introduced pursuant to the Health and Social Care (Quality and Engagement) (Wales) Act 2020 and any Guidance issued in relation to the implementation of this duty and the 2020 Act, where an outcome triggers the duty of candour procedure.
- 23.5 Where a matter is considered to be a review of funding decisions it will be dealt with in accordance with the Review Process set out in the All Wales Policy for Making Decisions on Individual Patient Funding Requests.
- 23.6 If either Health Board receives any formal inquiry, complaint, claim or threat of action (which is not a Concern or Complaint (as defined in the Regress Regulations) from a third party (including, but not limited to, claims made by a supplier or requests for information made under the Freedom of Information Act 2000) or under the Data Protection Legislation in relation to the Project (“Receiving Health Board”), such inquiry, complaint, claim or threat of action shall be dealt with by that Receiving Health Board, having regard to its internal policies and procedures and all relevant law. Where either Health Board receives a formal inquiry, complaint, claim or threat of action from a third party which requires information from the other Health Board prior to responding, the other Health Board shall assist and cooperate in a timely manner to enable the requesting Health Board to comply with its information and other disclosure obligations. If the Health Board providing the information to assist the other Health Board considers that the information is confidential or otherwise not in its interests or in the public interest to disclose, it shall have the opportunity to make representations to the requesting Health Board and both Health Boards shall attempt to reach agreement as to what information is disclosable. The requesting Health Board shall have absolute discretion as to what information, provided by the other Health Board, may be disclosed when responding to a formal inquiry, complaint, claim or threat of action from a third party. In all cases, the Receiving Health Board shall report the matter to the Pathology ODN Operational Group.

## **24. AUDIT**

- 24.1 SBUHB will provide an effective independent internal audit function as a key source of its internal assurance arrangements. This will be in accordance with NHS Wales Internal Auditing Standards and any other requirements determined by the Welsh Government.
- 24.2 SBUHB will ensure that relevant external audit arrangements are in place which give due regard to the functions of the ODN.

## **25. EFFECT OF ODN ON SBUHB’S CORE FUNCTIONS**

- 25.1 In the event of SBUHB’s determining (acting reasonably) that the performance by SBUHB of its obligations under this Transitional MoU is having a detrimental effect on SBUHB’s ability to fulfil its core functions, SBUHB may instruct the ODN Senior Responsible Officer and SBUHB’s Chief Executive to review the operation of this Transitional MoU.
- 25.2 In carrying out a review of this Transitional MoU further to clause 25.1 above, the ODN Senior Responsible Officer and SBUHB’s Chief Executive shall consider the source and manner of any detriment identified by SBUHB’s Board further to clause 25.1 and shall put forward such amendments and variations to this Transitional MoU and the associated

governance arrangements between the ODN and SBUHB as they may consider appropriate.

- 25.3 SBUHB's Board shall consider the recommendations made further to clause 25.2 and may recommend to the ODN Senior Responsible Officer and the Chief Executive of SBUHB that this Transitional MoU and the associated governance arrangements are amended accordingly.

**26. STATUS**

- 26.1 This Transitional MoU is not intended to be legally binding, and no legal obligations or legal rights shall arise between the Health Boards from this Transitional MoU. The Health Boards enter into the Transitional MoU intending to honour all their obligations.
- 26.2 Nothing in this Transitional MoU is intended to, or shall be deemed to, establish any partnership or joint venture between the Health Board, constitute either Health Board as the agent of the other Health Board, nor authorise either of the Health Board to make or enter into any commitments for or on behalf of the other Health Board.

Signed for and on behalf of

SWANSEA BAY UNIVERSITY LOCAL  
HEALTH BOARD

Signature: .....

Name: .....

Position: .....

Date: .....

Signed for and on behalf of  
HYWEL DDA UNIVERSITY LOCAL HEALTH  
BOARD

Signature: .....

Name: .....

Position: .....

Date: .....

**CONTACT POINTS**

**SBUHB**

Name: .....

Office address: .....

.....

Tel No: .....

E-mail Address: .....

**HDUHB**

Name: .....

Office Address: .....

.....

Tel No: .....

E-mail Address: .....

## **ANNEX A    The Project**

### **Project overview**

The South West Wales Pathology Programme has two key components:

1. The development of a single Regional Pathology service via an Operational Delivery Network (ODN) approach, with Swansea Bay as the host organisation.
2. The development of a Hub Laboratory Centre of Excellence on the Morrison Hospital site to provide fit for purpose modern laboratory service for the region and local laboratory refurbishments via Welsh Government Capital investment processes.

This MOU focusses on the development of the Operational Delivery Network (ODN). The Business Case for development of the Hub building and local laboratory refurbishments has separate governance led by SBUHB.

The development of the ODN aims to provide stability and sustainability to pathology service across the region. Developing critical mass of service delivery, joint training and quality management systems, single digital information systems and collective recruitment for hard to recruit to roles will all contribute to decreasing risk with current service delivery methods. The balance of risk between the organisations does need to be considered as part of the establishment of the network and arrangements with regard for example capital investment in retained local laboratory services outside of any investment secured by the capital process will need to be considered i.e. significant backlog maintenance to existing buildings.

One of the key aims of the network is to ensure consistency of service delivery to the regional population regardless of their location. This will be achieved through the implementation of digital pathology solutions where possible, the development of a robust regional transport and logistics network and the timely analysis and reporting of investigations. Developing consistent service models and equipment and processes in all laboratories will also shore up business continuity through the movement of samples in the event of any laboratory down time in any site.

### **Background**

To progress the transformation plan for Pathology services in South West Wales, the Health Boards agreed the need to create a Regional Pathology service model. This approach, new for NHS Wales but not across the United Kingdom would enable joint recruitment, collaborative development of service plans, standardisation of approach, equipment and facilities and the benefits of consolidation. A number of possible options of how a regional management model could operate that would be underpinned by a strong governance framework and an agreed set of principles were considered.

A Joint Executive meeting between SBUHB and HDUHB was held on 24<sup>th</sup> November 2021; these points were discussed and a subsequent visioning workshop was held on 29<sup>th</sup> November 2021, chaired by the then CEO of Swansea Bay UHB.

A Regional Pathology Task and Finish (T&F) Group convened in 2022, chaired by Andrew Carruthers COO HDUHB, and supported by Christine Morrell as SRO for the ARCH Regional Pathology Transformation Programme. The group considered their options for the management



model and undertook an appraisal and sought advice from NHS Wales Legal and Risk services. The detail of the decision making process is covered in the November 2022 paper considered by both Health Boards (see Appendix). The conclusion was the development of an Operational Delivery Network (ODN) for Pathology services with an aim to be operational by Q4 2022/23,

Following the establishment of the ARCH Pathology team in early 2023/24 the task of delivering the ODN model moved forward at pace. The terms of reference of the T&F group were revised to form an ODN Transition Board and sub groups established to consider implications for Finance and Commissioning, Workforce and Digital services. In addition, Legal & Risk advice has been retained to work with both HB governance teams on the Memorandum of Understanding and legal agreements required to deliver the network.

To date the following developments have been agreed:

1. Development and agreement of a Mortuary MOU for the Region. This has facilitated closer working between the mortuaries and the appointment of a regional mortuary team, joint training processes and rotations.
2. Development and agreement of joint regional management structure and job descriptions and person specifications for those roles
3. Baseline assessment of performance, resources, quality/accreditation, compliance and workforce for the region
4. Review of existing logistics and transport arrangements
5. Continued development of regional Digital Cellular Pathology pilot in the region
6. Staff engagement in all laboratories in the region to develop the identity and culture of the regional service and understand the current strengths and challenges on each individual site.
7. Appointment of a single Designated Individual (DI) for the regional mortuary service following the retirement of the current HDUHB post holder. This has been achieved by appointment of the same individual to take responsibility for both Health Board licenses, although licenses still remain separate.

Current work is focussing on:

1. Development of a regional 'compliance' team structure to combine functions in both organisations in pathology, IT, Quality, Health and Safety and Training
2. LIMS 2.0 roll out regionally by February 2025. To ensure that the region has a consistent pathology digital system with replicable supporting processes in both health boards
3. Consideration of the regional recruitment and training of non-consultant medical staff to histopathology
4. Development of a Transitional Pathology Regional MOU for consideration by both Boards to support the development of the regional management team and integrated service change
5. Development of the Service Specification and commissioning arrangements for the Pathology service for consideration by both organisations.

The proposal therefore is to continue to regionalise the service via the Transition Board but also move into the territory over the next 12 months of harmonising workforce arrangements. Once the commencement date of the Network is agreed by both Boards the process of appointing into the senior leadership team and subsequent TUPE transfer of staff into the new service model will commence.

## **Transitional MOU**

This transitional MOU has been developed by a task and finish group established under the leadership of the ARCH Programme Director with input from NHS Wales Shared Services – Legal and Risk, and SBU and HDUHB Governance Teams. The group has met monthly to develop the attached draft MOU for the Transition period.

The Transitional MOU takes the same form as the proposed final MOU but with the following differences:

- Transitional MOU only covers the period to April 2025. It has no permanence as the organisations will need to agree to the formal MOU once developed for the recurrent networked service
- The ToR for the ODN will be developed during the Transition period and therefore this annex and others are under development through the Transition period
- The

The Transitional MOU seeks to support:

- Development of the Service Specification for the Pathology ODN
- Development of Commissioning arrangements including quality management and assurance
- Support to start implementing the leadership team for the regional service
- Information and data sharing of staff information and clinical service information

## **ANNEX B    Information Sharing Protocol**

The Health Board Information Governance Teams will work with the ARCH Programme Team and ODN Board to develop and approve an Information Sharing protocol between the organisations.

This is already in place for the separate Mortuary MOU and will form the basis of the overall Pathology Protocol.

A DPIA has been undertaken to assist in the development of the protocol

## **ANNEX C Pathology ODN Delivery Board Terms of Reference**

### **(a) Remit:**

In Transition phase the ODN will have two key tasks:

- To develop and approve the various documents that will finalise the Pathology ODN formation and seek approval via public board. This will include: service specification and commissioning approach, MOU (permanent), TUPE arrangements, assurance and monitoring processes
- To appoint to the Network Director roles

The Board will also oversee the Operational Group and shape the regional service provision and assurance through this transition phase.

### **(b) Membership Decision-making:**

#### **SBUHB:**

Chief Operating Officer (Lead Director)

Director of Therapies and Health Sciences

Director of Finance

Medical Director's Office representative

Workforce Director representative

Network Director, Pathology ODN

Network Clinical Director, Pathology ODN

Programme Director, ARCH Pathology (Transitional ODN only)

#### **H DUHB:**

Director of Therapies and Health Sciences

Director of Operations (*Transition Chair*)

Director of Finance

Medical Director's Office representative

Workforce Director representative

**(c) Meetings:**

The meeting will take place monthly

Papers will be circulated one week in advance

Meetings will routinely take place via MSTeams or in person if required

Quorum will be three representatives from each organisation.

**Pathology ODN Operational Group Terms of Reference**

**(a) Remit:**

The Pathology ODN Operational Group will provide a regional focus to operational service management and operational delivery.

The group will develop a standing agenda through the Transition phase to ensure oversight of Pathology operational matters on a Regional footing.

This should include (but not be limited to):

- activity and performance information,
- accreditation updates,
- quality and safety information and;
- financial performance.

The group will be cognisant of the developing service and commissioning specification for Pathology and will be charged with developing information in the Transition phase to ensure the delivery of the commissioned service can be monitored and assurance provided to the ODN Board

The group will also be charged with developing the Pathology ODN annual plan, detailing service developments and improvements as well as developing any investment cases for Board approval.

**(b) Decision-making:**

- Network Clinical Director, Pathology ODN (Chair)
- Network Director, Pathology ODN
- Service Manager, Cellular Pathology, Pathology ODN
- Clinical Director, Cellular Pathology, Pathology ODN
- Service Manager, Laboratory Medicine, Pathology ODN
- Clinical Director, Laboratory Medicine, Pathology ODN
- Quality and Safety Lead, Pathology ODN
- Training Lead, Pathology ODN

- Service Group Director, Morriston Hospital
- Pathology Workforce Manager
- Pathology Finance Manager

**(c) Meetings:**

The meeting will take place monthly; 2 weeks following/prior to the ODN Board.

Papers will be circulated one week in advance

Meetings will routinely take place via MSTeams or in person if required

Quorum will be one of each of the Network Director, Cellular Pathology, Laboratory Medicine lead roles and workforce and finance representatives.

**Pathology ODN Transitional Sub Groups**

Three sub groups have been established to support the development of the ODN: Finance and Commissioning; Workforce and OD and Digital. All contain representatives from respective departments in both Health Boards, the ARCH Pathology Team and Service leads from both Health Boards.

The ARCH Pathology Team provide business support to the sub groups and the transition board. The host organisation will take on secretariat of these groups following the establishment of the ODN. The ARCH Pathology team will be disbanded at this stage

## **ANNEX D Contributions**

The Finance and Commissioning Sub Group are tasked with developing the Service Specification and Commissioning arrangements for the ODN. The ODN Board will have to approve these in Transition prior to any decision to fully establish the ODN. This will confirm the resource responsibilities and risk sharing on commencement of the ODN and assurance and monitoring arrangements.