

CYFARFOD BWRDD PRIFYSGOL IECHYD UNIVERSITY HEALTH BOARD MEETING

DYDDIAD Y CYFARFOD: DATE OF MEETING:	30 January 2025
TEITL YR ADRODDIAD: TITLE OF REPORT:	Aseptic Project – Business Justification Case Review
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Jill Paterson, Director of Primary Care, Community and Long Term Care
SWYDDOG ADRODD: REPORTING OFFICER:	Owain Williams, Clinical Director of Pharmacy and Medicines Management Stuart Rees, Clinical Pharmacy Lead for Patient Services Rachel Stuart, Planning Project Manager

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

The Aseptic Project is an interim solution for the Hywel Dda University Health Board (HDdUHB) to continue to deliver safe, sustainable aseptic services in advance of the opening of the South West Regional Aseptic Unit under the Transforming Access to Medicines (TrAMS) Programme.

This report provides an update on the Aseptic project and provides assurance that the Business Justification Case (BJC) is being robustly reviewed. A previous review was undertaken between December 2022 and September 2023 of the Aseptic BJC (based on budget cost estimates) which was scrutinised by the Health Board's internal scrutiny process, concluding with submission to Board in January 2023 and subsequent onward submission to Welsh Government (WG) for scrutiny. Currently, the BJC (based on robust tender costs) and appendices, **see Attachment 1** is undergoing the Health Board's internal scrutiny process to gain approval for onward final submission to WG. The scrutiny journey is shown below:

- Aseptic Stakeholders (Internal and TrAMS) Review – 3 January 2025 - completed;
- Aseptic Project Group – Review - 3 January 2025 - completed;
- Executive Team – Review 8 January 2025 - completed;
- Strategic Development & Operational Delivery Committee (SDODC) Chairs Action – 10 January 2025 - completed;
- University Health Board – Review 30 January 2025 – to be completed.

This report provides the Board with an overview of the BJC and seeks the Board's approval of the BJC for onward submission to Welsh Government (WG) for further scrutiny and approval.

Cefndir / Background

In 2018, Clinical Pharmaceuticals and Technical Services (CPTS) carried out an audit of all aseptic units in Wales. The University Health Board's three units at Withybush General Hospital (WGH), Bronglais General Hospital (BGH) and Glangwili General Hospital (GGH) were classified as 'high-risk critical'. The GGH unit closed in December 2018.

In 2019 the University Health Board submitted a Business Justification Case (BJC) to Welsh Government (WG) for the consideration of securing capital funding in the region of £10m to establish a stand-alone Aseptic and Radiopharmacy Unit on the WGH site.

Since then, Radiopharmacy services have been transferred to Swansea Bay University Health Board (SBUHB) and WG has approved the TrAMS programme to transform the facilities in which NHS Wales procures, produces and delivers pharmaceutical aseptic and radiopharmacy products. Discussions between the Health Board and the Chief Pharmaceutical Officer for Wales, the Director for TrAMS and WG Capital Team concluded that an interim solution was required in advance of, and to be aligned to, the development of the South West Regional Aseptic Unit under the TrAMS Programme of work.

Asesiad / Assessment

The aim of the Aseptic Project is to deliver an interim solution for the University Health Board to continue to deliver safe, sustainable aseptic services in advance of the opening of the South West Regional Aseptic Unit under the Transforming Access to Medicines (TrAMS) Programme by:

- Constructing a new demountable unit at WGH;
- Decommission and refurbish the current aseptic unit at WGH as a cold storage area;
- Decommission and refurbish the aseptic unit at BGH for use as pharmacy clinical support space.

Strategic Case:

Case for Change:

Between 2021 and 2023, the number of cancer treatments requiring aseptic preparation administered at HDdUHB has increased from 12,718 to 16,648 (an average of 14% each year). This increase in demand for aseptically produced medicines such as cancer treatment is due to:

- Our ageing population.
- New medicines and technologies.
- Reduction in capacity and capability to prepare medicine at the bedside.

In February 2024, an audit carried out by the national Quality Assurance Lead Pharmacist confirmed the units at WGH and BGH to be deemed a high risk to patient safety as the facilities do not meet regulatory standards. This is reported in the University Health Board's Corporate Risk Register number 1810, along with mitigating actions currently being undertaken to manage this. If this issue is not addressed and the units fail, the University Health Board will need to outsource all aseptic requirements. This will have a significant negative impact on patient care, due to the fragility of external providers with a consequent impact on compliance with cancer treatment targets, as well as an estimated additional annual outsourcing cost of £0.824m with increased risk to service delivery as there is currently no other viable alternative option available to source cancer treatments for Health Board patients without a functioning

aseptic unit. The impact of failed or forced closure of the WGH aseptic unit would mean the University Health Board being unable to prepare chemotherapy for cancer treatments and being entirely reliant on outsourcing at higher cost. Each year this would result in:

- £0.824m per annum additional costs for procuring cancer drugs;
- Delayed or cancelled cancer treatments due to outsourcing service issues;
- Over 500 cancer treatments not being administered in HDdUHB (treatments which cannot be outsourced and need local preparation)

The business need is therefore an aseptic unit(s), compliant with current and anticipated future regulatory standards, which could assist the Health Board to reduce its requirement to outsource, until the South West Hub becomes operational under the TrAMS Programme. The Project also provides the University Health Board with an opportunity to meet further business needs for additional clinical pharmacy space, to provide efficiencies in service delivery and estate usage, through the refurbishment of BGH and WGH aseptic units.

Drivers – Spending Objectives – Benefits.

Drivers	Spending Objective	Benefit	Expected Outcome
Effectiveness	Reduce the risk of negative impacts on patient care by providing a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme.	Provision of sufficient in-house capacity to meet activity projections.	Improved quality of patient treatment. Reduced delivery times.
Efficiency	Consolidate aseptic services on one site to enable the early closure of the BGH aseptic unit, to provide efficiencies in service delivery and estate usage.	Refurbishment of the current BGH aseptic unit to provide additional clinical pharmacy space and refurbishment of the current aseptic unit at WGH to cold and ambient storage.	Increased pharmaceutical production.
Economy	Minimise the risk of negative financial impacts.	Reduction in the risk of failure of the aseptic estate.	Reduced reliance on outsourcing.
Compliance	Put in place a new unit which will comply with Quality Assurance of Aseptic Preparation Services (QAAPS) standards and latest building guidelines.	To end the University Health Board's reliance on the WGH and BGH aseptic units, which both have been deemed as a high risk to patient safety.	Improved audit ratings and quality of service.
Replacement	Replace outdated equipment where possible to maximise the efficiency and compliance of the unit until the South West Hub becomes operational under the TrAMS Programme.	Improved equipment standards.	Reduced risk of service failure.

Note: Swansea Bay University Health Board do not currently have the capacity to support Hywel Dda, as their Pharmacy and Chemotherapy Day unit are experiencing internal capacity issues. Having an aseptic unit that complies with regulatory standards at Hywel Dda could increase the likelihood of Hywel Dda being able to support Swansea Bay in the future.

Key Project Business Risks

Description	Mitigation
Reputational risk arising from failure to, for example: - Meet required timescales. - Achieve quality standards. - Meet patient needs.	Technical capability of the aseptic project group.
Non-compliance with QAAPS 2016 standards.	Technical capability of the aseptic project group and wider TrAMS programme. Annual audits by the Quality Assurance Lead Pharmacist for Wales.
Failure to deliver an acceptable and timely solution will threaten the safe delivery / continued support of local cancer and neonatal services.	Technical capability of the Aseptic Project Group. HDDUHB approval of BJC for onward submission to WG. WG approval of BJC – capital allocation. Mitigations included on corporate risk register 1810.
Design does not meet regulatory standards.	Technical capability of the Aseptic Project Group.
Failure to secure capital funding in time and / or in entirety.	Engagement with WG.
Capital and / or revenue costs are higher than projected.	Technical capability of the Aseptic Project Group and wider TrAMS programme. Engagement with Welsh Government A risk allowance has been included in the capital estimates of 7.5% plus provisional sums of 15% planning contingency and 2% cost indices.
Delay in BJC approval leading to tender cost increases.	Risk contingency figure for cost indices associated with late approval within Development Approval Cost Form.

Key Project Service Risks:

Description	Mitigation
Tendered price is higher than cost estimates.	Estates team to follow process prior to tender for construction and engineering projects. University Health Board, Shared Services and WG will review and scrutinise the full Business Justification Case fully tendered costs
Failure to achieve planning permission and/ or building regulations approvals	Planning permission has been achieved. Building Regulations will be submitted for review and approval.
Risk to patient safety and access for emergency services at WGH during construction period (related to construction and moving of equipment).	Engagement with Emergency Services. Programme planning and management.
Noise pollution during construction	Noise reduction / abatement requirements to be detailed in tender specifications.
Risk associated with potential reduction in parking spaces, including disabled spaces, during construction.	Requirements to be detailed in tender specifications
Lead times for procurement of equipment overshoot the project timelines	Management through the project programme.
As no tender is in place for procurement of the demountable and therefore no commitment given to any manufacturer, there is a risk that a factory slot may not be available when the unit is required.	20 weeks have been allowed within the project programme for the mobilisation / manufacture stage. Timelines have been advised to the principal contractor.
Variations of Design	Minimise by full and appropriately timed design and construction detailing. Utilise contractor's expertise to mitigate any future variations due to buildability problems.

Key Project Constraints:

Area	Constraint
Policy decisions	The Project is constrained by the scope and timescales of the TrAMS Programme, specifically delivery of the South West Hub. The new aseptic unit may therefore be required to be operational for a shorter or longer timescale than currently anticipated.
Regulations	The new aseptic unit must be compliant with QAAPS 2016 requirements and standards.
Timescales	The unit must be in place and operational within a constrained timescale to maintain integrity of supply.
Affordability – Capital / Revenue	The unit must be delivered within the affordability constraints shown in Section 5 (Funding and Affordability).
External factors	The Health Board's ability to outsource supply if the new aseptic unit is not capable of meeting demand will be constrained because supply is already known to be limited and the market is unlikely to be capable of supplying more than current levels.
Quality of Build	The aseptic unit must be of sufficient quality to serve until the TrAMS Programme becomes operational.

Key Project Dependencies:

Area	Dependency
TrAMS Programme	The scope of the Project is dependent on decisions which may be made on the TrAMS Programme outside the influence of the University Health Board. If the scope and / or timeline of the TrAMS Programme were to change, in particular of the South West Hub, the University Health Board would need to rethink its solution and potentially enter into a new business case process.
Approvals	The Project will be dependent on internal approvals from the University Health Board and external approvals from WG.
Availability of capital	The Project will be dependent on capital funding from WG. This could be vulnerable to inflation and / or competing priorities at a national level.
Supply market availability	The Project will be dependent on the capacity of the supplier market to meet the Project's requirements.

Economic Case.

Critical Success Factors.

Critical Success Factors	Descriptor
Strategic Fit	Meets the project Drivers and Spending Objectives.
Business needs	Enhanced quality of service and improved outcomes. Equitable access to services. Equitable delivery of time critical products to patients based on location.
Value for Money (VfM)	Optimisation of costs and benefits. Minimises risks. Enables a timely solution. Provides flexibility for future use.
Affordability	Potential affordability (capital).
Achievability	Practicality of delivery. Site constraints or challenges. Supports functional requirements (design). Supply side capacity and capability (including clean room capability).

Options Analysis.

Options considered and discounted:

Options	Rational for Discounting
1. Do Nothing	The option does not enable the Health Board to meet its Spending Objectives and Critical Success Factors.
2. Modular Build at WGH (aseptic and radiopharmacy)	Following the transfer of radiopharmacy services to SBUHB and the publication of the TrAMS programme, this option is no longer strategically, financially or operationally viable.
3. Do Minimum: Small Scale Refurbishment at WGH Aseptic Unit and Repurposing of BGH Aseptic Unit	This option does not meet all of the projects Spending Objectives or Critical Success Factors. Closure of the WGH unit for at least 11 months would expose patients and the Health Board to unacceptable levels of risk and potential cost. The Health Board would continue to need to outsource supply, therefore this option will not address patients' and the Health Board's exposure to supply and cost risk.

Preferred Option:

Option	Rational
4. Demountable unit at WGH	<ul style="list-style-type: none">➤ This option meets all the Spending Objectives and Critical Success Factors.➤ This option will not require any interruption to existing service and will provide the Health Board with a compliant and fully functional aseptic unit on a single site until the South West Hub becomes operational.➤ Delivery of this option will mitigate risk of unit failure and the consequent risk to patient care, and additional outsourcing costs estimated at up to £0.824m per annum.➤ The Forecast Project Outturn Cost against the 100% costs of outsourcing if the unit were to fail and the risks that carries, this option therefore offers better VfM.➤ The long life of the unit means that it will provide the University Health Board with premises suitable for future uses once the aseptic unit is decommissioned.➤ Provides the University Health Board with an opportunity to meet a further business need for additional clinical pharmacy space, to provide efficiencies in service delivery and estate usage, through the refurbishment of BGH and WGH aseptic units.➤ The Forecast Project Outturn Cost against the 100% costs of outsourcing if the unit were to fail and the risks that carries, this option therefore offers better VfM.➤ This option will provide additional storage space for outsourced treatments at WGH to allow cost efficiencies to be made through outsourcing products as “batch” rather than “patient specific”. This option would also allow the aseptic unit at BGH to be repurposed for clinical work to support the department at achieving the targets set out in Welsh Government’s Review of Clinical Pharmacy Services at NHS Hospitals in Wales.

Commercial Case.

Procurement Route:

The procurement route for all goods, services and works pertaining to the Aseptic project will comply with Hywel Dda Standing Orders and Standing Financial Instructions and ensure due regard to statutory requirements (including Public Contract Regulations), WG and central government policy and Audit Commission guidelines are followed.

Outputs:

- Phase 1: WGH Enabling Work;
- Phase 2: WGH Provide New Demountable Units. One for designated aseptic processes, and the smaller unit for clinical support and storage;
- Phase 3: WGH Decommissioning of the current aseptic unit and refurbishment as cold and ambient storage;
- Phase 4: BGH Decommissioning of the aseptic unit and refurbishment as clinical pharmacy and support space.

Contracting Arrangements:

- The NHS Wales Terms and Conditions for Contract for Good or Services will normally form the basis of any contract entered into with suppliers unless otherwise agreed.

- The University Health Board used the NHS Wales Standard Contract for procuring the isolators.
- The University Health Board used Construction Frameworks for Swansea Bay and Hywel Dda University Health Boards (CAP-OJEU-91888) Framework Lot 4 West: Hywel Dda University Health Board - £200k to £2million.

Payment Terms:

- Payment terms will be relevant to the procurement and will be determined by the terms and conditions under the framework. Payment terms for isolators and any other equipment procured separately will include part payment 30 days from receipt of the equipment and balance upon commissioning of the equipment.
- The University Health Board will also require whole life warranties for the demountable and equipment.
- Phases 1,2,3 and 4, the health board will be protected when entering the construction phase of the project via a legal agreement. The contract being administered by the health board's appointed quantity surveyor's is a JCT Intermediate Form of Contract (IFC) 2016. The contract ensures the work is clearly defined and costed with interim valuations and payments to verify works have been completed in accordance with the contract terms. As the works progress, a retention is held from the valuations. This retention is 2.5% at practical completion, the following 2.5% retention is released one year after practical completion. A year defects period provides the contractor an incentive to return to rectify defects.

Financial Case.

Funding and Affordability – Capital and Operating Costs for Preferred Option:

The University Health Board is seeking funding only for the capital costs element of the Project on the Forecast Project Out-turn Cost based on tender costs DAF v.17 of £3,962m (post-VAT recovery). This includes a risk allowance of 7.5%. Plus provisional sums of 15% planning contingency and 2% cost indices.

Recommended Option Capital Expenditure: (£'m)

Capital Expenditure	Total	Y1 24/25	Y2 25/26	Y3 26/27	Y4 27/28	Notes
Works	2,557	0	2,302	0.256	0	
Fees	0.449	0.068	0.344	0.037	0	
Non-works	0.488	0.142	0.295	0.052	0	
Equipment	0.161	0	0.128	0.032	0	
Contingency	0.383	0	0.344	0.038	0	
Less VAT Recoverable	-0.076	-0.005	-0.065	-0.006	0	VAT assessment on works costs undertaken by VAT advisors. Estimated at 10%
Total Capital Costs	3,962	0.205	3,348	0.409	0	

The total annual operating costs are estimated at £23k which will be offset by a reduction in outsourcing costs due to the ability to produce additional products in-house.

Recommended Option Capital Expenditure: (£'m)

Operating Expenditure	Total	Y1 24/25	Y2 25/26	Y3 26/27	Y4 27/28	Notes
Staff	0	0	0	0	0	
Premises	0.117	0	0.002	0.023	0.023	Additional costs associated with increased building footprint
Outsourcing	0	0	0	0	0	
Transport	0	0	0	0	0	
Other Costs	0	0	0	0	0	
Total Operating Costs	0.117	0	0.002	0.023	0.023	

The cost savings net impact is currently forecast to be a saving of £33k. Further efficiencies may become evident once the unit is in operation through a reduction in outsourcing and being able to deliver a more robust service in a modern, compliant facility; however, these will need to be assessed over time.

Recommended Option Cost Savings: (£'m)

Cost Savings	Total	Y1 24/25	Y2 25/26	Y3 26/27	Y4 27/28	Notes
Additional Capacity	0.286	0	0.006	0.056	0.056	Reduction in outsourcing through manufacturing in house.
Staff Costs	0	0	0	0	0	Option not expected to generate any efficiencies. Remain as status quo
Maintenance	0	0	0	0	0	Option not expected to generate any efficiencies. Remain as status quo
Premises	0	0	0	0	0	Option not expected to generate any efficiencies. Remain as status quo
Total Operating Cost Savings	0.286	0	0.006	0.056	0.056	
Project Net Costs	3,793	0.205	3,344	0.376	-0.033	

Management Case.

Delivery Arrangements

Project management:

- The Project will be undertaken in line with NHS Infrastructure Investment Guidance and using established project management methodology.
- The University Health Board set up the Aseptic Project Group (the Project Group) on 23 June 2022. The Project Group is responsible for good management and governance of the Project, to ensure its delivery within available resources, on time and to agreed service model specifications and that the Spending Objectives are met.
- The Project Group is accountable to the SRO, being the Director of Primary Care, Community and Long Term Care; and the Project Director, being the Clinical Pharmacy Lead for Patient Services. The Project Group reports to SDODC through the Capital Sub-Committee (CSC).

Implementation Plan

Implementation	Completion
BJC HB Internal Scrutiny Process	January 2025
BJC WG Scrutiny and Approval	May 2025
Construction Phase 1: Enabling Work WGH	August 2025
Construction Phase 2: Demountable WGH	December 2025
Construction Phase 3: Cold/Ambient Storage WGH / Commissioning	July 2026
Construction Phase 4: Decommission /Refurbishment /Commissioning to Clinical Pharmacy Space BGH	March 2026

Under the TrAMS programme, the Health Board's aseptic production will transfer to the South West Hub; however, TrAMS has an aspiration timescale for delivery of 2027, but as yet no site has been selected and the business case is yet to be developed. This timescale is likely to slip, and poses a potential risk to patients in the Health Board.

Argymhelliad / Recommendation

The Board is requested to **APPROVE** the Aseptic Business Justification Case (BJC) for onward submission to Welsh Government for further scrutiny and approval.

Amcanion: (rhaid cwblhau)

Objectives: (must be completed)

Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol: Datix Risk Register Reference and Score:	A project risk register is held and managed by the Project Group. Risks are summarised under the assessment section of this SBAR.
Parthau Ansawdd: Domains of Quality Quality and Engagement Act (sharepoint.com)	1. Safe 2. Timely 4. Efficient 1. Safe
Galluogwyr Ansawdd: Enablers of Quality: Quality and Engagement Act (sharepoint.com)	1. Leadership
Amcanion Strategol y BIP: UHB Strategic Objectives:	3. Striving to deliver and develop excellent services 5. Safe sustainable, accessible and kind care 6. Sustainable use of resources
Amcanion Cynllunio Planning Objectives	4 Planned care, diagnostics and cancer Recovery

Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2021-2022	4. Improve Population Health through prevention and early intervention, supporting people to live happy and healthy lives
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Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	Compliance with QAAPS 2016 standards.
Rhestr Termau: Glossary of Terms:	Included in the body of the report.
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol: Parties / Committees consulted prior to University Health Board:	Aseptic Project Group Key Leads UHB Key Leads Senior Responsible Owner Project Director TrAMS Board Executive Team SDODC (Chair's Action)

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: Financial / Service:	Minimise the risk of negative financial impacts Included in the body of the report.
Ansawdd / Gofal Claf: Quality / Patient Care:	Reduce the risk of negative impacts on patient care by providing a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme.
Gweithlu: Workforce:	No additional workforce costs are anticipated as a result of this development.
Risg: Risk:	Included within the body of this report.
Cyfreithiol: Legal:	Not Applicable.
Enw Da: Reputational:	Reputational risk arising from failure to, for example: <ul style="list-style-type: none"> • Meet required timescales. • Achieve quality standards. • Meet patient needs.
Gyfrinachedd: Privacy:	Not Applicable.
Cydraddoldeb: Equality:	Equality Impact Assessment screening has been undertaken and, at this stage, does not indicate adverse impacts for protected groups.