

Aseptic Project Update

Strategic Development & Operational Delivery Committee

Friday 16th December 2022



The Purpose of the Aseptic Project:

Aseptic Project

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 located close to the entrance of the Physiotherapy Unit of Withybush General Hospital (WGH).
- Refurbish the current aseptic unit at WGH as a cold storage area.
- Decommission the aseptic unit at Bronglais General Hospital (BGH) so that it can be refurbished as clinical pharmacy space;

Strategic Case: Background and Case for Change

Aseptic Project

- In 2018 the clinical pharmaceuticals and technical services (CPTS) group carried out an audit of all aseptic units in Wales. The University Health Board's three units at WGH, BGH and Glangwili General Hospital (GGH) were classified as 'high-risk critical'. The GGH unit closed in December 2018.
- In 2019 the 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 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. In the Strategic Outline Case (SOC) for TrAMS it anticipates construction commencing in summer 2025.
- Both WGH and BGH units now no longer meet the required GMP standards for facilities. The number of items required to be prepared per annum in HDdUHB is expected to be around 20,000 by 2028, rising to around 23,000 by 2031, however the facilities cannot meet this demand and the Health Board has significant concerns about external suppliers' ability to meet both demand and required quality standards. A solution is therefore required until the South West unit comes on-line under the TrAMS Programme which will meet the projects Spending Objectives.

Strategic Case: *Business Needs*

Aseptic Project

- There is an increasing demand for aseptically produced medicines due to:
 - Our ageing population.
 - New medicines and technologies.
 - Reduction in capacity and capability to prepare medicine at the bedside.
- The business need is therefore an aseptic unit(s), compliant with current and anticipated future regulatory standards and which will help Health Board to reduce its requirement to outsource, until the South West Hub becomes operational under the TrAMS Programme.
- The Project also provides the an opportunity to meet a further business need for additional clinical pharmacy space, which can be provided by the repurposing of the BGH aseptic unit.

Strategic Case: Drivers – Spending Objectives – Benefits **Aseptic Project**

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.	Increased pharmaceutical production.
Economy	Minimise the risk of negative financial impacts.	Cost efficiencies through reduced level of outsourcing.	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 ‘highly critical’ audit ratings.	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. Reduced maintenance costs

Strategic Case: Key Project Business Risks

Aseptic Project

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. Annual audits by the Quality Assurance Lead Pharmacist for Wales.
Failure to deliver services in quantity / to quality required, resulting in need to outsource.	Effective recruitment and quality control.
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. Sensitivity analysis.
Project management costs over-run.	Effective project management through the Procurement Team
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

Strategic Case: Key Project Service Risks

Aseptic Project

Description	Mitigation
Failure to achieve planning permissions and / or building regulations approvals	Engagement with local authorities as required
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.
Tendered price is higher than costs estimated in this BJC	Estates team to follow the University Health Board's project approval process prior to tender for construction and engineering projects.
Lead times for procurement of equipment overshoot the project timeline.	Management through the project plan
Risk associated with potential reduction in parking spaces, including disabled spaces, during construction	Requirements to be detailed in tender specifications

Strategic Case: Key Project Constraints

Aseptic Project

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.

Strategic Case: Key Project Dependencies

Aseptic Project

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

Aseptic Project

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).

Economic Case: Options Analysis **Aseptic Project**

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	<p>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.</p> <p>The Forecast Project Out-Turn Cost of the option is approximately 14.7% higher than that of Option 4 (preferred Option).</p>

Economic Case: Options Analysis - (continued) **Aseptic Project**

Preferred Option:

Option	Rational
4. Demountable unit at WGH	<ul style="list-style-type: none"> • 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. • 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. The decommissioned unit could be used as office space, training space or storage. • Financial and operational risks are manageable. • The option will enable the BGH aseptic unit to be repurposed for other pharmaceutical use. • The Forecast Project Outturn Cost is lower than Option 3 and it carries lower risk; it therefore offers better VfM.

Commercial Case: Procurement Route – Outputs

Aseptic Project

Demountable:

- Purchase and fit-out of a demountable unit to be located close to the entrance of the Physiotherapy Unit of WGH to house aseptic production and a cold room with the necessary equipment.
- The unit will consist of two ‘Portakabin’-style buildings, a larger one designated for aseptic processes, and the smaller attached unit for clinical support and storage, this design will provide sufficient space for storage and segregation of products.
- There will be a glazed link to connect the two demountable buildings.

Construction:

- Enabling works at WGH for demountable and the existing WGH and BGH aseptic facilities to be reconfigured into clinical space, offices and storage.

Capital Cost Estimates:

Cost	Net cost (£)	VAT @ 20%	Gross cost (£)
Works cost	1,377,926	267,585	1,605,511
Fees	306,259	35,294	341,554
Non-works costs		58,214	349,284
Equipment costs	142,952	28,590	171,543
Contingency	200,688	40,137	240,826
Forecast Project Out-turn Cost (pre VAT recovery)	2,278,897	429,822	2,708,719
Less recoverable VAT		35,294	35,294
Forecast Project Out-turn Cost	2,278,897	394,527	2,673,425

Commercial Case: Procurement Route – Contracting Arrangements / Payment Terms

Contracting Arrangements:

- The demountable requirement under the Recommended Option (and specific to the relevant Framework contract), the Health Board may be able to use any one of a range of standard forms of building contract including JCT / SBCC, NEC3 / NEC4, ACE, PPC, TPC, FAC1, or their own in-house agreement.
- For the isolators the Health Board will use the NHS Wales Standard Contract.
- For the enabling works the Health Board will use a JCT form of standard contract.

Payment Terms:

- For the demountable unit the University Health Board is likely to propose payment terms whereby a percentage is paid on delivery of the unit to site, with the remainder released once the unit has been fully commissioned.
- For the isolators and any other equipment procured separately. Part payment 30 days from receipt of the equipment and balance upon commissioning of the equipment.
- For the enabling work typical payment terms are monthly payment.

Financial Case: Funding and Affordability - Capital and Operating Costs for Preferred Option

Capital Expenditure	Total	Y1	Y2	Y3	Y4	Notes
Works	1,606	803	803	0	0	Cash flow profile is not yet known. Arbitrary split of 50% in 2023/24 and 50% in 2024/25 utilised for illustration purposes on all capital costs
Non Works Costs and Fees	690	345	345	0	0	
Equipment	171	86	86	0	0	
Contingency	241	121	121	0	0	
Less VAT Recoverable	(35)	(18)	(18)	0	0	VAT assessment will be undertaken with VAT advisers on approval of funding. VAT recovery % to be notified to WG
Total Capital Costs	2,673	1,337	1,337	0	0	
Operating Expenditure						
Staff	0	0	0	0	0	
Premises	0	0	12	20	20	0 in Y8. Additional costs associated with increased building footprint.
Outsourcing	0	0	0		0	Outsourcing is likely to reduce in the Recommended Option, however we have not shown a saving as the timing and quantum of any reduction is difficult to forecast.
Transport	102	0	7	19	19	0 in Y8. Additional transportation costs due to the closure of BGH Aseptic Unit
Total Operating Costs	102	0	19	39	39	0 in Y8.
15/19	2,775	1,337	1,356	39	39	0 in Y8.

Management Case: Delivery Arrangements

Aseptic Project

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 23rd 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 Director of Pharmacy and Medicines Management.

Management Case: Delivery Arrangements

Aseptic Project

Implementation - Milestones	Timeline
BJC HB Internal Scrutiny Process	28 January 2022 to 3 rd February 2023
BJC WG Scrutiny and Approval	6 th February 2023 to 31 st March 2023
Planning Approvals Received by	6 th January 2023
Appointment of project design team	28 th April 2023
Detailed technical design completed	21 st July 2023
Tender period	24 th July 2023 to 13 th October 2023
Contractor mobilisation and manufacture	16 th October 2023 to 1 st March 2024
repurpose the BGH aseptic unit	4 March 2024 to 7 th June 2024.
Demountable installation	4 th March 2024 to 24 th May 2024
Demountable commissioning	27 th May 2024 to 16 th August 2024
Demountable Operational go-live	2 nd September 2024
Repurpose the WGH aseptic unit	9 th September 2024 to 22 nd November 2024

Business Justification Case: Approval Process

Aseptic Project

The BJC over the coming weeks will be taken through the Health Boards internal scrutiny business case review process, which was approved by the Executive Team and the Capital Sub-Committee in September 2022.

The purpose of the review process is to:

- Provide early scrutiny & challenge to the BJC;
- Improve the robustness of business case;
- Ensure that the evidence used is robust;
- Test the strategic fit.

The journey through the HB:

- Key Leads;
- TrAMS Board.
- Use of Resources Group;
- Executive Team;
- Board.

It is currently anticipated that the BJC will be presented to Board for approval before submission to WG.

Business Justification Case: SDODC Members are asked To Note

Aseptic Project

The Strategic Development and Operational Delivery Committee is asked to **NOTE** the progress update on the Aseptic Services Business Justification Case (BJC) and endorse the presentation of the case to Board once the internal scrutiny of the case is complete.

It is currently anticipated that the BJC will be presented to Board for approval before submission to WG in January 2023.

END