GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

Canolbarth a Gorllewin Iachach
Cenedlaethau'r dyfodol yn byw bywydau iach

Hywel Dda University Health Board

Aseptic Project

Business Justification Case v.10

DRAFT

Contents

Hywel Dda University Health Board Aseptics Business Justification Case

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Organisation:	Hywel Dda University Health Board

	Name	Date	Comments
Prepared by:	Greg Haddock, PwC	4th December 2022	Final draft for review and acceptance by the University Health Board
		06 January 2023	Updated final draft which incorporates review comments received in December 2022 and January 2023
Budget Cost Estimates Reviewed by:	Aseptic Project Group, Project Director and SRO	December 2022	Review completed for BJC on budget cost estimates
	University Health Board Scrutiny Key Leads	December 2022	Review completed for BJC on budget cost estimates
	TrAMS Board	December 2022	Review completed for BJC on budget cost estimates
	Use of Resources	December 2022	Review completed for BJC on budget cost estimates
	Executive Team	December 2022	Review completed for BJC on budget cost estimates
	Strategic Development and Operational Delivery Committee	December 2022	Noted update and endorse presentation of the case to Board for the BJC on budget cost estimates
	Hywel Dda Board	January 2022	Review completed for BJC on budget cost estimates
	Welsh Government	February 2022	Reviewed with scrutiny comments provided on BJC with budget cost estimates
	Greg Haddock, PwC	May 2023	Reflects responses to WG scrutiny comments
Tender Return Costs Reviewed by:	HDdUHB Key Leads	Nov / Dec 2024	Completed.
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	Project Group	Jan 25	Completed.
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	Welsh Government	Feb 25 to Apr 25	To Be Completed.

Glossary of Abbreviations

Abbreviation	Definition
AHMWW	A Healthier Mid and West Wales
AME	Annually Managed Expenditure
ASU	Aseptic Services Unit
BGH	Bronglais General Hospital
BJC	Business Justification Case
CPTS Group	Clinical Pharmaceutics and Technical Services Group
CSF	Critical Success Factor
CSC	Capital Sub-Committee
GGH	Glangwili General Hospital
GMP	Good Manufacturing Practice (the minimum standard that a medicines manufacturer must meet in their production processes)
HDUHB	Hywel Dda University Health Board
IAAP	Integrated Assurance and Approval Plan
JCT	Joint Contracts Tribunal
MHRA	Medicines & Healthcare products Regulatory Agency
MMC	Modern Methods of Construction
OBC	Outline Business Case
PBC	Programme Business Case
PCR	Project Closure Report
QAAPS	Quality Assurance of Aseptic Preparation Services
RPA	Risk Potential Assessment
SDODC	Strategic Development and Operational Delivery Committee
SAB	Sustainable Drainage Approval Body
SBUHB	Swansea Bay University Health Board
TrAMS	Transforming Access to Medicines
UHB	University Health Board
VfM	Value for Money
WG	Welsh Government
WGH	Withybush General Hospital
WHBN	Welsh Health Building Note
WHTN	Welsh Health Technical Note
WPA	Welsh Procurement Alliance

Executive Summary

1. The purpose of this Business Justification Case (BJC) is to seek approval for Hywel Dda University Health Board (the University Health Board or HDUHB) to invest in the:

   - enabling work (phase 1) and construction of a new demountable aseptic unit at Withybush General Hospital (WGH) (Phase 2);
   - decommissioning and refurbishment of the current aseptic unit at WGH as a cold and ambient storage area (phase 3); and
   - decommissioning and refurbishment of the aseptic unit at Bronglais General Hospital (BGH) as pharmacy clinical Support Space (phase 4).

   as 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.

2. The description above is termed 'the Project' throughout this BJC.

3. The Project is required because of the following:

   - In 2018 the Clinical Pharmaceutics 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. (The high-risk ratings of the WGH unit was confirmed in the audit which took place in February 2022, 2023 and again 2024 – note **Appendix 1** Letter from WG Chief Pharmaceutical Officer)
   - In 2019 the Health Board submitted a Strategic Outline Case (SOC) 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 this time the radiopharmacy service have been transferred to Swansea Bay University Health Board and WG has approved the TrAMS programme where three new regional manufacturing facilities will be built in North, South West and South East Wales to replace existing aseptic units. Discussions between the Health Board, the Chief Pharmaceutical Officer for Wales and the Director for TrAMS 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 2023 BGH aseptic unit became non-operational with the production of services consolidated at WGH. This action was taken to meet regulatory standards. This allowed more time and resource to be provided to the service at WGH. Therefore the Health Board is reliant on the unit at WGH to supply cancer treatments. An audit undertaken in February 2024 by the national Quality Assurance Lead Pharmacist confirmed that the facilities are a high risk to patient safety. This is reported in the University Health Boards Corporate Risk Register number 1810 along with mitigating actions currently being undertaken to manage this.by:

     - transfer of radiopharmacy to SBUBH in 2022;
     - more time and resource provided to the quality system;
     - increased training of aseptic staff;
     - increased outsourcing commercial suppliers;
     - procurement of new pharmaceutical isolators;
     - preparation of products near to the time of use;
     - stringent gowning process;

- stringent cleaning and monitoring programmes;
- oversight and steer from Capital Sub-committee.

4. The Transforming Access to Medicines programme has an aspiration timescale for the delivery of the South West Hub by 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 this poses a potential risk to the patients in HDdUHB. Once the programme is delivered, it is anticipated that following a transition period, production at the WGH aseptic unit will cease and the unit will be decommissioned. The demountable unit could then be used for alternative purposes, e.g. cold storage, training space or office accommodation. See **Appendix 1a** confirming that the TrAMS Programme strongly supports the need to develop the project.

5. The Forecast Project Out-turn Cost based on tender costs is £3,961,797.88 (post-VAT recovery), see **Appendix 2**. The project completion date for all four phases of this project under the timeline agreed for the Project is July 2026.

6. In 2022/23 the University Health Board and WG carried out an Aseptic draft BJC review at a relatively early stage between December 2022 and May 2023 based on budget cost estimates. This was in response to the urgency of the project regarding the risks to the unit failing, which was scrutinised by the Health Board, concluding in submission to Board in January 2023 and subsequent onward submission to WG for review and comment. WG scrutiny comments were received, and a Health Board response provided in May 2023.

7. This BJC is submitted on robust tendered costs and has been scrutinised by the University Health Board's key stakeholders, TrAMS Programme Board key stakeholders, the University Health Board's Executive Team, Strategic Development and Operational Delivery Committee (SDODC) and Board.

8. This BJC follows the five-case model, and an overview of the cases follows:

Strategic Case

I. In 2018 the Clinical Pharmaceutics 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 GGH were classified as 'high-risk critical'. The GGH unit closed in December 2018.

II. WGH and BGH units no longer meet the required GMP standards for facilities and currently, the unit at BGH is no longer operational with the Health Board fully reliant on the unit at WGH to supply cancer treatments. BGH aseptic unit is still being serviced to allow it to be re-opened at short notice to mitigate against any issues occurring at WGH. Therefore the Health Board is reliant on the unit at WGH to supply cancer treatments, which recently underwent an audit in February 2024 confirming that the facilities are a high risk to patient safety.

III. The number of items required to be prepared per annum in HDUHB is expected to be around 30,000 by 2028, rising to around 40,000 by 2031, however the facilities cannot meet this demand and the University 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 following Spending Objectives:

- **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
- **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

- **Economy:** Minimise the risk of negative financial impacts.
- **Compliance:** Put in place a new unit which will comply with QAAPS standards and latest building guidelines.
- **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.

IV. The strategic context within which the Project is being developed comprises:

- The overarching regulatory framework.
- The University Health Board's 'A Healthier Mid and West Wales Strategy and Programme Business Case (PBC).
- The TrAMS Programme.
- The transfer of Radiopharmacy services to Swansea Bay University Health Board (SBUHB).

V. The main benefits include:

- Provision of sufficient in-house capacity to meet activity projections.
- Refurbishment of the current BGH aseptic unit to provide additional clinical pharmacy space and refurbishment of the current aseptic unit at Withybush to cold and ambient storage.
- Reduction in the risk of failure of the aseptic estate.
- To end the University Health Board's reliance on the WGH and BGH aseptic units. Both facilities have been deemed as a high risk to patient safety
- Reduce risk of service failure.

VI. The main risks include:

- Failure to secure capital funding in time and / or in entirety.
- The Health Board will be unable to continue manufacturing cancer treatments for its patients.

  This is reported in the University Health Boards Corporate Risk Register number 1810 along with mitigating actions currently being undertaken to manage this.

Economic Case

I. The University Health Board has identified four options:

- Option 1 – Do nothing / Business As Usual.
- Option 2 **–** Modular Build at WGH (aseptic production and radio pharmacy), as described in the Aseptic and Radiopharmacy Suite Strategic Outline Case (SOC), submitted to WG in December 2019 but not pursued.
- Option 3 **–** Do Minimum: Small Scale Refurbishment at the WGH and BGH Aseptic Units.

- Option 4 - Demountable Unit at WGH and the Decommissioning and Refurbishment of WGH and BGH aseptic units.

II. The options have been assessed against Spending Objectives (SO) and Critical Success Factors (CSFs) for Strategic Fit, Business needs, Value for Money, Affordability, and Achievability. Option 4 has been identified as the Recommended Option.

Commercial Case

I. The University Health Board will procure under 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, the following:

II. £200k to £2million, the following:

Section One (1) of the works will be:

- **Phase 1 at Withybush General Hospital (Block 28 – Near Physiotherapy Entrance)** Undertake enabling works; such as but not limited to the civil, structural, utility connections and so forth to allow a new demountable to be sited at Withybush General Hospital. The enabling works will need to be undertaken in the form of disposing of two demountable buildings and relocating two shipping containers, and the demolition of an outbuilding formerly utilised by laboratories.

- **Phase 2 at Withybush General Hospital (Block 28 – Near Physiotherapy Entrance)** Provide new demountable units located close to the entrance of the Physiotherapy Unit of Withybush General Hospital (WGH), fire-rated within 3 metres of the main hospital; the unit will consist of two demountable 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;

Section Two (2) of the works will be:

- **Phase 3 Withybush General Hospital (Block 3 – Existing Aseptics Suite)** Refurbish the current aseptic unit at WGH as a cold and ambient storage area; and

- **Phase 4 at Bronglais General Hospital (Block 2 – Existing Aseptics Suite)** Decommission the aseptic unit at Bronglais General Hospital (BGH) so that it can be refurbished as pharmacy clinical Support Space

III. The Payment Terms will be relevant to the procurement and will be determined by the terms and conditions under the framework and will differ to the payment terms for the procurement of the isolators, which will be procured via the NHS Wales Terms and Conditions for Goods. The University Health Board will also require whole life warranties for the demountable and equipment.

IV. The proposed start date on site is August 2025 and proposed completion date for all phases is June 2026.

Financial Case

I. Total Capital Costs are estimated at £3.962m (post-VAT recovery). Total annual revenue 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. The net impact is currently forecast to be a saving of £33k. Further efficiencies may become evident once the unit is in operation.

II. The estimated depreciation charges are £0.206m per annum for the Recommended Option. It is assumed that additional depreciation charges will be funded by WG. It is estimated that the Recommended Option will impact on the balance sheet of the University Health Board by increasing the value of fixed assets by £2.7m. The estimated impairment of this scheme on completion will be £1.2m. The University Health Board is assuming that Annually Managed Expenditure (AME) impairment on completion of the new build will be funded as AME funding via WG.

Management Case

I. The University Health Board set up the Aseptic Project Group (the 'Project Group') on 23rd June 2022, responsible for the controls in managing, monitoring and governing the delivery of the Project. The Project Group is accountable to the Senior Responsible Officer (SRO), being the Director of Primary Care, Community and Long-Term Care, and the Project Director, being the Clinical Pharmacy Lead for Patient Services at Hywel Dda University Health Board.

Jill Paterson	**Stuart Rees**
Director of Primary Care, Community and Long-Term Care at Hywel Dda University Health Board	Clinical Pharmacy Lead for Patient Services at Hywel Dda University Health Board

1 Strategic Case

1.1 Organisational Overview

1.1.1. The University Health Board is the planner and provider of NHS healthcare services for a population of approximately 385,615 in Carmarthenshire, Ceredigion, Pembrokeshire, and bordering counties. The University Health Board delivers services through its four main hospital sites (Bronglais in Aberystwyth, Glangwili in Carmarthen, Prince Philip in Llanelli and Withybush in Haverfordwest) and through its community hospitals, minor injuries units, centres and clinics and mental health sites.

1.2 Strategic context

1.2.1. The strategic context within which the Project is being developed comprises:

- The University Health Board's 'A Healthier Mid and West Wales Strategy and Programme Business Case (PBC).

  In 2018, the University Health Board published 'A Healthier Mid and West Wales: Our Future Generations Living Well' (AHMWW)[1], a long-term strategy for transforming health services and delivering quality care closer to home.

  Following publication of the strategy, the University Health Board developed a PBC which describes how the infrastructure requirements of the strategy were to be delivered.

  In the current economic climate, it is acknowledged that the pace of infrastructure transformation envisaged in the PBC is no longer achievable. A realistic planning assumption for a new hospital would be mid-to late 2030's. This delay further increases the need for this investment in the interim period.

- The TrAMS Programme.

  The programme is an NHS Wales initiative aimed at establishing a shared pharmacy technical service for Wales. Set up in 2021, the focus of the TrAMS Programme has been on increasing regional and national co-operation to improve the productivity and efficiency of the pharmacy supply chain and patient access to medicines in Wales. Its aim is to revolutionise access to critical medicine, improve patient outcomes and enhance pharmaceutical care across Wales. It has been developed in the following context to focus on the:

  - deteriorating condition of 15 existing units;
  - rising Demand;
  - rising regulatory standards;
  - supplier fragility;
  - staffing sustainability;
  - lack of contingency;
  - lack of space.

  The TrAMS PBC published in December 2020 makes the case for a transformational change and recommended the following preferred option:

[1] Available at https://hduhb.nhs.wales/about-us/healthier-mid-and-west-wales/healthier-mid-and-west-wales-folder/documents/a-healthier-mid-and-west-wales-strategy/

- A hosted All Wales service, regionally delivered to give the best balance of resilience and efficiency delivered through:

  - Three integrated regional hubs – North, South West and South East.
  - Additional satellite units where geography requires.
  - A medicines logistics service.
  - A structured investment programme and migration from legacy facilities.

- Risk, quality, and assurance to be addressed at a national level.

- Open book accounting which includes fair and sustainable allocation of discretionary capital and an operating budget that invests in people to save on medicines.

- Investments that deliver increased economic activity, resilience, and prosperity in Wales, securing the wellbeing of future generations.

A SOC for the South West Hub was published in July 2022 and endorsed by the TrAMS Programme Board on 26 September 2022. Currently the programme is awaiting site selection and is working towards developing a business case with a TrAMS programme aspirational timescale to deliver the South West Hub in 2027.

➢ The Transfer of Radio Pharmacy Services to Swansea Bay University Health Board (SBUHB).

Until October 2022 the WGH aseptic unit also provided a radio pharmacy service which manufactured and delivered approximately 660 critical diagnostic products to the nuclear medicine department per annum.

This activity was undertaken within the aseptic unit, however governance around nuclear medicine and pharmacy indicated that the arrangements were not robust and that, as a specialised area with a small number of staff, production lacked resilience. SBUHB has a fully licensed radio pharmacy unit and has often provided support when needed. The University Health Board and SBUHB therefore concluded a Service Level Agreement for HDUHB's radiopharmaceutical activity to transfer to the Radio pharmacy Unit at Singleton Hospital Swansea from October 2022. This move is fully aligned to the TrAMS service model.

This transfer of radiopharmaceutical activity from WGH to Singleton Hospital has facilitated the 'demountable' option – Option 4 – which is discussed in Section 3 (Options Analysis).

➢ Regulatory Frameworks

A number of regulatory frameworks govern the legal and professional standards against which all pharmacy services must be compliant. These include:

- Medicines Act (1968)
- Misuse of Drugs Act (1971)
- QAAPS: Professional Standards (2016)
- The Royal Pharmaceutical Society document for the Professional Standards for Hospital Services – Optimising patient outcomes from medicines (England, Scotland and Wales) V3 (2017).

As a consequence, there are a number of external inspections which require significant evidence of compliance with the standards, including by the:

- General Pharmaceutical Council
- QAAPs 2016
- Home Office

The design and operation of the new unit at WGH will comply with this regulatory framework,

however it will operate under the section 10 exemption of the Medicines Act 1968 and the University Health Board will not seek to attain a Manufacturing Specials licence from the MHRA.

1.3 Case for Change

1.3.1. This section sets out the Existing Arrangements, and the Business Needs.

1.3.2. Existing Arrangements:

In 2018 the Clinical Pharmaceutics and Technical Services (CPTS) group carried out an audit of all aseptic units in Wales. The facilities were judged against contemporaneous standards in the Rules and Guidance for Pharmaceutical Manufacturing (HMSO, 2017) and The Quality Assurance of Aseptic Pharmaceutical Services (Pharmaceutical Press, 5th Edition) and categorised under three risks:

- High-risk **–** action required in next 3 years.
- Moderate-risk **–** review / action required in 3-6 years.
- Low-risk **–** review in next 7-10 years.

1.3.2.1. The University Health Board's three units at WGH, BGH and Glangwili General Hospital (GGH) were classified as 'high-risk critical'. Overall the audit found that, of the fifteen aseptic units in Wales, eight were high-risk (of which six were high-risk critical), three were moderate risk, and four were low risk. (The high-risk ratings of the WGH unit was confirmed in the audit which took place in February 2022, 2023 and again 2024).

1.3.2.2. The GGH unit closed in December 2018 following a succession of four water leaks in as many months, due to the risk of providing contaminated products to patients as it was not possible to fully resolve the leak, this meant that the WGH and BGH units then needed to provide chemotherapy to cancer patients across the whole of HDUHB with each site operated by a single-handed pharmacist where cross-cover between the sites was not practicable. This has caused significant challenges in coordinating chemotherapy treatment and ensuring that patients receive medication within acceptable timescales. To maintain continuity of service the University Health Board has found it essential to outsource products needing to be made aseptically, and this has resulted in additional financial and logistical pressures. Currently 85% of treatments are outsourced with 263 reported service and quality-related incidents (e.g. delayed or failed deliveries) linked to outsourcing from commercial suppliers between April 2023 and March 2024 in HDdUHB. The reliance on commercial suppliers poses a risk to cancer patients in HDUHB due to the service and quality-related incidents experienced. Table 1 below highlights issues experienced by University Health Boards / Trusts in Wales with current suppliers from 2020 to 2024.

Table 1: Challenges with outsourcing for the period August 2020 – March 2024

UHB / Trust	Total no. of reports submitted	Type of incident		Supplier				Impact on patients				
		Service	Quality	Bath ASU	Baxter	ITH Pharma	Quantum	Inconvenience	Other	Treatment delayed	Treatment cancelled	Not stated
Aneurin Bevan UHB	22	18	4	19	0	3	0	17	3	2	2	0
Cardiff & Vale	11	9	2	9	1	1	0	10	1	0	0	0

UHB												
Cwm Taf UHB	13	12	1	8	4	0	1	7	4	1	1	0
Hywel Dda UHB	620	610	10	612	0	1	7	524	3	4	0	89
Swansea Bay UHB	28	25	3	25	1	2	0	26	1	1	0	0
Velindre NHS Trust	22	21	1	22	0	0	0	16	0	6	0	0

1.3.2.3. In 2019 WGH and BGH units underwent an external audit against QAAPS standards at the start of 2019 by the National Quality Assurance Lead for Wales. Critical concerns were highlighted, with urgent resolution required to enable the units to continue operating for the next 18 to 36 months and prior to any consideration of repatriation of outsourced activity from GGH. Minor refurbishment works were carried out in 2019, including resurfacing of floors and walls at the BGH unit, new office space at the WGH unit and new air units at both. However, this can be described as a 'sticking plaster' approach which is not sustainable.

1.3.2.4. The University Health Board submitted a SOC to WG in 2019 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 this time the radiopharmacy service has been transferred to SBUHB and WG has approved the TrAMS programme where three new regional manufacturing facilities will be built in North, South West and South East Wales to replace existing aseptic units. Discussions between the Health Board, the Chief Pharmaceutical Officer for Wales and the Director for TrAMS 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.

1.3.2.5. In 2023 BGH aseptic unit became non-operational with the production services consolidated at WGH. This action was taken to mitigate against negative impacts on the team's ability to meet regulatory standards due to recruitment challenges at BGH. Had the unit at BGH remained operational, insufficient resource would have been available to improve the service at WGH, which would have increased the risk of forced closure and HDdUHB being left with no operational aseptic unit. The BGH unit is still being serviced to allow it to be re-opened at short notice to mitigate against any issues occurring at WGH. Therefore the University Health Board is reliant on the unit at WGH to supply cancer treatments.

1.3.2.6. Recently, in February 2024 the units underwent an audit confirming that the facilities are a high risk to patient safety. The unit at WGH which is over seventeen years old, operates under the section 10 Exemption of the 1968 Medicines Act, which permits the production of aseptic products without a licence provided certain conditions are adhered to. Executive Letter (97) 52 (NHS Executive 1997) introduced a requirement in England for the regular audit of unlicensed aseptic units by Regional Quality Assurance Specialists, to ensure that appropriate standards are achieved and maintained. This practice was adopted throughout Wales and unlicensed units are currently audited by the National Quality Assurance Lead for Wales according to the regulatory framework provided in QAAPS 2016.

1.3.2.7. The Transforming Access to Medicines programme has an aspiration timescale for the South West Hub 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 this poses a potential risk to the patients in HDdUHB. It is anticipated that, following a transition period, production at the WGH aseptic unit will cease and the unit will be decommissioned. The demountable unit could then be used for alternative purposes, e.g. cold storage, training space or office accommodation.

1.3.2.8. HDdUHB has a slightly higher incidence of cancer than the Welsh average, as pockets of high economic deprivation are associated with increased incidence of all types of cancer. The University Health Board supports diagnostic services and chemotherapy for most of the cancer sites. Oncology is supported by SBUHB, and all radiotherapy takes place in Singleton or Velindre Hospitals. A significant volume of specialist oncology surgery takes place in SBUHB and Cardiff and Vale UHB.

1.3.2.9. Table 2 below shows the current total annual output and cost of aseptically prepared items. The total number of items supplied by the pharmacy aseptic team is 20,726 of which approximately 85% are outsourced. As noted above this presents a significant risk to service delivery.

Table 2: Current Annual Output / Cost Activity – dated October 2024

Site	Number of workstations	Age of workstations (years)	Number of items manufactured on site p.a.*	Number of items outsourced p.a.	
BGH	1	19	0	1,704	
GGH	0	N / A	0	0	
WGH	2	11, 15	2,469	16,553	
Total	3	-	2,469	18,257	
Cost[2]			£3.743m	£7.235m	£10.978m

*Volume and cost data for the period April – September 2024 has been extrapolated for the full year.

1.3.3. Business Needs:

1.3.3.1. 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.

[2] University Health Board spend on injectable chemotherapy between September 2021 and August 2022.

1.3.3.2. Clinical advances and increasing regulatory demands are expected over the course of this decade which, in turn, will increase the demands on aseptic services. The TrAMS project team considers that the demand for aseptically prepared products is increasing nationally by 12% each year. Over time, products have also increased in complexity and require more time and skill to manipulate. Consequently, the NHS aseptic service's workload is increasing at a faster rate.

1.3.3.3. The total number of cancer treatments used by the University Health Board in 2023 was 16,648. The demand for aseptically prepared cancer treatment increased by on average 14% each year between 2021 and 2023 in HDUHB. The TrAMS project team consider the demand for cancer treatments is increasing by 12% each year. Using the 12% per annum predicted growth rate, the number of aseptically prepared cancer treatments required each year in HDUHB is expected to be around 30,000 by 2028, rising to around 40,000 by 2031. Approximately 85% of cancer treatments are outsourced from commercial suppliers at HDUHB.

1.3.3.4. In February 2024 the 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 did not meet the regulatory standards. This is reported in the University Health Boards Corporate Risk Register number 1810 along with mitigating actions currently being undertaken to manage this. These mitigations have so far have provided assurance to the national Quality Assurance Lead Pharmacist that WGH unit can continue to function until the interim solution is operational. If this 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 premium of £0.824m. There would be increased risk to service delivery as there is currently no other viable alternative option available to source cancer treatments for HDdUHB patients without a functioning aseptic unit at WGH.

1.3.3.5. Discussions around potential options were held between the University Health Board and the Chief Pharmaceutical Officer for Wales, the Director for the TrAMS Programme and the WG Capital Team. These discussions concluded that an interim solution was required in advance of, and to be aligned to, the development of the South West Hub under the TrAMS Programme. The Transforming Access to Medicines programme has an aspiration timescale for the South West Hub 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 this poses a potential risk to the patients in HDdUHB. The University Health Board's aseptic production will transfer to the South-west Hub. For the reasons stated above, a University Health Board position to await the opening of the South-west Hub is untenable, and this position is supported by the National Quality Assurance Lead for Wales.

1.3.3.6. The University Health Board's business need is therefore an aseptic unit, compliant with current and anticipated future regulatory standards and which could assist the University Health Board to reduce its requirement to outsource, until the South West Hub becomes operational under the TrAMS Programme. Given the critical nature of the service, the University Health Board does not consider that it is possible to describe 'core', 'desirable' and 'optional' levels of coverage. The impact of failed or forced closure of the WGH aseptic unit would mean HDdUHB 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).

1.3.3.7. The Project also 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, as follows:

- The aseptic team require additional storage space for outsourced treatments to allow cost efficiencies to be made. Cancer therapy can be outsourced from commercial suppliers as "patient specific" doses where single doses are purchased for individual patients, or as "batch" doses where larger quantities of commonly prescribed doses are ordered, kept as stock and dispensed by Aseptics for individual patients when required. Aseptics generally order the majority of cancer therapy as patient specific doses due to insufficient space to store batch doses. Ordering batch doses is significantly more cost effective than ordering patient specific doses. If the pharmacy had additional storage space to order and store batch doses rather than patient specific doses, the cost reduction, based on the 2023/24 spend of £5.633m would be £255,747 per annum. Without additional storage space, Aseptics would be required to continue purchasing cancer therapy as patient specific doses. The cost of patient specific doses has increased since July 2024 meaning the additional cost of purchasing all doses as patient specific doses would be an additional £232,283 each year compared against the 2023/24 spend of £5.633m. A temporary demountable storage solution is currently being sourced by the Health Board, however due to the increase in demand for cancer therapy, the space within this temporary storage space will be insufficient by 2028.

- Decommissioning the existing aseptic unit at WGH would generate appropriate storage facilities to store new drug technologies such as Outpatient Parenteral Antimicrobial Therapy (OPAT) as they become available. This would enable patients to receive treatment closer to home, supporting the population to take more responsibility for their own health and wellbeing. Decommissioning the existing aseptic unit at BGH would generate clinical space to allow the pharmacy to address the action points in WG's review of clinical pharmacy services at NHS Hospitals in Wales (September 2023).

1.4 Spending Objectives

1.4.1. Our Spending Objectives are shown in Table 3 below. They build on the Spending Objectives stated in the December 2019 Aseptic and Radiopharmacy Suite SOC and have been further debated by the Aseptic Project Group described in section 5 (Delivery Arrangements). All are Specific, Measurable, Achievable, Realistic and Time-bound:

Table 3: Spending Objectives

	Driver	Spending Objective	Specific	Measurable	Achievable	Realistic	Time-bound
1	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.	✓	✓	✓	✓	✓
2	Efficiency	Consolidate aseptic	✓	✓	✓	✓	✓

	Driver	Spending Objective	Specific	Measurable	Achievable	Realistic	Time-bound
		services on one site to enable the early closure of the BGH aseptic unit, to provide efficiencies in service delivery and estate usage.					
3	Economy	Minimise the risk of negative financial impacts.	✓	✓	✓	✓	✓
4	Compliance	Put in place a new unit which will comply with QAAPS standards and latest building guidelines.	✓	✓	✓	✓	✓
5	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.	✓	✓	✓	✓	✓

1.5 Main Benefits

1.5.1. Anticipated benefits of the Project are shown in Table 4 below. Benefits have been classified by Beneficiary, Type and Class, as follows:

- Cash Releasing Benefits such as reductions in costs (CRB).
- Non-Cash Releasing Benefits such as staff time saved (Non-CRB).
- Quantifiable Benefits such as achievement of targets (QB).
- Qualitative Benefits such as improved staff morale (Qual).

Table 4: Main benefits analysis

ID	Benefit	Expected outcome	Measures	Beneficiary	Benefit class
Driver – Effectiveness					
Spending Objective 1: Reduce the risk of any negative impacts on patient care, providing a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme.					
1.	Provision of sufficient in-house capacity to meet activity projections.	Improved quality of patient treatment. Reduced delivery times.	Improved quality standards. Improved delivery times.	Direct: HDdUHB. Indirect: Patients.	NCR QB Qual
Baseline current position and targets: The University Health Board currently outsources approximately 85% of treatments from commercial suppliers. Success would be to maintain and potentially increase the number of aseptically prepared products manufactured by the University Health Board. There were 263 reported service and quality-related incidents (e.g. delayed or failed deliveries) linked to outsourcing from commercial suppliers between April 2023 and March 2024 in HDdUHB. These incidents can have a consequent impact on patients' treatment. If in-house manufacture can increase, this will reduce the reliance on commercial companies, resulting in reduced risk of incidents that have a negative impact on patients. The University Health Board will monitor the number of incidents in relation to outsourcing going forward.					

ID	Benefit	Expected outcome	Measures	Beneficiary	Benefit class
Driver – Efficiency					
Spending Objective 2: 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.					
2.	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.	Increased pharmaceutical production.	Direct: HDdUHB. Indirect: Patients.	NCR
Baseline current position and targets: Centralising fully the aseptic service at one location will allow efficiencies avoiding duplicating work at two units (e.g. cleaning and monitoring two units). The demountable aseptic unit and cold room will create a more efficient service, which will allow an increase in the current baseline number of "batch" outsourced products purchased from commercial suppliers rather than "patient specific". These efficiencies would also allow an increase in the number of items manufactured in house – a 10% increase in the number of items manufactured in-house is a realistic and manageable target. Staffing resource can also be transferred from BGH to WGH, allowing increased capacity at WGH to prepare products in-house, reducing outsourcing. (Please note, the closure of the BGH aseptic unit has gone through consultation, there will be no job losses at BGH as all aseptic staff are rotational within the Pharmacy department and there are a number of vacancies within the department).					
Driver – Economy					
Spending Objective 3: Minimise the risk of negative financial impacts.					
3.	Reduction in the risk of failure of the aseptic estate.	Avoidance of an estimated additional annual cost of outsourcing of £0.824m	Reduce reliance on outsourcing.	Direct: HDdUHB. Indirect: Patients.	NCR
Baseline current position and targets: Should the unit fail, it would cost the University Health Board an additional £0.824m per annum in additional outsourcing costs. Success can be monitored through measuring the number of products prepared in-house and the outsourcing costs each year.					
Driver – Compliance					
Spending Objective 4: Put in place a new unit which will comply with QAAPS standards and latest building guidelines.					
4.	To end the University Health Board's reliance on the WGH and BGH aseptic units. Both facilities have been deemed as a high risk to patient safety.	Improved audit ratings and quality of service.	Audit ratings and quality measures.	Direct: HDdUHB. Indirect: Patients. Staff	Non-CRB QB
Current baseline position and targets: The University Health Board's aseptic units are audited by the National Quality Assurance Lead Pharmacist. Withybush aseptic unit is the only operational aseptic unit remaining in the Health Board. The audit in February 2024 rated the facilities at Withybush as a high risk to patient safety. Audits will be performed each year; therefore success will involve the facilities and equipment being rated as "satisfactory" in the audit following completion of the demountable unit.					
Driver – Replacement					

ID	Benefit	Expected outcome	Measures	Beneficiary	Benefit class
Spending Objective 5: 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.					
5.	Improved equipment standards.	Reduced risk of service failure.	Improved equipment performance.	Direct: HDdUHB. Indirect: Patients.	Non-CRB QB
Current baseline position and targets: The target is reduced risk of the isolators failing: failure of the isolators would result in an additional £0.824m spend in outsourcing costs each year, and an entire reliance on outsource with consequent impact on compliance with cancer treatment targets. Success would involve the equipment being rated as "satisfactory" in the audit by the National Quality Assurance Lead Pharmacist following completion of the project.					

1.6 Main Risks

1.6.1. Table 5 below shows the main business and service risks identified and proposed mitigations. Risks are managed through the Aseptic Project Group, and the approach to risk management is described in Section 6 (Delivery Arrangements).

Table 5: Main risks

No.	Risk categories	Counter measures
Business risks (retained by the University Health Board)		
1.	Reputational risk arising from failure to, for example: • Meet required timescales. • Achieve quality standards. • Meet patient needs.	Technical capability of the aseptic project group.
2.	Non-compliance with QAAPS 2016 standards.	Technical capability of the aseptic project group. Annual audits by the Quality Assurance Lead Pharmacist for Wales.
3.	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. WG approval of BJC – capital allocation. Mitigation included on corporate risk register 1810.
4.	Design does not meet regulatory standards.	Technical capability of the Aseptic Project Group.
5.	Failure to secure capital funding in time / or in entirety	Engagement with WG.
6.	Capital and / or revenue costs are higher than projected.	Technical capability of the Aseptic Project Group. Engagement with WG. A risk allowance has been included in capital estimates of 7.5%. Plus provisional sums of 15% planning contingency and 2% cost indices.
7.	Delay in BJC approval leading to tender cost increases.	Risk contingency figure for cost indices associated with late approval within Development Approval Cost Form.
Service Risks (may be shared with the supply side)		
8.	Tendered price is higher than costs estimated.	Estates team to follow the University Health Board's project approval process prior to tender for construction and engineering projects based on three key stages: Stage 1: Provisional cost estimate. Stage 2: Budget cost estimate. Stage 3: Pre-tender estimate. University Health Board, Shared Services and WG will review and scrutinise the full Business Justification Case fully tendered costs

No.	Risk categories	Counter measures
9.	Failure to achieve planning permissions and / or building regulations approvals.	Planning permission has been achieved. Building Regulations will be submitted for review and approval. Engagement with local authorities as required.
10.	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. Project planning and management.
11.	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.
12.	Lead times for procurement of equipment overshoot the project timeline.	Management through the project plan.
13.	Noise pollution during construction.	Noise reduction / abatement requirements to be detailed in tender specifications.
14.	Risk associated with potential reduction in parking spaces, including disabled spaces, during construction.	Requirements detailed in tender specifications.
15.	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.

1.7 Constraints

1.7.1. Table 6 below shows the external conditions and parameters within which the Project must be delivered:

Table 6: 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 University 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.

1.8 Dependencies

1.8.1. Table 7 below sets out the dependencies outside the scope of the Project upon which successful delivery is dependent.

Table 7: 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.

2 Economic Case

2.1 Critical Success Factors (CSFs)

2.1.1. The CSFs for the project are shown in Table 8 below. They build on the CSFs developed for the December 2019 Aseptic and Radio pharmacy Suite SOC and have been further debated by the WGH Aseptic Project Group described in Section 6 (Delivery Arrangements).

Table 8: CSFs

CSF	Descriptor
1. Strategic Fit	Meets the Spending Objectives drivers of: • Effectiveness. • Efficiency. • Economy. • Compliance. • Replacement.
2. Business needs	Enhanced quality of service and improved outcomes. Equitable access to services. Equitable delivery of time critical products to patients based on location.
3. Value for Money (VfM)	Optimisation of costs and benefits. Minimises risks. Enables a timely solution. Provides flexibility for future use.
4. Affordability	Potential affordability (capital).
5. Achievability	Practicality of delivery. Site constraints or challenges. Supports functional requirements (design). Supply side capacity and capability (including clean room capability).

2.2 Main Options

2.2.1. The Economic Case of the Aseptic and Radio pharmacy Suite SOC described:

- The generation of a long list of fifteen options through a longlist option development workshop held on 18 March 2019. The workshop was attended by a wide range of stakeholders from within the University Health Board as well as external stakeholders.
- The sifting of the long list of options against the CSFs identified.
- A resulting shortlist of six options.

2.2.2. The Aseptic Project Group established in May 2022 described in full in Section 6 (Delivery Arrangements) has taken cognisance of this work, however the transfer of radiopharmacy services to SBUHB and the publication of the TrAMS Programme PBC has enabled the Group to consider an additional temporary demountable option which is less complicated in terms of design and delivery and more cost-efficient than the options considered in the 2019 SOC.

2.2.3. Table 9 below sets out the options considered with Option 4 – Demountable Unit at WGH and the Decommissioning and Refurbishment of WGH and BGH Aseptic Units as the recommended option.

Please note: Since the transfer of radiopharmacy services to SBUHB and the approval of the TrAMS programme, option 2 is no longer viable, however we have left the option available for view to demonstrate the consideration of options over time and the due diligence and analysis given to deliver an interim infrastructure solution to continue the delivery of aseptic products for the population of HDdUHB.

Table 9: Summary of options appraisals

Option 1	Do Nothing: Business As usual (BAU)
Description	There will be no capital investment at WGH and BGH. Until new facilities are live under the TrAMS Programme, outsourcing of services and products will continue at current levels or higher to meet requirements.
Net Costs	• No capital investment undertaken. • The contemporary estimate for additional cost of outsourcing services and products is calculated on current contract prices and clinical activity to be £0.824m per annum,[3] should the unit fail. The additional cost varies with changes to contract prices and supplier availability.
Advantages	**Affordability** The option would avoid the capital costs which would be incurred under Options 2, 3 and 4.
Disadvantages	**Strategic fit:** • The option will not enable the University Health Board to meet any of the project's Spending Objectives and therefore impacts on ministerial priorities and targets such as the Single Cancer Pathway, A Healthier Wales. **Business needs:** • The units have been categorised as high risk-critical due to non-compliance with QAAPS 2016 standards. There is therefore a high and increasing risk of units failure, therefore closure at short notice is a possibility despite mitigating actions. This would result in 100% reliance on private sector suppliers with estimated additional costs of circa £0.824m per annum until the TrAMS hubs are operational. • Would not enable the full consolidation of aseptic services on one site to provide efficiencies in service delivery and estate usage. • Increased reliance on the private sector could damage oncology services (see paragraph 1.3.2.2 / Table 1 for examples).

[3] To calculate this figure, a report was generated from the Wellsky pharmacy system showing the current spend on starting materials used to manufacture aseptically prepared products at Withybush. Outsourcing from commercial companies is typically regarded as being 20-30% more expensive than preparing drugs in-house, therefore 22% was added to the current spend on starting materials to give an estimate of the additional spend if the products currently prepared in the aseptic units were outsourced from commercial companies.

	Value for Money: • The option does not minimise risk of unit closure and subsequent impact on business continuity, costs, negative patient outcomes and cancer targets. • Although there would be no capital investment and no project to implement, future capital costs to mitigate risks could be incurred and are unpredictable. The option would represent continuation of a 'sticking plaster' approach applied to date (see paragraph 1.3.2.3). • Future revenue costs are unpredictable. • The option would not provide flexibility for future use and increases in demand. **Affordability:** • The option may appear to be relatively affordable, but this is likely to be illusory as future costs incurred to mitigate risk could be substantial and unpredictable. **Achievability:** • Although the option may be achievable in the short term, it could impose future requirements and costs on the University Health Board which may be unachievable.
Conclusion	This option does not enable the University Health Board to meet its Spending Objectives and CSFs and is therefore discounted.
Option 2	Modular Build at WGH (aseptic and radio pharmacy)
Description	A permanent solution for HDdUHB to deliver aseptic and radiopharmacy services. The Aseptic and Pharmacy Suite SOC submitted by the University Health Board to WG in December 2019 identified Option 6 as the emerging preferred option i.e., a permanent new build facility at WGH which would allow consolidation of existing services into a single aseptic and radio pharmacy unit. The option would have entailed a permanent solution, building a standalone modular unit housing for both aseptic and radio pharmacy services, built to cater to current demand and future demand and fully compliant with QAAPS 2016 standards, including Centralised Intravenous Additive Service, intravenous chemotherapy and radio pharmacy. The unit would have housed a total of 4 isolators with a clean room each. The option was scoped as a permanent solution to the University Health Board's aseptic and radiopharmaceutical needs, which have since been transferred to SBUHB and the approval of the TrAMS programme of work offering a South-west Wales aseptic solution.
Net Costs	Total costs (as at the date of the SOC -2019) = £14.2m (Capital costs – £10.05m Radio pharmacy costs – £4.15m).
Advantages	**Strategic Fit:** • The option would have partially met Spending Objective 1, by providing a safe, sustainable aseptic service solution. • It would have met Spending Objectives 2 and 3 by fully consolidating services on one site and minimising the risk of negative financial impacts. • The new build would have been accompanied by new equipment for the aseptic improving patient services and ensuring business continuity for the University Health Board, thereby meeting Spending Objective 5.

	Business needs: • The option would have met Business Needs by providing enhanced quality of service and improved outcomes, and equitable access and supply.
Disadvantages	**Strategic Fit:** • The option is now over-scoped as: – The TrAMS Programme now means that services will transfer from the University Health Board to the South West Hub between 2027/28 and the unit will be decommissioned. – Radiopharmaceutical services have transferred to SBUHB. **Value for Money:** • The permanent modular solution would not have provided VfM, as it would have incurred a high level of capital expenditure which is no longer justified, given that aseptic services will transfer to the South West Hub under the TrAMS Programme and radio pharmacy services have transferred to SBUHB. **Affordability:** • The estimated capital expenditure identified in the SOC is no longer justified. **Achievability:** • The option is no longer achievable in terms of practicality of delivery due to the change in the strategic direction.
Conclusion	This solution was considered in 2019 as an aseptic and radiopharmacy solution for the University Health Board. Radiopharmacy services have since been transferred to SBUHB and the publication of the TrAMS programme which provides an aseptic solution for the University Health Board in South-West Wales, has rendered this option as no longer strategically, financially or operationally relevant and is therefore discounted.
Option 3	Do Minimum: Small Scale Refurbishment at WGH and BGH Aseptic Units
Description	An interim solution for HDdUHB to deliver aseptic services whilst awaiting the delivery of the South-west TrAMS Programme. Under this option refurbishment of the existing aseptic unit at WGH would have been undertaken over an estimated period of 11 months, involving the provision of a changing room, sufficient cold storage facilities and extensive heating, ventilation, and air conditioning (HVAC) ducting and roof work to ensure adequate air flow to the air pressure room. During construction the service would be decanted to BGH. It was planned that following refurbishment there would be a full consolidation of services on one site which would allow the early closure and refurbishment of the BGH aseptic unit so that it can be used as pharmacy clinical support space. The closure period could be considerably longer – discussions with the National Quality Assurance Pharmacist have indicated that a comparable refurbishment at Glan Clwyd Hospital in Bodelwyddan (operated by Betsi Cadwaladr University Health Board) took approximately 18 months.
Net Costs	The University Health Board has produced a Development Cost Appraisal Form for this option which shows a Forecast Project Out-Turn Cost of £2.482m (post-VAT Recovery). There are not expected to be any additional revenue costs.
Advantages	**Strategic Fit** • The option would have met Spending Objective 1 to provide a safe, sustainable aseptic service solution until services can be transferred to facilities to be provided under the TrAMS Programme. However, because this option would effectively be a continuation of the 'sticking plaster' approach used to date,

	there is a risk that any reduction in risk to patient care would be temporary (in addition to being outweighed by risk incurred during the 11-to-18-month closure of the WGH unit). • The option would have met Spending Objective 2 by consolidating services on one site at WGH. • The option would have met Spending Objective 4 by bringing the WGH unit up to QAAPS 2016 standards, however compliance may also prove to be temporary only because of the 'sticking plaster' approach adopted. **VfM** • The forecast project out-turn cost of the option is approximately 37% lower than that of Option 4 Demountable solution. **Affordability** • Forecast Project Out-Turn Cost of the option is £1,478m less the cost of Option 4 the Demountable unit at WGH.
Disadvantages	**Strategic Fit** • The option would not have encompassed replacement of outdated equipment and therefore would not meet Spending Objective 5. **Business Needs** • During the refurbishment period there would be no functional aseptic unit at WGH. The unit at BGH could be utilised to prepare some items, but nonetheless more outsourcing from commercial companies would have been required. This was estimated to cost up to an additional £0.824m per annum and came with a risk of patient treatment delays due to service issues. There are some drugs with very short expiries (4 hours) which cannot be outsourced, and the likelihood was that the University Health Board could not offer these drugs to patients during the refurbishment unless the patients were to travel to BGH presenting difficulties to many patients. • Quality and supply issues with outsourcing companies exposing patients to quality and supply risks. The University Health Board has concluded that, were it to pursue this option, it would need to look to outsource from other specialist companies where costs would be far higher. This option poses a significant business continuity and service quality risk which should be avoided if possible. • If the University Health Board were to continue to use its current suppliers, it would need to seek a total commitment service for the anticipated closure period, however the National Procurement Lead Pharmacist for Wales has indicated that it is unlikely that any of them would be in a position to commit currently, and if they did the costs would probably be a significant uplift on the current product costs to ensure they could deliver: it would require a robust forecast on your requirement line by line in order for them to engage and provide the costings. **VfM** • The refurbishment would have been relatively superficial in scope and further costs may be incurred subsequently. • The closure of the WGH unit during refurbishment would have exposed the University Health Board to unpredictable costs from commercial suppliers. • Risks to patient care were not minimised but increased through additional outsourcing requirements during the decant/construction period.

	• The limited nature of the refurbishment was unlikely to provide flexibility for future use of the space. **Achievability** • In 2022 when this option was being considered the National Quality Assurance Lead pharmacist raised concerns (see above – disadvantages in business need) that refurbishing the current aseptic unit would likely result in a prolonged period of shutdown. An 18-month shutdown was estimated based on experience at refurbishing other aseptic units in Wales. This was not deemed to be a suitable option as it would leave Hywel Dda without a functioning aseptic unit for 18 months which would result in increased outsourcing costs and the inability to supply certain treatments that cannot be outsourced at Hywel Dda.
Conclusion	This option does not meet all of the projects Spending Objectives or Critical Success Factors as noted above. Furthermore, the closure of the WGH unit for a period of 11 to 18 months is an insurmountable problem, exposing patients and the University Health Board to unacceptable levels of risk and potential cost, therefore this option is discounted.
Option 4	Recommended Option: Demountable Unit at WGH and the Decommissioning and Refurbishment of WGH and BGH Units.
Description	An interim solution for HDdUHB to continue to deliver aseptic services whilst awaiting the delivery of the South-west TrAMS Programme. Construction of a new demountable unit at Withybush General Hospital (WGH), 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; enabling works will need to be undertaken in the form of relocating portacabins and two shipping containers, and the demolition of an outbuilding formerly utilised by laboratories; Decommission and refurbishment of the current aseptic unit at WGH as a cold and ambient storage area; and Decommissioning and refurbishment of the aseptic unit at BGH so that it can be refurbished as pharmacy clinical Support Space.
Net Costs	The University Health Board had produced a Development Cost Appraisal Form for this option which shows a Forecast Project Out-Turn Cost of £ 3.962m (post-VAT Recovery). Annual revenue 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. The net impact is currently forecast to be a saving of £33k. Further efficiencies may become evident once the unit is in operation.
Advantages	**Strategic Fit** • Spending Objective 1 - There would be no interruption to the provision of aseptic services until the TrAMS Programme becomes operational. • Spending Objective 2 **–** consolidation on one site to provide efficiencies in service delivery and estate usage. • Spending Objective 3 **–** minimising risk of negative financial impacts **–** is met as the option is likely to enable the University Health Board to reduce expenditure on outsourcing. • Spending Objective 4 **–** compliance is met as the new unit will comply with QAAPS standards and latest building guidelines. • Spending Objective 5 – procuring new equipment to maximise the efficiency and compliance of the unit until the South-west Hub becomes operational under the TrAMS Programme is met. **Business Needs** • The option will enable the University Health Board to mitigate the risk of failure of the existing estate;

	and the risk to patient care and estimated additional financial cost of up to £0.824M which would result from the need to fully outsource production. • The option is expected to enable the University Health Board to repatriate production which is currently outsourced, A 10% increase in capacity would be realistic and it has been estimated that this would generate savings in the region of £56k per annum. • The opportunity to meet a further business need for additional clinical pharmacy space, which can be provided by the refurbishment of the BGH aseptic unit into clinical pharmacy support space and the refurbishment of WGH aseptic unit into cold and ambient storage. **Value for Money** • The lifespan of the demountable is 15 to 20 years, and one supplier has stated that the building will have a design life of 60 years and a building life of 30 years. The option therefore offers flexibility for future use, and following its decommissioning as an aseptic unit could be repurposed, for example, as dedicated cold storage, training space or support office accommodation. • There would be a functional aseptic unit at WGH throughout the entire implementation, mitigating the reliance on commercial companies during the decant to BGH which would be incurred in Option 3. • As the option would involve refurbishing the existing WGH facility as a cold / ambient storage unit, it would be possible to hold larger stocks, which would create financial efficiency and reduce clinical risk. See para 1.3.3.7. • As the option would involve the refurbishment of the existing BGH aseptic unit into pharmacy clinical support space, it would support the site at achieving the targets set out in the Review of clinical pharmacy services at NHS hospitals in Wales. **Affordability** • The capital costs are considered affordable by the University Health Board on the assumption these are fully funded through this business case. • The total annual revenue 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. The net impact is currently forecast to be a saving of £33k. Further efficiencies may become evident once the unit is in operation. **Achievability** • This is a small-scale project, and the University Health Board has demonstrated that the supplier market is able to deliver and provide clean room capacity. • This option has been developed significantly and is the timely solution which will provide a sustainable interim solution for the University health board to continue to deliver aseptic services from until the TrAMS programme is delivered in South-West Wales, mitigating against any potential programme delays.
Disadvantages	**Affordability** • The Forecast Project Out-Turn Cost of the option is approximately £1.48m more than the cost of Option 3 (see above). **Achievability** • As the placement of the unit will be implemented on a functioning hospital site, there is a risk of disruption

	related to noise and / or construction related activity on site. This will be managed contractually. • There is some risk to design variations. This will be managed by utilising full and appropriately timed design and construction detailing and the utilise of contractor's expertise to mitigate any future variations due to buildability problems.
Conclusion	This option is the University Health Boards recommended option it meets all the Spending Objectives and Critical Success Factors. This option will not require any interruption during construction to the existing service exposing patients and the University Health Board to unacceptable levels of risk and potential cost and will provide the University 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. 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.

2.2.4. The Financial Annex showing the financial appraisal of options 1, 3 and 4 is attached at **Appendix 3** and the Development Approval Forms for the ‘Recommended’ and ‘Do Minimum’ Option at **Appendix 2 / 2a** respectively. Please note that we have not included a financial appraisal of option 2 as this option is no longer available and is included for reference purposes only, to show the work previously done by the University Health Board in consideration of future aseptic products provision.

2.3 Recommended Option

2.3.1. Based on the appraisal above, option 4 is the Recommended Option.

2.3.2. The University Health Board has produced an Estates Annex for the Recommended Option at **Appendix 4.** Site selection for Option 4 identified five possible sites (‘Sites A-E’) for the placement of the demountable unit at WGH. The relative advantages and disadvantages of each site were identified during a site options appraisal and are contained within the Estates Annex, where ‘Site B’, which is located close to the entrance of the Physiotherapy Unit, was confirmed as the preferred site at a meeting of the Aseptic Project Group held on 2nd September 2022.

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3 Commercial Case

3.1 Introduction

3.1.1. This Section describes:

- The outputs to be procured (demountable unit, equipment and enabling works).
- The procurement route for the outputs.
- Payment terms.
- How the procurements will be contracted.
- Legal and personnel implications of the Recommended Option.

3.2 Outputs to be procured

3.2.1. 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. The outputs which will be procured:

Section One (1) of the works will be as follows:

- **Phase 1 at Withybush General Hospital (Block 28 – Near Physiotherapy Entrance)** Undertake enabling works; such as but not limited to the civil, structural, utility connections and so forth to allow a new demountable to be sited at Withybush General Hospital. The enabling works will need to be undertaken in the form of disposing of two demountable buildings and relocating two shipping containers, and the demolition of an outbuilding formerly utilised by laboratories.

- **Phase 2 at Withybush General Hospital (Block 28 – Near Physiotherapy Entrance)** Provide new demountable units located close to the entrance of the Physiotherapy Unit of Withybush General Hospital (WGH), fire-rated within 3 metres of the main hospital; the unit will consist of two demountable 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;

Section Two (2) of the works will be as follows:

- **Phase 3 Withybush General Hospital (Block 3 – Existing Aseptics Suite)** Refurbish the current aseptic unit at WGH as a cold and ambient storage area; and

- **Phase 4 at Bronglais General Hospital (Block 2 – Existing Aseptics Suite)** Decommission the aseptic unit at Bronglais General Hospital (BGH) so that it can be refurbished as pharmacy clinical Support Space.

The Schedules of Accommodation (SoA) for Phases 2, 3 and 4 can be viewed in full on at **Appendix 4** Estates Annex - SoA

3.2.2. The Forecast Project Out-turn Cost based on tender costs of the project is £3,961,797.88.

Table 10: Forecast Project Out-turn Costs (£)

* HDUHB's Development Approval Form does not account for VAT on Fees, as such are 100% recoverable

Cost	Net cost (£m)	VAT @ 20% (£m)	Gross cost (£m)

Works cost	2.130	0.426	2.556
Fees *	0.415	0.034	0.449
Non-works costs	0.406	0.082	0.488
Equipment costs	0.134	0.027	0.161
Contingency	0.320	0.064	0.384
Forecast Project Out-turn Cost (pre-VAT recovery)	3.405	0.633	4.038
Less recoverable VAT		(0.076)	(0.076)
Forecast Project Out-turn Cost	3.405	0.557	3.962

3.3 Procurement route

3.3.1. Introduction and underlying principles

3.3.1.1. The procurement route for all goods, services and works pertaining to the WGH aseptic unit 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.

3.3.1.2. The procurement process will strive to:

- Achieve VfM on behalf of NHS Wales, with VfM defined as the optimum combination of whole-life cost and quality (or fitness for purpose) to meet the user's requirement. Depending on the nature of the contract, whole-life costs may include implementation costs, ongoing operating costs, training, and end-of-life disposal.
- Ensure all suppliers compete on a fair and equal basis.
- Ensure compliance and probity.
- Ensure that all equipment and consumable products purchased are of appropriate specification for their intended purpose.
- Ensure that key processes and procedures are in place to ensure the right quality, price, source, quantity, and timing are achieved.
- Monitor and manage contract performance to ensure the contract is being delivered as specified.

Construction Framework Lot 4 West: Hywel Dda University Health Board - £200k to £2million.

3.3.1.3. The Contract Award for Phases 1 to 4 will be in-line with Section 10 of the NHS Wales Infrastructure Investment Guidance. HDUHB, intend to establish a single Call-Off Contract via NHS Wales Shared Services Partnership's ("NWSSP") Construction Framework. Call-off Contract will be actioned by the Design Team, utilising standard JCT contract templates (Intermediate Form of Contract & Agreements in place by Legal Team - Bevan Brittan). The framework is structured by awarding contracts on a rotational basis. The Call-Off option of direct award is available subject to supplier being

next on rotation.

3.3.1.4. This multi-supplier framework agreement covers the provision of qualified construction contractors to undertake various packages of minor/intermediate and major works which meets HBUHB's requirements. All suppliers have been added to the framework following a robust and compliant tendering process enabling the inclusion of suppliers both willing and able to provide customers with the construction related works required to meet the Health Board's strategic objective.

3.3.1.5. The NHS NWSSP Construction Framework did have social value as part of the framework award and have been asked scored questions as part of their tender submission. The purpose of the questions was to allow contractors the opportunity to demonstrate its commitment to support HDUHB in meeting its obligations under the Well-being of Future Generations (Wales) Act 2015 ("WBFG"), strengthening local supply chains in Wales, and reducing carbon to support the NHS becoming net zero carbon by 2030.

Professional Services Contract Process

3.3.1.1. To support HDUHB with meeting this requirement, NHS Wales Shared Services Partnership (NWSSP) invited bids from suitably qualified providers to deliver the following professional services.

- Mechanical & Electrical.
- Quantity Surveying.
- Civil & Structural.
- Construction Design Management Principal Designer.

3.3.1.2. The professional services that have been appointed have also been sighted of the NHS Net Zero Building Standard, which directs the development of sustainable, resilient, and energy-efficient buildings that meet the needs of patients now and in the future. The NHS Building Standard document also further provides guidance on the design and construction of energy efficient, low carbon footprint buildings, and provides a whole-life carbon compliance tool to help ensure that the buildings meet these standards.

3.3.1.3. The designs have been drafted and modelled using Autodesk's REVIT architectural package. This BIM software can aid decarbonisation by reducing the carbon footprint of the construction industry by eliminating uncertainties or interpretation errors at a design stage that lead to increased emissions and wasted materials through delays and rework. The software can also help to optimise the energy efficiency of the facility by simulating the energy performance of a building and identifying areas for improvement. This can help to reduce the carbon footprint of the site over its lifetime. The NHS Building Standard document that is being used to guide the design of the facility also provides guidance on how to report on operational energy and carbon compliance.

3.3.1.4. Across the UK, demountable units have been used successfully to house aseptic services, as shown in the following examples.

- University Hospital Southampton has set up a modular Good Manufacturing Practice (GMP) oncology suite to provide services and treatment facilities for the oncology department of the hospital, licensed Grade D by the Medicines & Healthcare products Regulatory Agency (MHRA). A demountable unit was used to deliver these needs due to the urgency of the requirement, and a part of the unit was built off-site which enabled the project to be fast tracked and delivered within three months and a budget of £2m.

- The Royal Marsden Hospital, Sutton has set up a support area, clean rooms and lab suites with a Grade B MHRA licence. The modularity of the structure and built in interior finishes have minimised the hard-to-clean areas and have enabled the delivery of the new facility within sixteen months and a budget of £2m.

- Singleton Hospital Swansea has set up a Good Manufacturing Practice (GMP) aseptic and radio pharmacy facility to prepare and manufacture chemotherapy and other critical medicines. The unit was partially manufactured off site, and the custom brick fascia crafting on site enabled the new extension to blend with the surrounding buildings. The unit enabled the hospital to achieve a Grade C and D MHRA licence within twelve months and a budget of £1.9m, including the supply of isolators.

- Other relevant examples include pharmacy aseptic units constructed using a demountable unit at Royal Preston Hospital, Pilgrim Hospital Boston, the MAC plc Clinical Trials Facility within the Manchester Royal Infirmary campus, King's College Hospital London and Leighton Hospital Crewe.

3.4 Equipment

3.4.1. Most of the existing equipment at WGH and BGH is dated and has limited further lifespan, therefore the University Health Board will not transfer it to the new aseptic unit. With the exception of isolators, equipment will be procured as part of the demountable solution contract and associated phases.

3.5 Implementation plan

3.5.1. An implementation plan for the Recommended Option is provided at **Appendix 5** (Project Programme – Recommended Option). Key dates are summarised below:

Table 11: Project Programme Key Dates

Task Name	Start	Finish
Construction Phase		
Phase 1 – Enabling Work WGH	07 July 2025	01 August 2025
Phase 2 – Interim Demountable Solution WGH	11 August 2025	12 December 2025
Phase 3 – Cold and Ambient Storage WGH / Commissioning	06 April 2026	24 July 2026
Phase 4 – Decommission / Refurbishment / Commissioning clinical pharmacy space BGH	05 January 2026	27 March 2026

3.6 Payment terms

3.6.1. Payment terms will be relevant to the procurement and will be determined by the terms and conditions under the framework and will differ to the payment terms for the procurement of the isolators, which will be procured via the NHS Wales Terms and Conditions for Goods.

3.6.2. Payment terms for isolators and any other equipment procured separately will include:

- Part payment 30 days from receipt of the equipment.

- Balance upon commissioning of the equipment

3.6.3. The University Health Board will also require whole life warranties for the demountable and equipment.

3.6.4. 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.

3.7 How the procurement will be contracted

3.7.1. 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.

3.7.2. For the isolators the University Health Board will use the NHS Wales Standard Contract.

3.7.3. For Lot 4 (intermediate works) £200,001.00 to £2,000,000.00 - JCT Intermediate Form of building Contract (JCT IFC) for Phases 1 to 4.

3.8 Legal and personnel implications

3.8.1. Planning permission for the demountable has been obtained. However, as the building will be under 100m^2 in area, a Sustainable Drainage Approval Body (SAB) application will not be required.

3.8.2. Prior to any procurement all Health Boards are obliged to ensure that the procurement process is carried out in accordance with the public procurement rules, NHS Guidance and the instructions of the Auditor General's Office. Accordingly, employees / individuals will not be permitted to participate in any aspect of the procurement process or to make recommendations in respect of the procurement unless they confirm that they agree to be bound by those rules and instructions by signing a Declaration of Interest Form.

3.8.3. Our standard internal Human Resources processes will be followed to support staff who currently work at the BGH aseptic unit during the transfer. An Organisational Change Procedure is already in place to address this.

3.8.4. Longer term the University Health Board in collaboration with the TrAMS Programme will consider the implications for staff who will work at the WGH aseptic unit once the South West Hub opens under the TrAMS Programme, which is likely to be in 2028 at the earliest.

4 Financial Case

4.1 Capital and Operating Costs

4.1.1. 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. The capital and operating costs of the Recommended Option are shown in the table below. The costs are also provided in the Financial Annex attached at **Appendix 3.**

Development Approval Form Costs for the 'Recommended' and 'Do minimum' options can be found at **Appendix 2/2a respectively.**

Table 12: Cost of the Recommended Option (£'m)

Costs	Total	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Notes
Capital expenditure	Total	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	
Works	2.557	0	2.302	0.256	0	0	0	0	
Fees	0.449	0.068	0.344	0.037	0	0	0	0	
Non-Works	0.488	0.142	0.295	0.052	0	0	0	0	
Equipment Costs	0.161	0	0.128	0.032	0	0	0	0	
Contingency	0.383	0	0.344	0.038	0	0	0	0	
Less Recoverable VAT	-0.076	-0.005	-0.065	-0.006	0	0	0	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	0	0	0	
Costs	Total	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Notes
Operating Expenditure									
Staff	0	0	0	0	0	0	0	0	
Premises	0.117	0	0.002	0.023	0.023	0.023	0.023	0.023	Additional costs associated with increased building footprint
Outsourcing	0	0	0	0	0	0	0	0	
Transport	0	0	0	0	0	0	0	0	
Other Costs	0	0	0	0	0	0	0	0	
Total Operating Costs	0.117	0	0.002	0.023	0.023	0.023	0.023	0.023	

Total Project Costs	4.079	0.205	3.350	0.432	0.023	0.023	0.023	0.023	
Costs	Total	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Notes
Cost Savings									
Additional Capacity to produce more products	0.286	0	0.006	0.056	0.056	0.056	0.056	0.056	Reduction in outsourcing through manufacturing in house.
Staff Costs	0	0	0	0	0	0	0	0	Option not expected to generate any efficiencies. Remain as status quo
Maintenance	0	0	0	0	0	0	0	0	Option not expected to generate any efficiencies. Remain as status quo
Premises	0	0	0	0	0	0	0	0	Option not expected to generate any efficiencies. Remain as status quo
Total Cost Savings	0.286	0	0.006	0.056	0.056	0.056	0.056	0.056	
Net Cost	3.793	0.205	3.344	0.376	-0.033	-0.033	-0.033	-0.033	

*Note: VAT Accounting Treatment, see **Appendix 10** Letter from VAT advisors, advising on VAT accounting and recovery treatment position.*

4.1.1. Total annual revenue 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. 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.

4.1.2. No increased staff costs are anticipated as all affected staff are based in WGH.

4.2 Balance Sheet Treatment

4.2.1. The estimated depreciation charges are £0.206m per annum for the Recommended Option. It is assumed that additional depreciation charges will be funded by WG.

4.2.2. It is estimated that the Recommended Option will impact on the balance sheet of the University Health Board by increasing the value of fixed assets by £2.7m.

4.2.3. The estimated impairment of this scheme on completion will be £1.2m. The University Health Board is assuming that Annually Managed Expenditure (AME) impairment on completion of the new build will be funded as AME funding via WG.

4.2.4. The calculations underlying the above figures are attached at **Appendix 6** DEL - AME Charges.

Management Case

4.3 Project management and governance

4.3.1. The Project will be undertaken in line with NHS Infrastructure Investment Guidance and using established project management methodology.

4.3.2. 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's Terms of Reference are provided at **Appendix 7.**

4.3.3. 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. Their key responsibilities are outlined in Table 13 below:

Table 13: SRO / PD Key Responsibilities

Role	Responsibility
Senior Responsible Owner (SRO) Director of Primary Care, Community and Long-Term Care	Defines the project objectives, ensuring that they are met to agreed time, cost and quality constraints. Represents the University Health Board in defining what is required and oversees the effectiveness of the Aseptic Project Group, ensuing the appropriate project management structure is in place to deliver the project objectives and that the benefits are realised. Provides a broad specification of what the Project should deliver and ensures that any change in circumstance affecting the Project is evaluated and appropriate action taken.
Project Director Clinical Pharmacy Lead for Patient Services.	Provides project management and direction. Acts as the lead reporting officer for Board, Committees and Sub-committees. Briefs key stakeholders on the Project's progress, benefits, risks and financial arrangements. Manages the University Health Board's interest in the Project, including coordination of and production of the brief for contractors. Selects and appoints consultants and contractors who will undertake the design and construction activity and ensures they deliver according to the Programme Plan. Acts as the point of contact in all dealings with contractors and other external organisations and provides all decisions and directions on behalf of the University Health Board.

4.3.4. The Project Director will be supported by the Project Manager, whose role will be to work closely with the Project Director and the Project Group to enable the successful delivery of the Project and the Project's Management Case.

4.4 Principal duties

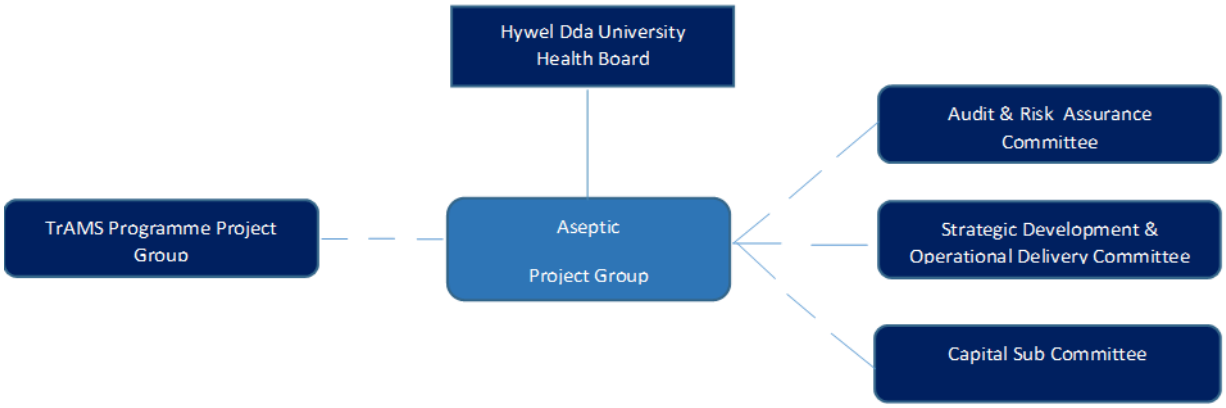
4.4.1. Following are some of the principal duties of the Project Group, a full list of which is detailed in the Terms of Reference at **Appendix 7:**

- To ensure the project plans are aligned to the TrAMS Programme of work.
- To ensure that all activity is managed and monitored so that the safe, efficient, and effective delivery of Aseptic project is not compromised.

- To ensure that all governance processes are in place, including the management of risks, issues, decisions, emerging opportunities, constraints, and dependencies.
- To ensure appropriate escalation of any issues which may compromise patient care and / or the reputation of the University Health Board.

4.5 Governance structure

4.5.1. The Project Group is integrated within the HB's governance structure as shown below:



4.5.2. As part of its principal duties, the Project Group's highlight reports are submitted to the Capital Sub Committee on a bi-monthly basis, drawing specific attention to any significant risks, issues and matter under consideration.

4.5.3. No external specialist advisers have been brought in to assist in the implementation of the Project.

4.6 Project Assurance

The project reporting arrangements are summarised in Table 14 below:

Table 14: Reporting Arrangements.

Forum	Requirement	Format
Committees of the Board: Strategic Development and Operational Delivery Committee (SDODC) Audit and Risk Assurance Committee	Updates or approval requests from the SRO (when required)	Written or verbal.
Executive Team	Update or approval requests from the SRO (when required)	Written or verbal.
Capital Sub-Committee (CSC)	CSC highlight reports	Written or verbal
Project Group	**Monthly Standing Items:** RIBA Stage development Project finance	Written or verbal

Forum	Requirement	Format
	Project timeline Project risk register Construction risk register Project issues register. Project decisions register	

4.6.1. In order to ensure the quality delivery and management of the project, an Integrated Assurance and Approval Plan (IAAP) has been included at **Appendix 8.** In addition, varying reports are created and discussed during the Project Group meetings. Furthermore, the bimonthly reports provided to the Capital Sub-Committee include a RAG status report on the delivery and associated risks and issues.

4.6.2. In addition to the above reporting, the Project Group may provide project status highlight reports to the TrAMS Programme Group, SDODC and the Board of the University Health Board as and when required.

4.7 Communications and engagement

The Communication and Engagement for this project is driven by the TrAMS Programme. The project will not be impacting on any changes in services provided within the University Health Board. A communications and engagement exercise highlighted a relatively small number of staff that would be impacted by the repurposing of the BGH unit for pharmaceutical purposes and WGH aseptic service transfer to the South-West TrAMS Programme Unit. This will be managed through the University Health Boards OCP change management process by the aseptic service and workforce partners.

Those affected by this scope.
The site will need to consider other hospital areas in close proximity and car parking restrictions, these will be recorded in the project construction risk register held separately. An Equality Impact Assessment (EqIA) has been developed and signed off by the Project Director, **see Appendix 11**. Our standard internal Human Resource processes will be followed to support staff at BGH aseptic unit during consolidation. An Organisational Change Procedure (OCP) is already in place to address this.

4.8 Benefits realisation

4.8.1. A benefits realisation exercise will form part of the Project Closure Report (PCR), a key product in the post implementation and evaluation process (further detailed in section 5.9 below). This process will ensure that a robust analysis is carried out to understand whether the Project has achieved its Spending Objectives, through an assessment of the extent to which benefits have been realised.

4.8.2. The benefits realisation exercise will compare the current position at the time of the post-project evaluation against the Measures shown in Table 4: Main Benefits. 2023/24 data will be used as the baseline. The benefits owner is the Aseptic Senior Responsible Owner in the University Health Board.

4.8.3. The PCR, its contents and process will be informed by best practice guidance from project methodologies such as PRINCE2 and Better Business Case guidance.

4.9 Project risks

4.9.1. Risk management:

4.9.1.1. The risk management process, conducted through the Project Group to date, has comprised the following steps:

- Completion of a Risk Potential Assessment (RPA) – attached at **Appendix 9**.
- Creating a register of perceived risks and updating it on a regular basis.
- Assigning / agreeing the ownership of risks.
- Actively managing the agreed actions to mitigate risk.

4.9.1.2. Each risk is assigned an owner responsible for its management. The Project Manager assists the owners of the risks by monitoring and overseeing their progress in managing the risk.

4.9.2. Risk registers:

4.9.2.1. There are two risk register:

- The Project Risk Register – managed by the Project Manager; and
- The Construction Risk Register – this will be managed by the University Health Board's Estates Project Manager.

4.9.2.2. The risk registers enable all risks – either project or construction related – to be captured.

4.9.2.3. The project risk register is a risks, issues and decisions register used to capture the organisational risks that sit outside of the construction programme, actions from the respective project groups, issues and key decisions made in the Project. It is a live document reviewed and updated on a regular basis by the Project Manager during the Project Group meetings. The Project Manager may also convene periodic workshops to review and update the risk register. During these reviews, new risks identified are added, and existing risks revisited to agree whether the risk factor should be altered and ensure that the agreed management action is being adequately undertaken by the risk owner.

4.9.2.4. The risks in the risk register are scored a factor of 1 to 5 in terms of likelihood and 1 to 5 for impact.

4.9.2.5. The construction risk register will be similar to the project risk register and created following the appointment of the Principal Contractor. All risks that the Principal Contractor can foresee at the outset of the Project will be included and updated at the monthly project review.

4.9.2.6. All risk actions in the Construction Risk Register will be labelled as shown below:

Avoid	Risks that can be managed out, usually by design.
Reduce / share	Risks that have a high probability of occurring, which have some latitude in limiting the impact. There are few instances in construction where risk can be shared.
Transfer	Risks that can be transferred onto insurers or against contingencies.

4.9.3. Risk Reporting

4.9.3.1. The risk register forms an integral part of the monthly Project Group meetings. During the reviews new risks may be added and existing risks are revisited to agree whether the risk factor should be altered and ensure that the agreed management action is being adequately undertaken by the risk owner.

4.9.3.2. High risk items are included in the weekly Project Group agenda packs to ensure that mitigations are discussed, and escalations can be agreed. The Executive Team as sponsoring group for the Project will be informed of risks which are of particular concern and / or do not have appropriate mitigation in place.

4.10 Contract management

4.10.1. Issues arising from the Construction Risk Register will be managed by University Health Board's Estates Project Manager and discussed and assessed at Project Group to ensure the appropriate contingency is built into contracts with suppliers. Contingency has been included within the costs detailed in the Commercial Case.

4.11 Project evaluation

4.11.1. The Project will be evaluated by the Project Manager one-year post-implementation of the Recommended Option. This Post-Implementation Review will be undertaken to ensure that:

- The Project has achieved its Spending Objectives, mainly through assessing the extent to which benefits have been realised.
- Lessons are captured so that they can be absorbed into the Capital Planning Project Framework to aid the delivery of future capital projects.
- A formal project closure can take place, with any outstanding risks and remaining benefits to be tracked and monitored identified.
- Any outstanding audit recommendations are considered, addressed, reported on and closed.

Appendices

No.	Title	Paragraph reference	Description
1	Letter WG Chief Pharmaceutical Officer	3.	The high-risk ratings of the WGH unit was confirmed in the audit which took place in February 2022, 2023 and again 2024.
1a	TrAMS Confirmation of Support	4.	Email Confirming the TrAMS Programme Support for the Project.
2	Development Cost Approval Form (Recommended Option)	5. 8. FC I 2.2.3 (Table 9, assessment of Option 4) 2.2.4 3.2.2 (Table 10 DAF)	This document provides the forecast project out-turn costs based on Tender Cost for Capital Expenditure under the Recommended Option (Option 4). It has been used as the basis for the figures shown under Option 4 in the Financial Annex, and in Section 5.
2a	Development Cost Approval Form (Do Minimum)	2.2.4 4.1	1422 Do Minimum Refurb Option v11
3	Financial Annex	2.2.4 4.1	This appendix sets out projected Capital and Revenue Expenditure and Cost Savings (where applicable) for Options 1, 3 and 4.
4	Estates Annex	2.3.2	WGH Site Options Appraisal SoA Phases 2,3,4 Room Data Sheets Full Planning Permission Demountable Image Floor Plans ADET Report
5	Project Programme (Recommended Option)	3.5.1	This appendix sets out the current Project Programme for the Recommended Option (Option 4).
6	DEL - AME Charges	4.2.4	This appendix sets out projected depreciation charges and balance sheet and impairment impacts for Options 3 and 4.
7	Project Group Terms of Reference	5.2.1	This document provides current Terms of Reference for the Project Group described in Section 5.
8	Integrated Assurance Approval Plan	5.4.1	This appendix sets out the assurance activities that will be undertaken at portfolio, programme and project level, using pre-defined Gateway 0-5 and flexible Assurance Products (PAR, PVR, Critical Friend) as appropriate and proportionate.
9	Risk Potential Assessment	5.7.1.1	This document follows WG Independent Assurance Hub guidance to provide a self-assessment of the Project's level of risk under the headings shown below. The University Health Board's self-assessment of the level of risk is also shown: • Strategic Alignment & Commitment (Medium). • Financial/funding impact (Low). • Stakeholder engagement (Low). • Governance (Low). • Programme/Project Dependencies (Low).

No.	Title	Paragraph reference	Description
			The University Health Board's overall self-assessment risk rating is Low. The document was signed by the SRO on 18 October 2022 and remains current.
10	VAT accounting treatment and recovery considerations	4.1.1.	Letter from VAT advisors, advising on VAT accounting and recovery treatment position.
11	EqIA	4.7	Aseptic Project -EqIA Form draft v2

Tables

Approvals – BJC Aseptic Project – Hywel Dda University Health Board

Senior Responsible Owner: Jill Paterson Director of Primary Care, Community and Long-Term Care

Signature…… Date……

Executive Director of Finance: Huw Thomas

Signature…… Date……

Chief Executive: Philip Kloer

Signature…… Date……

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Hywel Dda
University Health Board