

## **Strategic Outline Case (SOC)**

### **Development of a Dedicated Vascular Hybrid Theatre at Morriston Hospital**



## Document control sheet

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## Executive Summary

### Introduction

This Strategic Outline Business Case (SOC) seeks support from Welsh Government (WGov) of between £6.996m and £11.293m (including non-recoverable VAT and Optimism Bias) for strategic capital investment to develop a dedicated Vascular Hybrid Theatre at Swansea Bay University Health Board's (SBU HB's) Morriston Hospital, Swansea.

This investment will provide the population of South West Wales with access to a state of the art hybrid operating theatre environment for the delivery of vascular surgical services. It will combine theatre functionality, and high-quality advanced radiology imaging devices such as fixed C-Arm imaging scanner intensifier, Computed Tomography (CT) scanners or Magnetic Resonance Imaging (MRI) scanners, and integrate with teaching and communication facilities. It will be utilised predominantly by Vascular Surgery and will employ minimally invasive techniques which are less traumatic for patients, improving patient pathways, reducing length of stay, waiting times and positively impacting on amputation rates.

### Background

**Vascular Surgery** is a discrete specialty separate from General Surgery and treats patients with arterial disease blood vessels, other than the heart that can lead to stroke, death or limb loss. The treatment of a patient with arterial disease may require an open operation and an interventional radiological procedure. The optimal treatment of vascular patients requires access to first class facilities, i.e. a fully equipped hybrid operating theatre with full imaging facilities.

#### Wales has three Vascular Networks:

- **North Wales Vascular Network** serves the population of Betsi Cadwalader UHB - In April 2019 the Health Minister opened North Wales' new £2.6m WGov funded hybrid theatre and vascular ward in Glan Clwyd Hospital. Described as *"one of the best in the UK"* this *"investment into new equipment and technology ... ensured the best possible services (was) in place"*, this investment *"already (had) attracted new staff and (will) provide a solid base to build local delivery and improve patient outcomes. These new arrangements put the needs of the patients first by ensuring excellent services which (will) be sustainable in the longer term"*.
- **South East Wales Vascular Network** serves the population of Cardiff and Vale, Cwm Taf Morgannwg and Aneurin Bevan University Health Boards - In 2020 a vascular hybrid theatre was developed as part of the new Specialist and Critical Care Centre in Cardiff, and a new hybrid theatre development is planned to be operational in 2021/22 at the University Hospital of Wales (UHW) to support the South East Wales Vascular service plan of vascular centralisation in order to comply with core clinical standards to improve clinical outcomes for vascular surgery. **South West Wales Vascular Network** serves the population of SB and Hywel Dda UHBs – Morriston Hospital is the designated arterial intervention site for South West Wales and is the most advanced and mature. It is working toward delivering a service that meets the standards of the Vascular Society of Great Britain and Ireland. It is the 18<sup>th</sup> busiest of over 80 vascular units within the UK but its operation is constrained by the lack of local access to a hybrid theatre facility to support best practice in vascular surgery.

If patients do not receive timely, hybrid interventions this will result in loss of limb and life, with the associated major financial burden to the NHS and Community services. Currently, a significant number of patients undergo staged procedures, with the inevitable unnecessary prolonged stays. This adds pressure to the number of bed days consumed and increases the constant pressure for inpatient beds within Morriston Hospital is constantly. Access to a hybrid theatre for vascular surgery would reduce risk, improve health outcomes, reduce length of stay and result in significant cost savings.

## The Strategic Case

### A. Strategic Context

Morriston Hospital is the designated arterial centre to deliver major vascular intervention for the South West Wales Vascular Network. The arterial centre was chosen after a full options appraisal, when centralisation was mandated. It was the only centre able to deliver the requirements of the Vascular Society of Great Britain (see **Appendix B - The Provision of Services for Patients with Vascular Disease 2015**) and Wales Abdominal Aortic Aneurysm Screening Programme (WAAASP) standards.

Patients are drawn from across South and West Wales area including, Pembrokeshire, Ceredigion, Carmarthenshire, Powys and Swansea Bay, a population of one million.

SB UHB has three acute hospitals providing a range of services; these are Singleton and Morriston Hospitals in Swansea and Neath Port Talbot Hospital in Port Talbot. SBU currently has 33 theatres across these hospitals, with plans to establish additional modular theatres at Singleton and NPT Hospitals. They are used for elective and emergency work covering all surgical specialities but we do not have a hybrid theatre and none of these theatres are dedicated for undertaking vascular procedures.

Pre-COVID, Morriston's vascular surgery service had access to four all-day lists per week and a fortnightly list supported by theatres in the Radiology Department - 80% of these patients were categorised as unscheduled/urgent. Vascular surgery utilised all available theatre capacity available at Morriston Hospital. The standard 40-weeks utilisation of theatres per annum, has increased to 51-weeks per annum. This is facilitated by the workforce utilising all the available theatre capacity, and by establishing a flexible rota and backfilling all sessions vacated by annual and study leave. Despite these efforts, there is still inadequate theatre capacity. This is being addressed by the plans to establish additional modular theatres.

As part of our developing COVID recovery plan the Health Board has increased the provision of emergency operating capacity in Morriston Hospital from 3.6 theatre per day to 6. As part of this allocation vascular surgery have dedicated access to 2 all day lists per week for their unscheduled work, and in addition, the service is allocated a minimum of 2 all day lists per week as part of the high priority case allocation process. These lists are provided consistently 50-weeks of the year, excluding Bank Holidays.

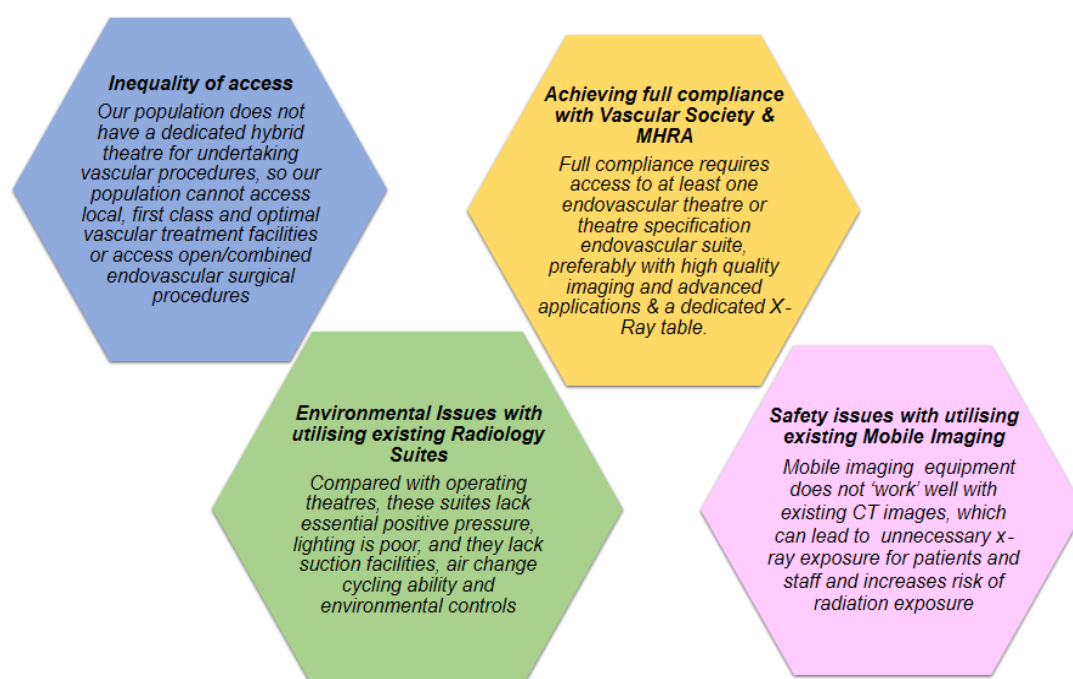
The Health Board has recently completed a significant public engagement exercise which gives a clear mandate for implementing the Clinical Services Plan (CSP). There are no plans to change the location of critical care and renal services, which are key dependencies for delivering centre of excellence major vascular interventions for South West Wales.

This project aligns with key national, regional and local strategic drivers. Both SBU and Hywel Dda UHBs support this business case, which 'fits' with SBU HB's Organisational Strategy: Better Health, Better Care, Better Lives 2019 - 2030, Clinical Services Plan 2019-2024 and Annual Plan 2021/22, and with the Masterplan for Morriston Hospital. It fits with Hywel Dda's Transforming Clinical Service Plan.

## B. The Case for Change

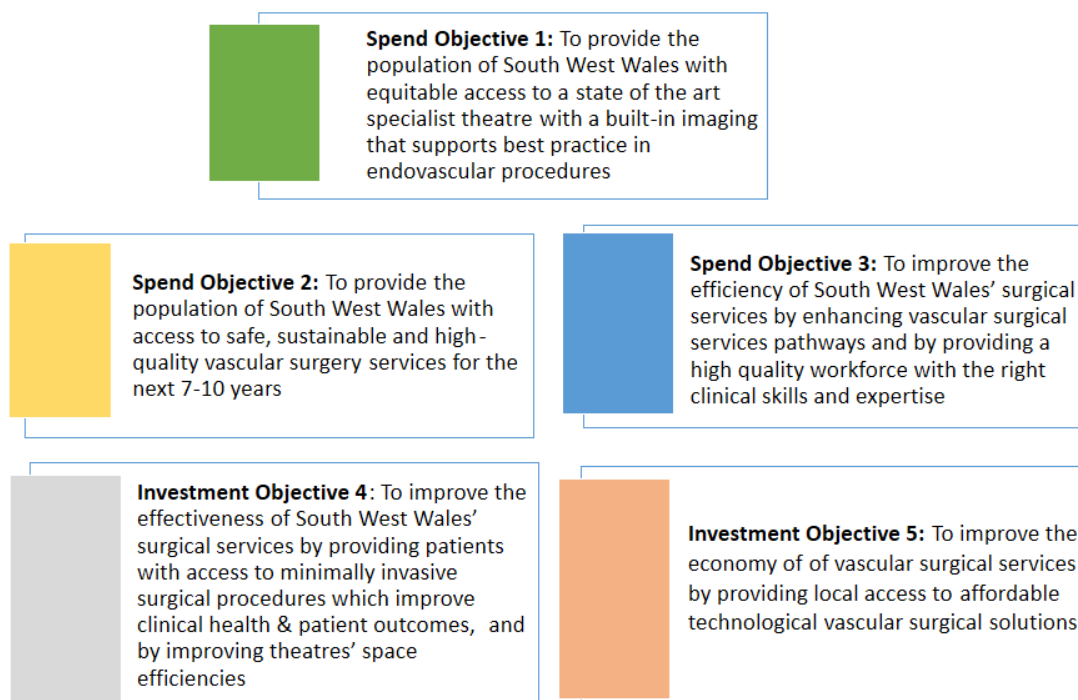
The problems with the status quo for South West Wales' vascular surgery patients are as follows:

**Figure – Problems with Status Quo**



In accordance with NHS Wales's guidance, the key spend objectives have been identified as follows:

**Figure – Spend Objectives**



All the above to be achieved by end of the 1st Qtr 2025 and evidenced by 1<sup>st</sup> Qtr 2026, subject to funding and planning approvals (please see **Appendix D – Benefits Realisation Register**).

The development of a dedicated hybrid theatre at Morriston Hospital will accommodate complex cases and allow patients in South West Wales to be treated closer to home and would support clinical efficiencies. Treating patients in-house, will reduce external referrals and therefore have significant cost savings. The provision of live-feed technology between the new theatre and lecture theatres, would support education, training and research in partnership with University of Swansea Medical School initiatives, and support Deanery Training Posts and recruitment. Access to a dedicated and appropriately equipped hybrid theatre would allow vascular surgeons to combine conventional surgical techniques involving a skin incision with interventional techniques using some sort of catheter-based procedure guided by fluoroscopic or MRI imaging in a hybrid room without interruption.

This investment:





- Improves clinical outcomes, supports minimal intervention for the patient and, streamlines patient pathways by reducing length of individual patient stays and reducing/removing the need for repeated admissions or staged procedures, enhancing the patient experience.
- Increases the range of best practice treatment options provided locally for the patient population of South West Wales.
- Improves recruitment and retention of senior staff.
- Provides state of the art teaching facilities with the ability to link in with national and international training/live cases/proctoring and proctorship.

## The Economic Case

A long list of framework options were developed to deliver this solution. Each long list option was compared against the spend objectives and Critical Success Factors (CSFs) for the project and four options were shortlisted as follows for detailed appraisal at Outline Business Case stage (please see **Appendices H1 – Framework Options and H2 – Framework Options Summary**).



**Figure – Shortlist Options**

	<b>Option 1 Do Minimum</b> Provide population of South West Wales with a local high quality dedicated hybrid theatre service with imaging capability. Solution involves re-modelling two existing theatres at <u>Morrison Hospital</u> .
	<b>Option 2 Intermediate (1)</b> Provide population of South West Wales with a local high quality dedicated hybrid theatre service with imaging capability. Solution involves a three-storey new build extension at <u>Morrison Hospital</u> (ground floor is a shell and core).
	<b>Option 3 Intermediate (2)</b> <ul style="list-style-type: none"> <li>Provide population of South West Wales with a local high quality dedicated hybrid theatre service with imaging capability with improved patient pathways. Solution involves a new build three-storey extension at <u>Morrison Hospital</u> and minor remodelling of internal areas within Theatres 1-7.</li> </ul>
	<b>Option 4 Do Maximum</b> <ul style="list-style-type: none"> <li>Provide population of South West Wales with a local high quality dedicated hybrid theatre service with imaging capability with improved patient pathways / recovery area. Solution involves a new build three-storey extension at <u>Morrison Hospital</u> and major remodelling of internal areas within Theatres 1-7.</li> </ul>

## The Commercial Case

This project's procurement strategy will be managed via WGov's Building for Wales Framework procurement route and will be publicly funded. The required services include enabling works as required, including the supply of essential infrastructure services, and development of a compliant Hybrid Surgical Theatre, and technical commissioning.

## Funding and Affordability

The indicative financial implications of the proposed investment for each shortlisted option are as follows:

**Figure – Capital Requirements (£000 incl. VAT and excluding Optimism Bias)**

	Option 1 Do Minimum	Option 2 Intermediate(1)	Option 3 Intermediate(2)	Option 4 Do Maximum
Departmental Costs	1,918	3,688	4,276	4,429
On Costs	378	600	585	585
Less Location Adjustment	-68	-128	-145	-150
<b>Works Costs Total</b>	<b>2,228</b>	<b>4,160</b>	<b>4,716</b>	<b>4,864</b>
Fees	663	969	1,057	1,080
Non Works Costs	339	389	467	467
Equipment Costs	3,155	3,204	3,562	3,570
Planning Contingency	957	1,308	1,470	1,497
<b>Total</b>	<b>7,342</b>	<b>10,030</b>	<b>11,272</b>	<b>11,478</b>
Less recoverable VAT	-481	-290	-463	-492
<b>Base Project Cost</b>	<b>6,861</b>	<b>9,740</b>	<b>10,809</b>	<b>10,986</b>

**Figure – Capital Requirements (£000 incl. VAT and including Optimism Bias)**

	Option 1 Do Minimum	Option 2 Intermediate(1)	Option 3 Intermediate(2)	Option 4 Do Maximum
Capital Outturn including OB Adjustment	6,251	8,578	9,650	9,826
Plus VAT	1250	1715	1930	1965
<b>Sub Total</b>	<b>7,501</b>	<b>10,293</b>	<b>11,580</b>	<b>11,791</b>
Less Recoverable VAT	-505	-295	-469	-498
<b>Project Costs (adjusted for OB)</b>	<b>6,996</b>	<b>9,998</b>	<b>11,111</b>	<b>11,293</b>

**NB. Option 1 excludes decant costs, which will confirmed following site surveys and detailed design.**

The overall revenue affordability of each shortlisted option are as follows:

**Figure – Revenue Impact (£000's)**

	<b>Option 1 Do Minimum</b>	<b>Option 2 Intermediate(1)</b>	<b>Option 3 Intermediate(2)</b>	<b>Option 4 Do Maximum</b>
Pay	0	0	0	0
General Non-Pay	120	120	120	120
Hotel Services	0	0	0	0
Estates	0	0	0	0
LTAs/ Other Commissioned Services	0	0	0	0
<b>Total</b>	<b>120</b>	<b>120</b>	<b>120</b>	<b>120</b>

A full assessment of capital and revenue affordability shall be made at Outline Business Case (OBC) stage.

## The Management Case

To ensure successful project delivery a robust project management reporting structure has been established. The Health Board's experience of developing and delivering complex projects in a Prince2 environment ensures diligent management and thorough clinical involvement throughout all parts of the development. The indicative milestones are set out below:

**Figure – Key indicative milestones**

<b>Activity</b>	<b>Due Date</b>
Health Board approves SOC	Jan. 2022
Submit SOC to WGov for approval	Feb. 2022
WGov approve SOC	April 2022
Health Board approves OBC	April 2023
Submit OBC to WGov for approval	April 2023
WGov approve OBC	June 2023
Health Board approves FBC	Nov. 2023
Submit FBC to WGov for approval	Nov. 2023
WGov approve FBC	Jan. 2024
Mobilise and commence works	Jan. 2024
Completed (subject to contractor's programme)	Jan. 2025
Commissioning	Feb. 2025
New build operational	March 2025
Technical Project Evaluation (approx. 3 months post new build handover)	June 2025
Benefits Realisation (12 months post operational)	April 2026

Please see **Appendix J - Management Control Plan**.

## Recommendation

This SOC presents a compelling case for change and we recommend on this basis that WGov approve this SOC and that this project progress to Outline Business Case (OBC) stage.

This scheme can be undertaken as a separate contract and building services could start 1<sup>st</sup> Qtr 2024, subject to funding approval.

..... Ms Kate Hannam, Service Director, Morriston Hospital  
Signed & Dated: Delivery Unit, SBUHB

# 1 The Strategic Case

## 1.1 Introduction

This Strategic Outline Business Case (SOC) seeks support from Welsh Government (WGov) of between £6.996m and £11.293m (including non-recoverable VAT and Optimism Bias) for strategic capital investment to develop a dedicated Vascular Hybrid Theatre at Swansea Bay University Health Board's (SBU HB's) Morriston Hospital, Swansea.

This investment will provide the population of South West Wales with access to a state of the art hybrid operating theatre environment for the delivery of vascular surgical services. It will combine theatre functionality, and high-quality advanced radiology imaging devices such as fixed C-Arm imaging scanner intensifier, Computed Tomography (CT) scanners or Magnetic Resonance Imaging (MRI) scanners, and integrate with teaching and communication facilities. It can also be combined with simulator technology, to enhance training opportunities - the first of its kind in Wales. It will be utilised predominantly by Vascular Surgery and will employ minimally invasive techniques which are less traumatic for patients, improving patient pathways, reducing length of stay, waiting times and positively impacting on amputation rates.

## 1.2 Background

**Vascular Surgery** is a discrete specialty separate from General Surgery and treats patients with arterial disease blood vessels, other than the heart that can lead to stroke, death or limb loss. Arterial disease affects blood vessels and results in narrowing or dilatation of the artery.

Population studies have found that 20% of people over 60 have some degree of peripheral arterial disease. Incidence is also high in people who smoke, people with diabetes and people with coronary artery disease. 1 to 2% of people with intermittent claudication (pain you feel when your leg muscles don't get enough blood) will eventually undergo amputation, although the risk is higher (about 5%) in people with diabetes. Of those presenting with intermittent claudication over a 5 year period approx. 10 to 15% will die of cardiovascular event and a further 20% will have a non-fatal cardiovascular event. Of those who develop critical limb ischaemia (a severe blockage in the arteries of the lower extremities, which markedly reduces blood-flow) there is a high mortality with approx. 25% dying within a year and about 33% requiring a major lower limb amputation within a year.

The most devastating disabling effects occur when the arteries to the brain and lower limb are affected resulting in stroke or limb loss. Dilated blood vessels are known as aneurysms. The most common is an abdominal aortic aneurysm however aneurysms also affect leg arteries and the main blood vessel in the chest (thoracic aorta). Abdominal and thoracic aneurysms most frequently rupture and are an immediate threat to life with 80% mortality. The treatment of a patient with arterial disease may require an open operation and an interventional radiological procedure. Open procedures are the traditional type of surgery in which an incision is made using a scalpel.

Open procedures are carried out in an operating theatre. Interventional Radiologists and Vascular Surgeons work together to perform minimally invasive Endovascular Aortic Aneurysm Repair (EVAR) to treat abdominal aortic aneurysm and thoracic aortic aneurysm. Currently Morriston carries out more than 60 EVARs p.a. These are done in two stages: interventional radiology procedure, then theatre procedure, or the reverse. If carried out sequentially on the same day, this involves the transfer between clinical treatment areas of a potentially unstable patient and treatment will occur during the same prolonged admission or require another admission episode. Occasionally an open operation may be carried out in the Radiology Suite (which has lower quality of sterility and poor lighting), or the radiological procedure is undertaken in the operating theatre with limited quality imaging.

The technical aspects of open and interventional procedures demands the highest standard of both disciplines to achieve optimal outcomes. Neither of the above situations is satisfactory. The optimal treatment of vascular patients requires access to first class facilities - a fully equipped hybrid operating theatre with full imaging facilities.

### Wales has three Vascular Networks:

- **North Wales Vascular Network** serving the population of Betsi Cadwalader UHB - In April 2019 the Health Minister opened North Wales' new £2.6m WGov funded hybrid theatre and vascular ward in

Glan Clwyd Hospital. Described as “one of the best in the UK” this “investment into new equipment and technology ... ensured the best possible services (was) in place”, this investment “already (had) attracted new staff and (will) provide a solid base to build local delivery and improve patient outcomes. These new arrangements put the needs of the patients first by ensuring excellent services which (will) be sustainable in the longer term”.

- **South East Wales Vascular Network** serves the population of Cardiff and Vale, Cwm Taf Morgannwg and Aneurin Bevan University Health Boards - In 2020 a vascular hybrid theatre was developed as part of the new Specialist and Critical Care Centre in Cardiff, and a new hybrid theatre development is planned to be operational in 2021/22 at the University Hospital of Wales (UHW) to support the South East Wales Vascular service plan of vascular centralisation in order to comply with core clinical standards to improve clinical outcomes for vascular surgery.
- **South West Wales Vascular Network** serves the population of SB and Hywel Dda UHBs – Morriston Hospital is the designated arterial intervention site for South West Wales and is the most advanced and mature. It is working toward delivering a service that meets the standards of the Vascular Society of Great Britain and Ireland. It is the 18th busiest of over 80 vascular units within the UK but its operation is constrained by the lack of local access to a hybrid theatre facility to support best practice in vascular surgery.

If patients do not receive timely, hybrid interventions this will result in loss of limb and life, with the associated major financial burden to the NHS and Community services. Currently, a significant number of patients undergo staged procedures, with the inevitable unnecessary prolonged stays. This adds pressure to the number of bed days consumed and increases the constant pressure for inpatient beds within Morriston Hospital is constantly. Access to a hybrid theatre for vascular surgery would reduce risk, improve health outcomes, reduce length of stay and result in significant cost savings.

## Part A - The Strategic Context

### *South West Wales' Designated Arterial Service*

Morriston Hospital is the designated arterial centre to deliver major vascular intervention for the South West Wales Vascular Network. The arterial centre was chosen after a full options appraisal, when centralisation was mandated. It was the only centre able to deliver the requirements of the Vascular Society of Great Britain (please see **Appendix B - The Provision of Services for Patients with Vascular Disease 2015**) and Wales Abdominal Aortic Aneurysm Screening Programme (WAAASP) standards. Patients are drawn from across South and West Wales area including, Pembrokeshire, Ceredigion, Carmarthenshire, Powys and Swansea Bay, a population of one million.

### *Theatre Capacity & Utilisation*

SB UHB has three acute hospitals providing a range of services; these are Singleton and Morriston Hospitals in Swansea and Neath Port Talbot Hospital in Port Talbot. SBU currently has 33 theatres across these hospitals, with plans to establish additional modular theatres at Singleton and NPT Hospitals. They are used for elective and emergency work covering all surgical specialities but we do not have a hybrid theatre and none of these theatres are dedicated for undertaking vascular procedures.

Pre-COVID, Morriston's vascular surgery service had access to four all-day lists per week and a fortnightly list supported by theatres in the Radiology Department - 80% of these patients were categorised as unscheduled/urgent. Vascular surgery utilised all available theatre capacity available at Morriston Hospital. The standard 40-weeks utilisation of theatres per annum, has increased to 51-weeks per annum. This is facilitated by the workforce utilising all the available theatre capacity, and by establishing a flexible rota and backfilling all sessions vacated by annual and study leave. Despite these efforts, there is still inadequate theatre capacity. This is being addressed by the plans to establish additional modular theatres.

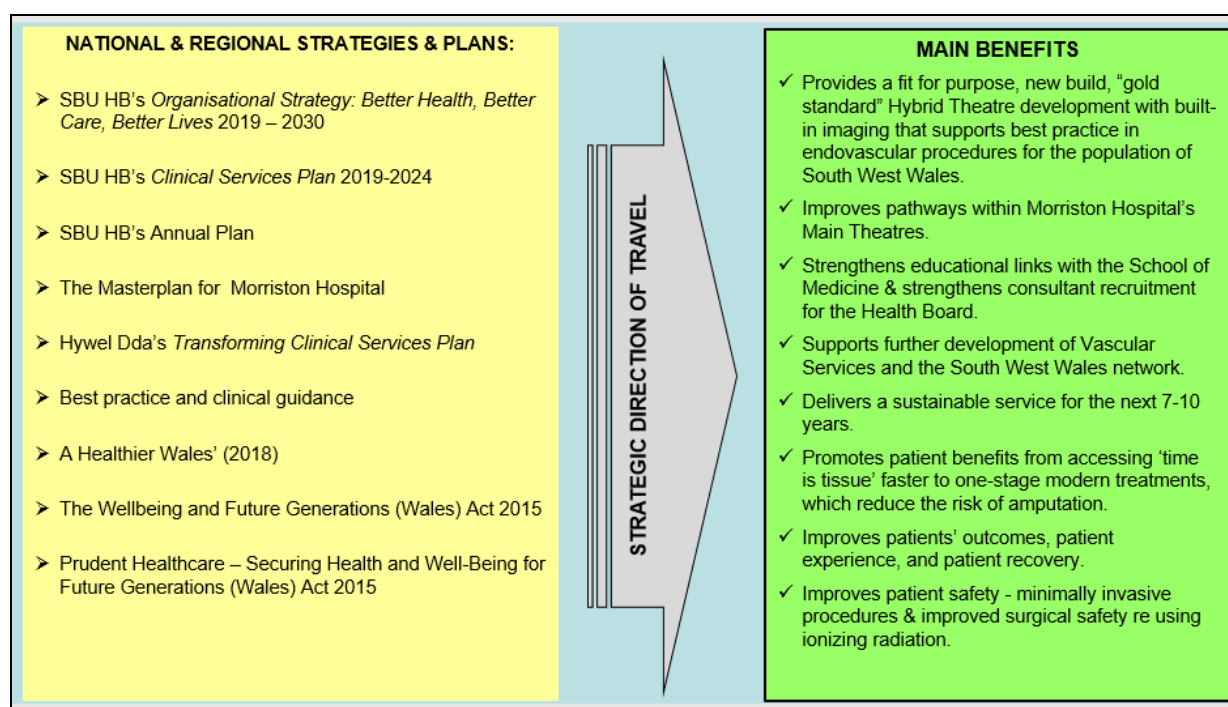
As part of our developing COVID recovery plan the Health Board has increased the provision of emergency operating capacity in Morriston Hospital from 3.6 theatre per day to 6. As part of this allocation vascular surgery have dedicated access to 2 all day lists per week for their unscheduled work, and in addition, the service is allocated a minimum of 2 all day lists per week as part of the high priority case allocation process. These lists are provided consistently 50-weeks of the year, excluding Bank Holidays.

The Health Board has recently completed a significant public engagement exercise which gives a clear mandate for implementing the Clinical Services Plan (CSP). There are no plans to change the location of critical care and renal services, which are key dependencies for delivering major vascular interventions for South West Wales.

### 1.3 Business Strategies

This SOC supports the following national, regional and local strategies plans and drivers for change and delivery of the main benefits:

**Figure 1 – Business Strategies**



This business case supports 'A Healthier Wales' (2018), the cluster approach to population health will underpin our plan to reconfigure the roles of our major hospitals and support the effective delivery of timely, high quality hospital based care when it is needed. Complex surgery will be undertaken in Morriston Hospital. This aligns with the plan for the development of a hybrid theatre in Morriston Hospital.

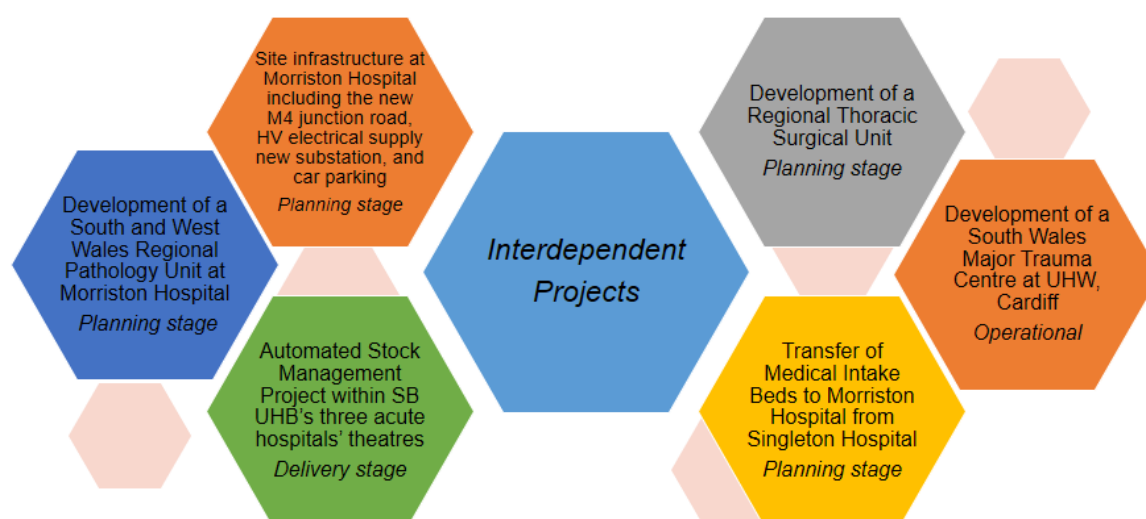
This project aligns with key national, regional and local strategic drivers. Both SBU and Hywel Dda UHBs support this business case, which 'fits' with SBU HB's *Organisational Strategy: Better Health, Better Care, Better Lives* 2019 - 2030, *Clinical Services Plan* 2019-2024 and Annual Plan, and with the Masterplan for Morriston Hospital. It 'fits' with Hywel Dda's *Transforming Clinical Service Plan*.

This investment 'fits' with A Regional Collaboration for Health (ARCH) programme wherein SB and Hywel Dda UHBs and partners are working to further enhance healthcare service delivery, research, education and innovation in healthcare and life sciences within the region.

### 1.4 Key Interdependent Projects

The following projects are interdependent with this investment:



**Figure 2 – Interdependent Projects**

## 1.5 Part B - The Case for Change

### *Current South West Wales Vascular Network Service*

The South West Wales Vascular Network serves the population of SB and Hywel Dda UHBs. Morriston Hospital is the designated arterial intervention site for South West Wales and is the most advanced and mature and as the designated arterial intervention site. Ranked as the 18<sup>th</sup> busiest of over 80 vascular units within the UK. Currently, Morriston carries out more than 60 Endovascular aneurysm repairs (EVARs) procedures. The number of combined peripheral procedures incorporating imaging and open surgery (emergency and elective) lower limb procedures equated to between 90-105 cases for imaging alone. The current EVAR rate is 50% compared to a typical level of 75% in other vascular surgery centres and procedures are carried out either within the theatre estate in generic theatres or in a DSA suite, neither of which are designed or purpose built to undertake these types of procedures.

Current facilities are either focused around the adaption of angiography suites to allow open access surgery or the uses of mobile imaging in a conventional theatre. Its operation is constrained by the lack of local access to a hybrid theatre facility to support best practice in vascular surgery. This means that complex EVARs that requires branches to maintain supply to kidney and other main branches of the aorta that supply blood to the gut. Consequently, complex cases are referred out of area for treatment to centres with hybrid theatre facilities and relevant expertise.

### *Mobile Imaging*

Currently, should imaging be required for the procedure within a generic theatre a mobile imaging system can be brought into the theatre. There are a number of limitations in using mobile systems<sup>1</sup>:

- “The first limitation of mobile systems “is the obvious inferiority of the images they generate in terms of quality in comparison with fixed x-ray systems. Despite improvements, mobile imagers are less powerful at usually less than 25kW compared to fixed systems that operate at 80-100kW. Imaging an obese patient, particularly at lateral angle, could produce an unsatisfactory image”;
- “Another drawback of mobile systems is their propensity to overheat during operating. Therefore conducting complex endovascular procedures using a mobile imaging system without backup imaging equipment could be considered unsafe practice”;

<sup>1</sup> Roa Vallabhane (2010)

- Furthermore, mobile equipment needs to be stored in a safe place and connected to an electrical charge when not in use, which creates logistical challenges. Moving the equipment between the site of storage and the operating room, setting up the equipment and network connections consumes time, slows down the intervention, creates a space issue within the theatre and creates an inefficiency, and finally;
- Mobile imaging does not have the facility to overlay (incorporate) existing CT images, with relevant mark up and planning measurements. This leads to additional radiation potentially unnecessary X ray exposure to the patient and staff. This goes against the ALARA (As Low as Reasonable Allowable) principal and is a health risk for staff.

### **Radiology Suites**

The importance of intra operative sterility is critical and radiology suites lack the positive pressure, air change cycling ability and environmental control of an operating theatre. There is an increasing body of evidence supporting the use of laminar air flow when implanting foreign bodies into patients<sup>2</sup>:

- An operating theatre is purpose built to allow rapid de-contamination and cleaning to maintain the sterile environment;
- Radiology suites are not designed to accommodate anaesthetic machines and the additional staff required for a general anaesthetic procedure. There are also the issues with adequate light and suction facilities if an open conversion is required;
- “Although EVAR complications requiring immediate open conversion are rare (3.8%), it is possible that, with the increasing volume of endovascular cases, complexity and the possibility of endovascular repair of ruptured aneurysms, the need for conversion may increase”;
- More complex endovascular aneurysm treatments combine open arterial bypass procedures, to ensure that an adequate area of the blood vessel to be covered to create a satisfactory sealing zone. An example is transferring the blood supply to the brain from one carotid artery in the neck, to the other carotid artery, to create a sealing zone. This procedure requires an open bypass using a cloth (Dacron) graft. If this were to become infected the result would be life threatening.

### **Hybrid Theatre**

The definition of a hybrid procedure in the literature varies widely. Nollert et al (2012) state that “a strict definition of a hybrid procedure is a major procedure that combines a conventional surgical part including a skin incision with an interventional part using some sort of catheter-based procedure guided by fluoroscopic or MRI imaging in a hybrid room without interruption”. Traditionally, in certain specialty areas patients have been treated via open procedures. However over the last 10-15 years advances in X-Ray, CT Scanning and other medical imaging technology has made it possible to diagnose and treat patients for a range of diseases through minimally-invasive surgical (MIS) techniques. As a result surgeons have now been trained in interventional radiology procedures and angioplasty and stenting. This means that surgeons have developed a whole new discipline which isn't one thing or another – in other words a 'hybrid' operating process. To undertake this work a Hybrid Theatre is required. The hybrid theatre allows the Surgeon to perform both minimally-invasive, image guided procedures, as well as traditional open surgery. In some cases both types of surgery will be required on the patient and with a Hybrid this can now be done in one operating session, under a single anaesthetic, rather than several stages in different theatre facilities within the hospital.

### **Procedures & Activity Information**

The preferred option is a hybrid theatre primarily designed for vascular surgery with advanced medical imaging devices, which has the potential to be used to centralise the open/endovascular surgery. EVAR procedures should run at a minimum of 100-110 cases per annum. Combined peripheral procedures incorporating imaging and open surgery (emergency and elective) lower limb procedures equate to between 90-105 cases per annum for imaging alone. This does not account for the expected uplift in combined endovascular interventions in addition to open procedures. A further 20-30 emergency Endovascular Aneurysm Repairs are expected, this has the added benefit of patients requiring less critical care bed days, earlier discharge. Emergency limb salvage procedures benefitting from vascular imaging / endovascular intervention equate to a further 50 cases per year. This equate to between 26 and 290 cases per year.

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<sup>2</sup> Portou et al (2011)

## 1.6 Problems with Status Quo

### *Inequality of access for South & West Wales' Vascular patients*

South and West Wales Network does not have a dedicated theatre for undertaking vascular procedures or a hybrid operating theatre, so, unlike the other two Welsh Vascular Networks, the South West Wales Network's patients cannot access first class and optimal vascular treatment or open/combined endovascular surgical procedures with full imaging facilities in a local and fully equipped facility unless this investment is supported.

### *Safety issues with utilising existing Mobile Imaging*

Currently within SB UHB, should imaging be required for a procedure within a generic theatre, a mobile imaging system can be brought into the theatre. However, there are a number of limitations in using mobile systems, including: inferior images in terms of quality compared with fixed X-ray systems; the propensity of portable imaging systems to overheat during an operation; safe-storage issues (mobile equipment requires electrical charge when not in use) and logistical challenges transferring equipment between storage site and the operating room, which can lead to clinical inefficiencies. Also, mobile imaging does not have the facility to overlay (incorporate) existing CT images, with relevant mark up and planning measurements, which leads to additional radiation from potentially unnecessary X-ray exposure to the patient and staff (this contravenes 'As Low As Reasonable Allowable' (ALARA) principals and is a health risk for staff.

### *Environmental issues with utilising existing Radiology Suites*

Occasionally an open operation may be carried out in the Radiology Suite but these facilities are not designed to accommodate anaesthetic machines and the additional staff required for a general anaesthetic procedure. Compared with Operating Theatres, these suites lack essential positive pressure, lighting is poor, and suction facilities, air change cycling ability and environmental controls (including laminar air flows).

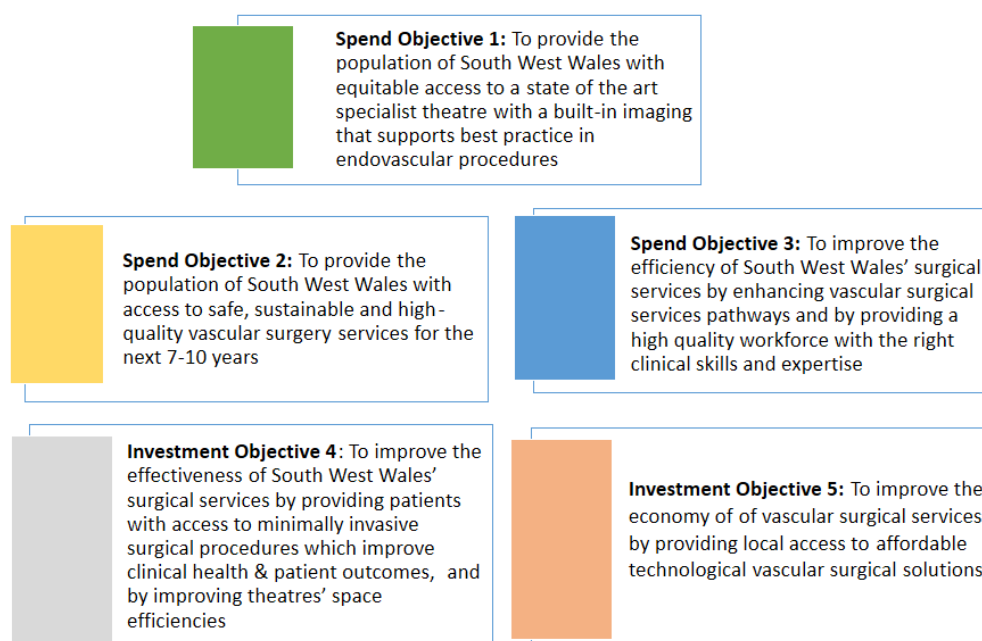
### *Failure to achieve full compliance with Vascular Society Recommendations & MHRA Guidance*

To achieve full compliance with MHRA Guidance SB UHB needs investment in at least one endovascular theatre or theatre specification endovascular suite, preferably with high quality imaging and advanced applications. A dedicated X-Ray table is also required to deliver the Vascular Society's recommendation that be provided to ensure full compliance with best practice.

## 1.7 Spend Objectives

In accordance with NHS Wales's guidance, the key spend objectives have been identified as follows:



**Figure 3 – Spend Objectives**

All the above to be achieved by end of the 1st Qtr 2025 and evidenced by 1<sup>st</sup> Qtr 2026, subject to funding and planning approvals (please see **Appendix D – Benefits Realisation Register**). There are no potential dis-benefits.

## 1.8 Vascular Service Model

### *UK Service Model*

There is well-established clinical guidance about how to deliver a high quality vascular service. Most recently this has been articulated in *The Provision of Services for Patients with Vascular Disease* (2015), published by the Vascular Society of Great Britain and Ireland (Please see **Appendix B - The Provision of Services for Patients with Vascular Disease 2015**). The paper states the following: “*The current Vascular Society advice, based on sound clinical evidence, is that high quality vascular care in the UK is best delivered with the establishment of integrated vascular networks. Such networks should decide upon a single hospital which will provide arterial surgery and complex endovascular interventions. The other hospitals in the network need to continue to provide the following clinical support: - vascular clinics; diagnostics; interventions such as renal access and varicose vein procedures; review of in-patient vascular referrals; and rehabilitation...This provides the patient with direct local access to the vascular service.*”

In terms of the benefits of this approach the above paper advises: “Concentrating arterial surgery and more complex endovascular interventions in one arterial centre has a number of benefits. Evidence shows that clinical outcomes are improved with increasing volumes of procedures. Sustainable on-call rotas can be achieved and effective multi-professional training is facilitated. Lack of exposure to sufficient numbers of training opportunities is the biggest problem facing current trainees. This problem is perpetuated when training opportunities are distributed around a number of providers performing small numbers of cases in a regional network. Finally there are significant economic benefits to be gained by avoiding the replication of expensive technology and staff in hospitals throughout the network”.

### *The Vascular Society*

The Vascular Society defines the following resources and facilities that should be in place to support delivery of high volume arterial hospital for a network:

- A 24/7 consultant on-call rota for vascular emergencies of 1:6 or greater, covered by a combination of vascular surgeons and interventional radiologists to ensure adequate care;
- A 24/7 critical care facility with ability to undertake mechanical ventilation and renal support and with 24/7 on-site anaesthetic cover;
- Wards for dedicated vascular patients;

- At least one endovascular theatre or theatre specification endovascular suite is required, preferably with high quality imaging, advanced applications and a dedicated X-ray table ((in accordance with Medicines and Healthcare products Regulatory Agency (MHRA) guidance));
- A minimum number of 60 Abdominal Aortic Aneurysm (AAA) and 40 carotid procedures (elective and emergency) are undertaken p.a.;
- The population covered by the network should be sufficient to generate the required volume of procedures at the arterial centre (a minimum of 800,000 is usually required for this);
- An on-site vascular laboratory should be available;
- Hospitals, vascular surgeons and interventional radiologists should submit cases to the National Vascular Registry (NVR) and publish their outcomes in line with the National HQIP programme. Actions should be taken to ensure all outcomes are satisfactory, and;

Vascular surgeons should undertake regular review of their practice and outcomes (morbidity and mortality/governance meetings).UK

### ***The Getting it Right First time (GIRFT) Programme National Specialty Report into Vascular Surgery***

Professor Michael Horrocks, in the foreword to The Getting it Right First Time (GIRFT) Programme National Specialty Report into Vascular Surgery published in March 2018, stated that “the most pivotal recommendation being made was that delivery of arterial surgery should be reconfigured so that all patients can be treated on an urgent basis”, by establishing hub and spoke networks, where the hubs have the capacity and flexibility to offer a seven-day service. This model is already supported by the Vascular Society and NHS England; where it has been adopted and embedded well, major improvements in wait times and other patient outcomes have been seen. Where well-embedded, this network model typically leads to improved perioperative care, by facilitating closer working with other medical specialties who are also treating these often very frail patients. That in turn could also help reduce length of stay and readmissions. These benefits underline the importance of ensuring that all vascular networks are established as required by the existing national service specification. The report recommends that a network model becomes the norm, with all providers’ part of a network and work clearly and consistently distributed between the hubs and spokes. The report goes on to describe the case for networks and how they can allow pooling of resources to invest in facilities such as CT scanners and hybrid Theatres.

## **1.9 External Advisory Organisations**

### ***NICE***

The National Institute of healthcare and Clinical Excellence (NICE) recommend the treatment of infrarenal abdominal aortic aneurysm by Endovascular Aneurysm Repair (EVAR). The MHRA recommend that EVAR be carried out in a Hybrid Operating Theatre and specify minimum standards for these facilities. The treatment of patients presenting with ruptured AAA, is recommended as part of clinical trials. Current evidence supports this approach for certain subsets, however as more data is acquired the indications will become clearer. ‘Gold standard’ assessment of vascular interventions includes post reconstruction imaging, with angiography. Other modalities are often used in combination. We do not currently utilise this modality.

### ***Medicine & Healthcare products Regulatory Agency (MHRA)***

MHRA is an Executive Agency of the Department of Health responsible for the regulation of medical devices and pharmaceutical products. In 2010 the MHRA became aware of number of adverse incidents of interventional procedures in relation to the placement if stent grafts, many of which were associated with inadequate imaging facilities for fluoroscopy. As a result guidance was then issued on the delivery of Endovascular Aneurysm Repair (EVAR) based on the recommendation of group of nominated experts. The MHRA Report (2010) outlined two essential elements for a dedicated EVAR facility as follows:

- High quality imaging equipment is crucial for the accurate positioning and deployment of the stent graft to avoid covering important branch vessels and compromising blood flow to essential organs such as the brain, upper limb or kidney.
- Theatre specification setting to provide a safe, appropriate environment to allow for induction of anaesthesia, surgical cut-down, post-operative recovery and conversion to open repair, should the need arise.

## **IRMER Guidance**

Ionising Radiation (Medical Exposure) Regulation (IR(ME)R 2000) is legislation intended to protect the patient from hazards associated with ionising radiation. The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)<sup>1</sup> derive from the European Council Medical Exposures Directive.<sup>4</sup> They are designed to ensure patient safety and were made under Section 2(2) of the European Communities Act 1972<sup>5</sup> but are enforced as if made under Section 15 of the Health and Safety at Work etc. Act 1974. Within SBU the lack of an integrated imaging facility means that patients may require repeat imaging rather than an image transfer. This results in the patient having additional radiation exposure, which is contrary to IRMER guidelines.

## **1.10 Education, Training and Recruitment**

SBU HB aims to be able to train both vascular surgeons and interventional radiology trainees in both environments, i.e. Radiology Suite and Hybrid Theatre. This will require mentorship and proctoring. A Training & Development Plan will be developed and detailed at OBC stage to ensure health outcomes and patient benefits are realised as planned.

### **University Initiatives**

The University of Swansea Medical School was established in 2001 and aims to be an internationally-recognised Centre of Excellence in research and medical education. It works closely with the Health Board to achieve excellence in teaching, research and clinical service. The establishment of a hybrid theatre with the facility to feed live procedures into a lecture theatre will enhance excellent teaching.

### **Supporting Deanery Training Posts & Recruitment**

The strategic aim of the Wales Deanery is to commission, quality assure and support the education and training of trainees, hospital doctors, GPs, dentists and DCPs in Wales. This includes the development of innovative models of education and training delivery, building training capacity and leading on postgraduate medical and educational research. The development of a dedicated hybrid theatre in SBU will support this goal for ongoing training within the Health Board and Wales. It will also allow live procedures to be transmitted to the training facilities.

## **1.11 Business Needs**

The development of a hybrid theatre for more complex cases allows patients in South West Wales to be treated closer to home and would support clinical efficiencies and significant cost savings.

Our population needs access to a dedicated and appropriately equipped hybrid theatre to allow vascular surgeons to combine a conventional surgical techniques involving a skin incision with an interventional techniques using some sort of catheter-based procedure guided by fluoroscopic or MRI imaging in a hybrid room without interruption. Local access to a hybrid theatre will allow Morriston's Vascular Surgeons to perform both minimally-invasive, image guided procedures, as well as traditional open surgery. In some cases both types of surgery will be required on the patient and with a hybrid theatre, to be done in one operating session under a single anaesthetic, rather than in several stages in different theatre facilities within the hospital.

Overall, this investment supports the following:

- Delivery of a new service model and patient pathways in compliance with UK vascular surgery best practice;
- Delivery of efficiency improvements in the overall vascular surgical pathway;
- An opportunity to modernise the outdated, inadequate post-operative recovery area within the main theatre department and improve patient flows at Morriston Hospital;
- Essential limb and life-saving interventions efficiently;
- Prevents multiple or extended admissions for complex procedures.
- Allows a timely revascularisation of limbs as a combined radiological and surgical procedure.
- Increases the rate of minimally invasive procedures.
- Improves patient pathways, reduce length of stay, waiting times and positively impact on amputation rates.
- Reduces the requirement for external referral / commissioning for complex procedures;

- Local access, eliminating significant travelling for patients and carers ;
- Improves the quality of care, provide fit for purpose, dedicated and networked Hybrid surgical services to the population of South & West Wales;
- Improves patient safety;
- Improves the patient experience and survival rates against UK standards - Reducing infection risk - prosthetics, wounds;
- Reduces radiation exposure to patients and staff in compliance with Ionising Radiation (Medical Exposure) Regulation ((IR(ME)R) Guidance 2000 legislation, which is intended to protect the patient from hazards associated with ionising radiation, is derived from the European Council Medical Exposures Directive.4, and is designed to ensure patient safety and were made under Section 2(2) of the European Communities Act 1972 but are enforced as if made under Section 15 of the Health and Safety at Work etc. Act 1974. Within SB UHB the lack of an integrated imaging facility means that patients may require repeat imaging rather than an image transfer. This currently results in the patient having additional radiation exposure, which is contrary to IRMER guidelines;
- Improved recovery area and patient flow through the main operating department.
- Meets Vascular Society and MHRA recommendations for delivering treatments in an appropriate environment;
- Makes SB UHB a competitive and attractive organisation within the recruitment market for Vascular Surgeons, Interventional Radiologists and Allied Health Professional staff.
- Aligns Morriston Hospital vascular surgery theatre infrastructure with the majority of other vascular hub hospitals in the UK, where 59% of hub hospitals have access to at least one hybrid theatre on site (National Vascular Registry Annual Report 2018), an increase from 43% in 2015;
- Complies with National Institute of healthcare and Clinical Excellence (NICE) recommend the treatment of infrarenal AAA by EVAR, and;
- Complies with The Medicine & Healthcare products Regulatory Agency (MHRA) recommendation that EVAR be carried out in a Hybrid operating theatre and specify minimum standards for these facilities. The treatment of patients presenting with ruptured AAA, is recommended as part of clinical trials. Current evidence supports this approach for certain subsets, however as more data is acquired the indications will become clearer. 'Gold standard' assessment of vascular interventions includes post reconstruction imaging, with angiography. Other modalities are often used in combination. SB UHB currently does not utilise this modality.

The Hybrid Theatre service at Morriston Hospital will be staffed by ten vascular surgeons providing scheduled and 24/7 emergency cover. Design of practices and services will comply with MHRA guidance and best practice Vascular Society recommendations and an evidence-based approach for optimising service delivery to patients and maximising survival rates (this will be detailed at OBC stage). Access to minimally invasive procedures will result in a significant reduction in operative stress to the patient, reduce the need for critical care beds and shorten patient stays.

The volume of interventional procedures undertaken is increasing and the development of the hybrid theatre will complement this new radiology facility and will move some of the work currently done in the radiology department, into the hybrid operating theatre. This work will, for the most part, be undertaken in partnership with Radiology, however it is envisaged that appropriately trained endovascular surgeons will also carry out some procedures independently in the hybrid operating theatre, as is the current practice in the radiological imaging suite. As more complex procedures are developed it is essential that the high degree of team working between radiology and vascular surgery continues.

Space released in Morriston's Main Theatres could be utilised by specialist services such as interventional cardiology or by specialised surgery that requires more intensive support, which have been limited in the past, e.g. obesity surgery, complex plastic surgery and sarcoma. Space released by re-providing, e.g. staff support facilities in the new build, could be utilised for essential equipment storage, improving pathways and efficiencies in the theatre area.

The design strategy for the new theatre will include best practice infection prevention measures health-care facilities. This will involve access to adjacent isolation facilities for infection prevention and control towards curbing the spread of Covid-19; Separation of clean and dirty areas and access routes within the existing theatre complex will comply with infection control requirements. Design within the storage and changing rooms in the new build will, within fire regulations constraints, enhance natural ventilation to maximise the movement of air within a space, and enhance daylight or sunlight to support good fenestrations and daylight in structures can sway the spread of airborne pathogens.

## 1.12 Forecast Activity

An additional 20-30 emergency EVARs p.a. are predicted above current baseline, which has the added benefit of patients requiring less critical care bed days and earlier discharge. Emergency limb salvage procedures benefitting from vascular imaging / endovascular intervention equate to a further 50 cases p.a. This equates to between 260 - 290 cases p.a.

## 1.13 Service Interdependencies

The following service interdependencies must be integrated or co-located with a hybrid theatre development:

- Theatre & Recovery services, Anaesthetic and Nursing Teams & Advanced Nurse Practitioners services;
- Respiratory Medicine (this is the prime referring speciality for most conditions requiring Hybrid surgery. Respiratory physicians are core members of lung cancer and emphysema MDTs);
- Out-patient clinic space, including facilities for pre-op assessment and pre-admission, and;
- Intensive Care.

## 1.14 Digital Technology

The new service will also need access to modern digital technology to support the following:

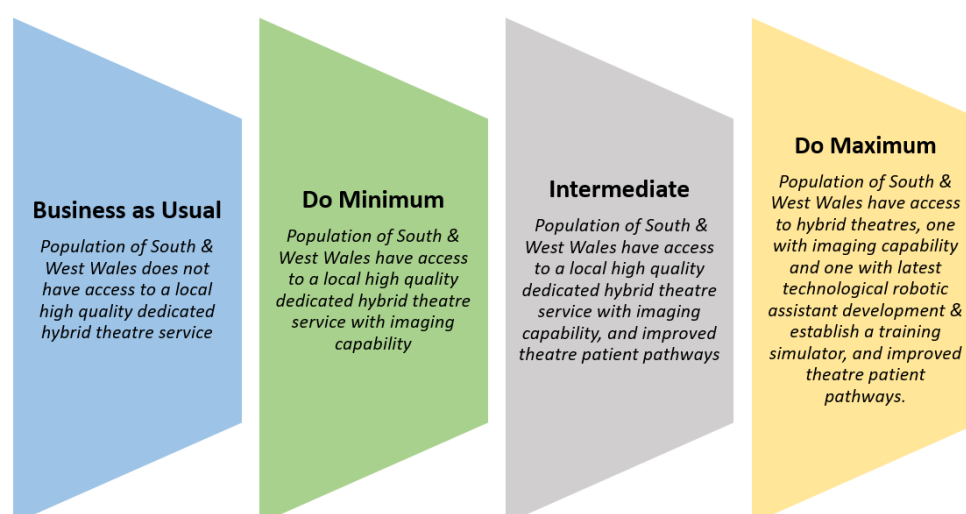
- Teaching and training, which allows the development of surgical skills without interruptions to the performing surgeon's field of view. This will enable visualisation of the open surgical field on surrounding monitors and reduce risks associated with overcrowding in and around the sterile field;
- Tele-medicine, which has multiple benefits from collaboration, sharing information, second opinions and tele-mentoring all of which are improving surgical practice, education, treatment and post-operative care. Sharing of medical expertise will only improve patient outcomes and in the long run, greatly reduce costs, and;
- The provision of live-feed technology between the new theatre and lecture theatres, would support education, training and research in partnership with University of Swansea Medical School initiatives, and support Deanery Training Posts and recruitment.

The Digital Strategy for this project will be detailed at OBC stage.

## 1.15 Potential Scope

This section describes the potential scope for the project in relation to the above business needs in terms of modalities and service drivers. The potential scope has been assessed against a continuum of need. The potential service scope framework options within these ranges are described in the figure below:

**Figure 4 - Potential Service Scope Framework Options**



The Health Board supports a continuum of service scope options that would allow investment in the short-term in a 'do minimum' or 'intermediate' solution (as proposed above) and allow a more ambitious option to form part of a future business case within in 5–10 years.



## 1.16 Main Outcomes and Benefits

The main potential outcomes benefits to patients, the Health Board and the wider health community would be classified in terms of cash releasing benefits (CRBs), non-cash releasing benefits (NCRBs), quantifiable or quantitative benefits (QBs), and non-quantifiable or qualitative benefits (NQBs). The main benefits include the following:

### ***Clinical Benefits***

A hybrid theatre environment delivers utmost patient safety as it allows the immediate conversion within the right environment of a minimally invasive procedure into an open procedure if this is required.

Access to high quality digital images would allow the use of the most advanced endovascular devices, and simultaneous multiple vascular access from different areas of the body (groin, upper limb, foot, chest abdomen)

The integration of the open and endovascular techniques in the same setting for the treatment of different vascular surgery pathologies, has driven the need for an adequate environment where the surgeons could perform such interventions to the highest standard of care possible. The hybrid theatre or Hybrid-OR is a facility where the interventional or cath-lab facilities (high standard radiograph, floating table. Workstation of imaging processing and storage, etc.) are fully integrated into a standard open theatre to ensure adequate sterility and lighting are met to perform open operations.

The need for Hybrid-OR is not restricted to vascular surgeons: cardiac surgeons and neurosurgeons have already developed hybrid procedures necessitating angiography systems in the OR, trauma surgeons, orthopaedics and urologist regularly use angiography equipment for their operations. Imaging needs and room set-ups requirements will vary between specialties.

### ***Benefits for the South West Wales Region (SBU and Hywel Dda University Health Boards)***

The establishment of a South West Wales Vascular Network has ensured that we have created a high volume centre in Morriston Hospital, which will allow us to deliver improved outcomes for the patient population of South West Wales. The development of a hybrid facility will ensure that SBU competes on a level platform with other large regional providers of complex cardiovascular services, in which we currently have a significant tertiary referral base. Hybrid facilities are recognised as the gold standard facility and are widely available throughout the UK. The proposed initiative will ensure that the South West Wales Vascular Network provide patients with access to facilities which enable clinicians to provide the best possible quality of clinical care for the patient population. This will be especially relevant to patients experiencing life threatening vascular emergencies, which require immediate intervention and are characterised by high levels of mortality.

### ***Benefits for Operational efficiency and productivity***

Patients undergoing an endovascular procedure experience consistently shorter post-operative inpatient stays compared to those undergoing open surgery. For all new patients who have endovascular rather than open surgery, there will be a saving of 5 bed days per patient, two to three of which are critical care bed days. The mean open aortic aneurysm stay in critical care was 2 days compared with 0 days for endovascular aortic aneurysm procedures. The overall inpatient stay was 9 days for open, 2 days for endovascular

There is an opportunity to concentrate endovascular activity within the new facility, which has the potential to increase utilisation compared to the existing arrangement. Currently there can be delays in complex revascularisation where a patient may need to wait until an operating list and a radiology list are both available. This would not be the case should a combined case be planned in a hybrid suite.

The ability to perform combined procedures in a hybrid suite would mean that instead of a dedicated radiology suite and operating theatre being on hold or standby when efforts are made for combined cases could be used efficiently for standard endovascular or open cases. Currently two suites are being used for one case with staffing for both sat idle whilst one section is being carried out.

### **Benefits to the Patients**

There will be the additional benefits to patient experience, as a result of more timely access to treatment access and improvements in the facilities and support services available.

- Co-location with main theatres will provide a safer operating environment for complex and unstable patients, particularly those requiring endovascular interventions.
- Patients requiring both open and endovascular interventions will experience faster more integrated treatment without the need to transfer between Radiology and open theatres.
- The ability to move increasingly towards endovascular procedures from open surgery is associated with improved patient outcomes. The approximate mortality rate for elective endovascular activity is 1.5% compared with approximately 4-5% for open surgery, although these figures are not risk adjusted.

Prompt revascularisation by means of complex procedures i.e. a combination of open and endovascular techniques currently takes significant logistical manoeuvring and this often results in significant delay in getting a definitive revascularisation carried out. By carrying out a combined procedure in a hybrid operating suite this delay will not happen and as a result a patient will have a limb revascularisation carried out sooner and hence reduce the risk of limb loss due to ischaemia.

### **Benefits in Teaching & Learning Opportunities for SBU and Wales**

In the future SBU will be an experienced clinical site for Hybrid technology and has the potential to offer short clinical fellowships. The clinical fellow could be assigned to an experienced team for 3-5 days. During the fellowship the fellow will experience the typical workflow in a Hybrid Theatre, including treatment decisions and surgery guided by an accomplished trainer.

Develop internships within the Health Board - the idea being that a department designates a 'Super User'. They will spend 1 week training with the Hybrid team to gain experience. This has been particularly useful to staff within radiology, cardiology and vascular services. Both of the opportunities above could be offered not just for SBU staff, but for staff across Wales. Tele-medicine has multiple benefits from collaboration, sharing information, second opinions and tele-mentoring all of which are improving surgical practice, education, treatment and post-operative care. Sharing of medical expertise will only improve patient outcomes and in the long run, greatly reduce costs. Please see **Appendix D – Benefits Realisation Register** for details of the main benefits (this will be further detailed at OBC stage).

### **1.17 Main Risks**

The main business and service risks associated with the potential scope across all the options for this project together with their counter measures, are detailed in **Appendix L – Risk Register**. Please refer to **Appendix K – Option & Risk Appraisal Group Membership** for details of the appraisal team members.

### **1.18 Constraints**

The key constraints are as follows:

- The new service model must demonstrate measurable health outcomes for patients requiring complex vascular surgery.
- Ability of SB UHB to recruit and retain sufficient qualified and non-professionally qualified staff.
- The solution must be located on the existing Morriston Hospital site, adjacent to the main theatre nucleus and support services (NB. all the general theatres on the Morriston Hospital site are too small to accommodate a hybrid theatre development – 'standard' theatres are 50m<sup>2</sup> and 'hybrid' theatres require approx. 100m<sup>2</sup> to accommodate mobile C-Arms and imaging equipment and procedures).
- The Health Board does not currently have a decant ward (the technical solutions could disrupt delivery of clinical services within a live 24/7 theatre environment and disrupt service delivery in adjacent wards during structural enabling works).
- The solution must be affordable in capital and revenue terms and be delivered within project budget.

### **1.19 Dependencies**

The success of this project is subject to:

- The availability of capital funding from the Welsh Government, and;
- Buildability of the technical solution, strategic 'fit' with the SDGP and planning permissions.

## 2 The Economic Case

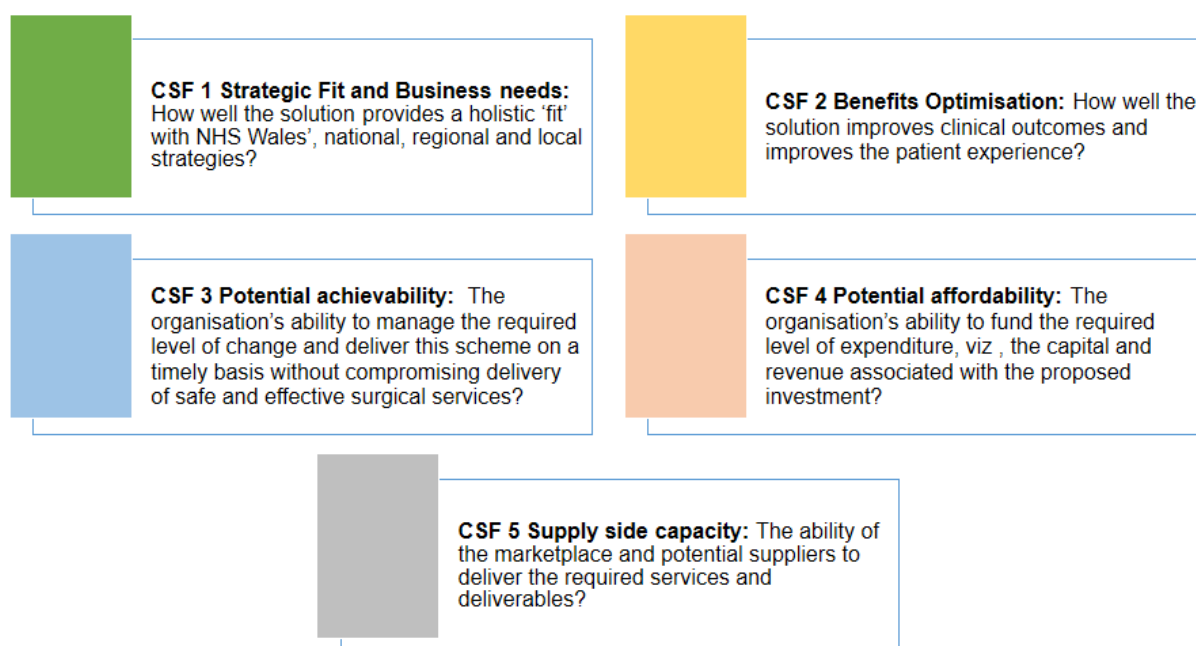
### 2.1 Introduction

In accordance with the Capital Investment Manual and requirements of HMT's *The Green Book: Central Government Guidance on Appraisal and Evaluation* (2018), this section of the business case demonstrates the wide range of options that have been considered in response to the potential scope identified in this SOC.

### 2.2 Critical Success Factors

The Critical Success Factors (CSFs) have been identified to allow evaluation of the potential options. These are shown below:

**Figure 5 – Critical Success Factors (CSFs)**



### 2.3 Methodology

The Appraisal Group identified a range of framework options (as follows) in accordance with Treasury Green Book and Capital Investment Manual. An Options Appraisal Workshop was held on in March 2021. A list of participants is attached in **Appendix K – Option & Risk Appraisal Group Membership**.

- **Potential Service Scope Options** – what is the potential coverage of the service to be delivered (the 'what');
- **Potential Technical Solution Options** – the potential technical (i.e. estates) options for delivering the preferred service solution option (the 'where');
- **Potential Implementation Options** – the potential timescales options for delivering the preferred service scope, preferred service solution, preferred technical solution options (the 'when');
- **Potential Service Delivery Options** – who will deliver the preferred service scope, preferred service solution, preferred technical solution, preferred implementation options (the 'who');
- **Potential Finance Options** – the potential funding and affordability options for delivering the preferred service scope, preferred service solution, preferred technical solution, preferred delivery options.



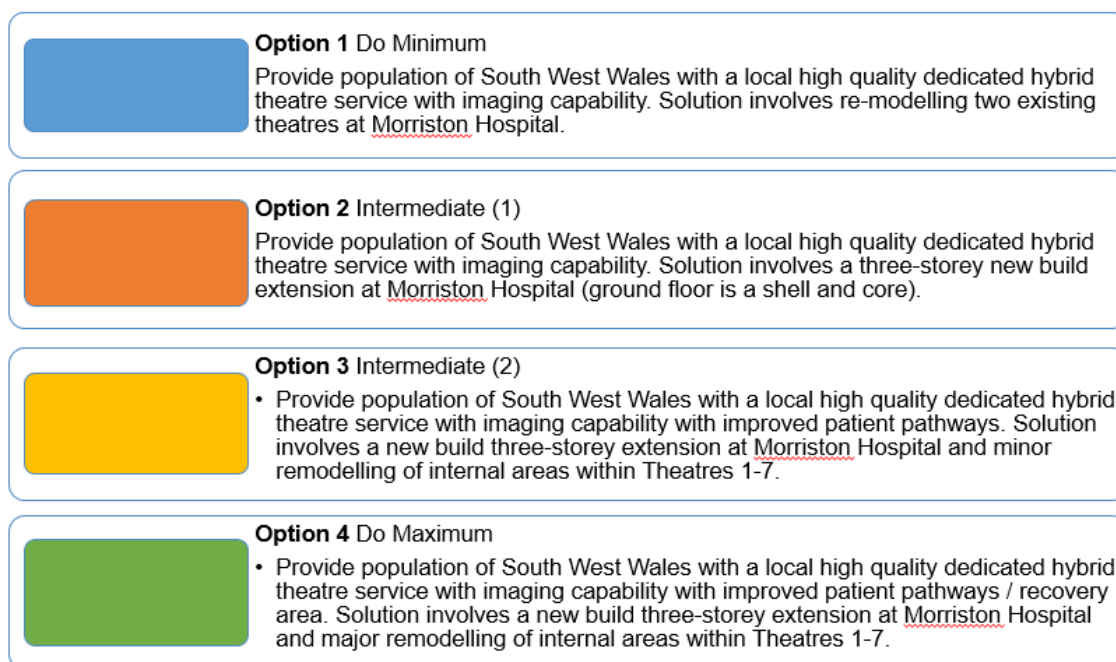
## 2.4 The Long Listed Framework Options

The long list of options was generated using the Scoping Options framework. The sections below summarise the assessment of each scoping option as they were assessed against the Investment Objective and CSF criteria to determine their short list suitability. The framework options findings are summarised in **Appendices H1 – Framework Options** and **H2 – Framework Options Summary**. The possible solutions were carried forward into the short list for further appraisal and evaluation. All the 'discounted' options were excluded at this stage.

## 2.5 Summary of Short List Options

Based on hi-level non-financial analysis the short list is as follows:

**Figure 6 – Short List Options**



The hi-level benefits and dis-benefits per option are summarised below:

Option 1	Option 2	Option 3	Option 4
Remodel two existing theatres to provide with imaging capability	New build extension (shell and core GF) adjacent to main theatres to provide imaging capability	New build extension adjacent to main theatres to provide imaging capability, and improved theatre patient pathways	New build extension adjacent to main theatres to provide imaging capability, and improved theatre patient pathways and improved recovery areas
<p>This solution may involve a decant solution to deliver essential ceiling and floor structural works (this could disrupt of ward(s) sited below the theatres area. Furthermore, noise and vibration from major building works in the two theatres could disrupt delivery of the adjoining Cardiac Theatre.</p> <p><i>Either scenario would incur a significant capital cost and extend the programme. The full extent of any structural works and/or decant requirements will be determined following site investigation.</i></p>	These solutions do not involve a decant solution, mitigating disruption to essential clinical services.		
	These solution involve construction access to the internal courtyard area and access is limited, potentially impacting on neighbouring support/clinical services during crainage over roof levels. This would have to be carefully managed to mitigate disruption.		
This solution reduces Theatre capacity at Morriston Hospital site and the services' ability to cope with other service pressures (full impact cannot be reasonably determined until we are in in post-Covid recovery delivery).	This solution will require additional storage but a shell & core GF in the new build will increase pressure on the Theatres area's existing limited stores.	These solutions provide additional storage in the new build and within the main theatres area, reducing H&S risks; Improve staff & patient flow.	
This solution reduces the number of patients requiring Recovery services.	This solution will increase theatre throughput and demand for Recovery services.		This solution provides additional Recovery space, which will allow theatres to cope with increased throughput, Also provides essential an Isolation Suite within this area, allowing separation of infectious patients

## 2.6 Indicative Capital and Revenue Costs of each Short Listed Option

### Capital Costs

The project's cost advisor, AECOM, has prepared indicative SOC stage capital costs. The indicative capital costs (excluding VAT and Optimism Bias) for each shortlisted option (please see **Appendix E – Cost Forms**) are as follows:

**Figure 7 – Indicative Capital Costs (excl VAT £000s and Optimism Bias above baseline)**

	Option 1 Do Minimum	Option 2 Intermediate(1)	Option 3 Intermediate(2)	Option 4 Do Maximum
Departmental Costs	1,598	3,073	3,564	3,691
On Costs	315	500	488	488
Less Location Adjustment	-57	-107	-121	-125
<b>Works Costs Total</b>	<b>1,856</b>	<b>3,466</b>	<b>3,931</b>	<b>4,054</b>
Fees	552	808	881	900
Non Works Costs	283	324	389	389
Equipment Costs	2,630	2,670	2,968	2,975
Planning Contingency	798	1,090	1,225	1,248
<b>Total</b>	<b>6,119</b>	<b>8,358</b>	<b>9,394</b>	<b>9,566</b>

Option 1 excludes decant costs, which will be confirmed following site surveys and detailed design.

The key assumptions underlying the development of the capital costs are:

- Capital Cost includes works, non-works, abnormals allowances, 'cost not to exceed' equipment costs (a detailed equipment list will be provided at OBC stage) and risk contingency, which is assessed at 15% per developable option, reflective of the buildability risk at this stage.
- VAT is excluded.
- The BIS PUB SEC indices at this stage is 269. The location factor is 97%.
- This SOC excludes a Generic Economic Analysis (GEM) at this stage.

The indicative capital costs (excluding VAT and including Optimism Bias) for each shortlisted option (please see **Appendix G – Optimism Bias Mitigations**) are as follows:

**Figure 8 - Capital Requirements (£000 excl VAT & including Optimism Bias)**

	Option 1 Do Minimum	Option 2 Intermediate(1)	Option 3 Intermediate(2)	Option 4 Do Maximum
Capital Outturn	6,149	8,409	9,452	9,625
OB Adjustment	102	169	198	201
<b>Sub Total</b>	<b>6,251</b>	<b>8,578</b>	<b>9,650</b>	<b>9,826</b>

**Figure 9 – Indicative Works Programme per Option**

	Option 1 Do Minimum	Option 2 Intermediate(1)	Option 3 Intermediate(2)	Option 4 Do Maximum
Start on site	Jan. 2024	Jan. 2024	Jan. 2024	Jan. 2024
Handover	Oct. 2024*	Jan. 2025	Jan. 2025	March 2024
Commissioning	Nov. 2024	Feb. 2025	Feb. 2025	April 2025
Operational	Dec. 2024	March 2024	March 2024	May 2025

\*Excludes decants

### Revenue Costs

The baseline and indicative future revenue cost for each shortlisted option are outlined in the figure below:

**Figure 10 – Revenue cost impact of the Shortlisted Options (£000's)**

	<b>Option 1 Do Minimum</b>	<b>Option 2 Intermediate(1)</b>	<b>Option 3 Intermediate(2)</b>	<b>Option 4 Do Maximum</b>
Pay	0	0	0	0
General Non-Pay	120	120	120	120
Hotel Services	0	0	0	0
Estates	0	0	0	0
LTAs/ Other Commissioned Services	0	0	0	0
<b>Total</b>	<b>120</b>	<b>120</b>	<b>120</b>	<b>120</b>

The revenue costings have been costed at 2021/22 prices.

### 3 The Commercial Case

#### 3.1 Introduction

This section of the SOC outlines the proposed 'deal' as outlined in the Economic Case. The SOC is seeking to secure public funding from the WGov's 'All Wales Capital Programme'.

#### 3.2 Required Services

The required services include enabling works at Morriston Hospital as required, including the supply of essential infrastructure services, development of a compliant Hybrid Surgery Centre, and technical commissioning.

#### 3.3 Key Appointments & Contract Arrangements

The following key appointments will be made via WGov's Building for Wales Framework procurement route to ensure delivery of this project:

- Supply Chain Partner (construction and design team services)
- Health Board Project Manager (HBPM)

The following will be appointed through an appropriate framework procurement route:

- Health Board Cost Advisor (HBCA).

Supervisor and other technical services are to be provided by the Health Board.

#### 3.4 Required Facilities and Compliance

The Hybrid Surgical Theatre will be in compliance with the following Health Building Note/Welsh Health Building Note (HBN/WHBN) & Health Technical Memorandum/Welsh Health Technical Memorandum (HTM/WHTM) - NHS design guidance: HBN 26: Facilities for Surgical Procedures..

The optimum site locations and buildability solution will be assessed in detail at OBC stage – please see **Appendix F1 – Site Drawings** for illustrations of each Options' proposed development area, and **Appendix F2 – Site plan** for a site drawing of Morriston Hospital, illustrating main theatre and adjacent areas.

#### 3.5 Potential for Risk Management

A risk register has been compiled and costed relative to risks that apply over the whole of the project lifecycle at this stage (please see **Appendix L – Risk Register**). The planning contingency has been assessed by an independent cost advisor. The planning contingency includes non-recoverable VAT and excludes OB. This assessment of risk and complies with NHS Wales Shared Services Partnership – Specialist Estates Services (NWSSP - SES) guidance at this planning stage.

#### 3.6 Indicative Timescales

The indicative milestones are set out below (please see **Appendix J – Management Control Plan**):

**Figure 11 – Key indicative milestones**

Activity	Due Date
Health Board approves SOC	Jan. 2022
Submit SOC to WGov for approval	Feb. 2022
WGov approve SOC	April 2022
Health Board approves OBC	April 2023
Submit OBC to WGov for approval	April 2023
WGov approve OBC	June 2023
Health Board approves FBC	Nov. 2023
Submit FBC to WGov for approval	Nov. 2023
WGov approve FBC	Jan. 2024
Mobilise and commence works	Jan. 2024
Completed (subject to contractor's programme)	Jan. 2025
Commissioning	Feb. 2025
New build operational	March 2025
Technical Project Evaluation (approx. 3 months post new build handover)	June 2025
Benefits Realisation (12 months post operational)	April 2026

## 4 Funding and Affordability

### 4.1 Introduction

The purpose of this section is to set out the indicative financial implications of the proposed investment (as set out in the Economic Case) and proposed Deal (as described in the Commercial Case).

### 4.2 Capital

A capital cost assessment of the shortlisted options has been undertaken by AECOM, Cost Advisors based on NHS Departmental Cost Allowances (DCAGs) applied to the proposed schedules of accommodation. The hi-level capital costs of the shortlisted options are as follows (please see **Appendix E – Cost Forms**):

**Figure 12 – Capital Requirements (£000 incl. VAT and excluding Optimism Bias)**

	Option 1 Do Minimum	Option 2 Intermediate(1)	Option 3 Intermediate(2)	Option 4 Do Maximum
Departmental Costs	1,918	3,688	4,276	4,429
On Costs	378	600	585	585
Less Location Adjustment	-68	-128	-145	-150
<b>Works Costs Total</b>	<b>2,228</b>	<b>4,160</b>	<b>4,716</b>	<b>4,864</b>
Fees	663	969	1,057	1,080
Non Works Costs	339	389	467	467
Equipment Costs	3,155	3,204	3,562	3,570
Planning Contingency	957	1,308	1,470	1,497
<b>Total</b>	<b>7,342</b>	<b>10,030</b>	<b>11,272</b>	<b>11,478</b>
Less recoverable VAT	-481	-290	-463	-492
<b>Base Project Cost</b>	<b>6,861</b>	<b>9,740</b>	<b>10,809</b>	<b>10,986</b>

**Figure 13 – Capital Requirements (£000 incl. VAT and including Optimism Bias)**

	Option 1 Do Minimum	Option 2 Intermediate(1)	Option 3 Intermediate(2)	Option 4 Do Maximum
Capital Outturn including OB Adjustment	6,251	8,578	9,650	9,826
Plus VAT	1250	1715	1930	1965
<b>Sub Total</b>	<b>7,501</b>	<b>10,293</b>	<b>11,580</b>	<b>11,791</b>
Less Recoverable VAT	-505	-295	-469	-498
<b>Project Costs (adjusted for OB)</b>	<b>6,996</b>	<b>9,998</b>	<b>11,111</b>	<b>11,293</b>

**NB. Option 1 excludes decant costs, which will be confirmed following site surveys and detailed design.**

The key assumptions underlying the development of the capital costs are:

- Capital Cost includes works, non-works, abnormals allowances, 'cost not to exceed' equipment costs (a detailed equipment list will be provided at OBC stage) and risk contingency, which is assessed at 15% per developable option, reflective of the buildability risk at this stage.
- VAT is at 20% except for the professional fee and other vat recoverable elements.
- The BIS PUB SEC indices at this stage is 269. The location factor is 97%.
- This SOC excludes a Generic Economic Analysis (GEM) at this stage.

### 4.3 Income and Expenditure Analysis

The hi-level revenue analysis is below and details the impact on Income and Expenditure is as follows:

**Figure 14 – Revenue Impact £000's above baseline**

	<b>Option 1 Do Minimum</b>	<b>Option 2 Intermediate(1)</b>	<b>Option 3 Intermediate(2)</b>	<b>Option 4 Do Maximum</b>
Pay	0	0	0	0
General Non-Pay	120	120	120	120
Hotel Services	0	0	0	0
Estates	0	0	0	0
LTAs/ Other Commissioned Services	0	0	0	0
<b>Total</b>	<b>120</b>	<b>120</b>	<b>120</b>	<b>120</b>

The key revenue assumptions are costed at 2021/22 prices.

## 5 The Management Case

### 5.1 Introduction

The section of the SOC addresses the achievability of the project.

### 5.2 Project Management Arrangements

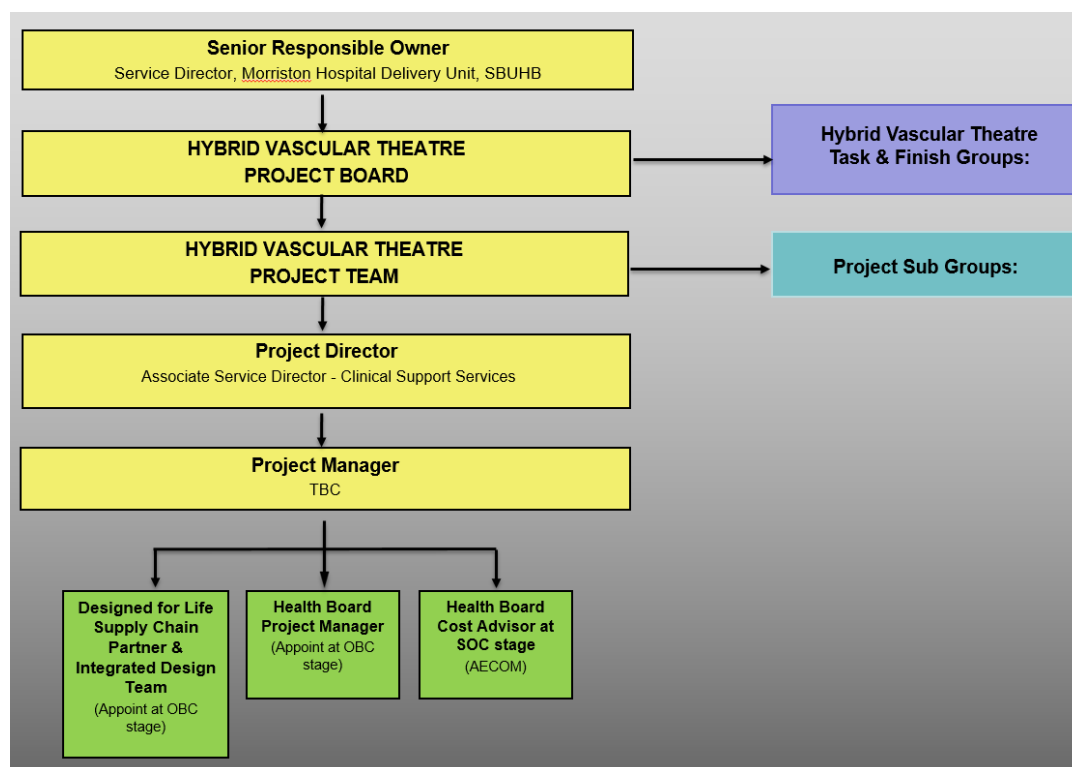
To ensure successful project delivery a robust project management reporting structure has been established. The structure is based on the Prince2 principles, with key members of the project team trained in Prince2 methodology.

The Health Board's experience of developing and delivering complex projects in a Prince2 environment ensures diligent management and thorough clinical involvement throughout all parts of the development:

- The Senior Responsible Owner (SRO) is Ms Kate Hannam, Service Director, Morriston Hospital Delivery Unit, SBUHB.
- The Project Director, (to be confirmed), has the authority and responsibility to manage delivery of the project on behalf of the key stakeholders. The Project Director reports via the Project Board to the SRO.
- The Project Manager, (to be confirmed) will support the Project Director.

The reporting structure is shown below:

**Figure 15 – Reporting Structure**



Please refer to **Appendices A – Hybrid Surgical Project Board Membership & M - Terms of Reference**.

### 5.3 Achieving Excellence Design Evaluation Toolkit (AEDET)

An AEDET assessment will be progressed with NWSSP-SES representatives at OBC stage once design proposals has been detailed.



## 5.4 Decarbonisation Strategy

A Decarbonisation Strategy will be detailed at OBC stage.

## 5.5 Community Benefits Strategy

A Community Benefits Strategy will be detailed at OBC stage.

## 5.6 Arrangements for Benefits Realisation

Please see **Appendices B - Benefits Register Plan and C - Benefits Realisation Register**. These will be detailed at OBC stage.

## 5.7 Arrangements for Risk Management

A risk framework has been established which outlines the process for managing risk associated with developing this project, including a structure for identifying and mitigating operational and construction related risks. The risk register would use qualitative and quantitative measures to calculate the overall level of risk according to likelihood of any risk occurrence multiplied by the potential impact. The Project Board would formally review the risk register at key stages of the project. A project risk register is attached at **Appendix L - Risk Register**.

## 5.8 Post Evaluation Arrangements / Lessons Learned

All projects are subject to evaluation, as appropriate to the investment, in accordance with best practice and NHS guidance.

## 5.9 NHS Wales Gateway Review (Stage 0 – Business Justification)

A Risk Potential Assessments (RPA) has been carried out for this project. A copy is included in **Appendix I - Gateway Review - RPA**. A Gateway '0' review could be arranged WGov would carry out post submission of this SOC and prior to the submission of an OBC in accordance with WGov Investment Guidance. Further Gateways would be completed according to Office of Government Commerce (OGC) guidelines following further evaluation.

## 5.10 Contingency Plans

The Health Board can identify two major category of project failure: failure to achieve business case approval to deliver the project; failure of the main contractor to deliver the new build to time.

The contingency plan for the project in the event of failure to achieve business case approval is for the Health Board to continue to revise its plans, working with WGov to develop a Hybrid Surgical solution for the population of South West Wales that is acceptable.

In the event of Supply Chain failure, SB UHB would seek recompense in line with the agreed contractual arrangements and other contractor to complete the project.

## Appendix A – Hybrid Surgical Theatre Project Board Membership

## Appendix B – The Provision of Services for Patients with Vascular Disease 2015

## Appendix C – Benefits Realisation Plan

## Appendix D – Benefits Realisation Register

## Appendix E – Cost Forms

## Appendix F1 – Site Drawings

## Appendix F2 – Site Plan



## Appendix G – Optimism Bias Mitigations

## Appendix H1 – Framework Options

## Appendix H2 – Framework Options Long List Summary

## Appendix I – Gateway Review - (RPA)

## Appendix J – Management Control Plan

## Appendix K – Option & Risk Appraisal Group Membership

## Appendix L – Risk Register *to follow*

## Appendix M – Terms of Reference



## Appendix N – VAT Letter

## Abbreviations

AEDET	Achieving Excellence Design Evaluation Toolkit	ICU	Intensive Care Unit
ABMU HB	Abertawe Bro Morgannwg University Health Board	IMTP	Integrated Medium Term Plan
AHP	Allied Health Professional	MDT	Multi-Disciplinary Team
AME	Annually Managed Expenditure	NCRBs	Non Cash Releasing Benefits
ARCH	A Regional Collaboration for Health	NEC	New Engineering Contract
BAU	Business as Usual	NICE	The National Institute for Health and Care Excellence
BIS PUBSEC	Business Innovation and Skills (Firm Price Index) Tender Price Index of Public Sector Building Non-Housing	NWSSP SES	NHS Wales Shared Services Partnership – Specialist Estates Services
BREEAM	Building Research Establishment Environmental Assessment	OBC	Outline Business Case
BRP	Benefits Realisation Plan	OCP	Organisational Change Policy
CRBs	Cash Releasing Benefits	OGC	Office of Government Commerce
CRUK	The Cancer Research UK's	OOHs	Out of Hours
CSF	Critical Success Factor	PDP	Portfolio Delivery Plan (ARCH)
CSP	(SB UHB's) Clinical Service Plan	PEP	Project Execution Plan
CSS	Clinical Support Services	PET	Positron Emission Tomography
CT	Computed Tomography	PIA	Privacy Impact Assessment
CVU HB	Cardiff and Vale University Health Board	PPE	Post Project Evaluation
DECAG	Departmental Cost Allowance Guide	QA	Quality Assurance
DCC	Direct Clinical Care	RIBA	Royal Institute of British Architects
DGH	District General Hospital	RPA	Risk Potential Assessment
DGM	Divisional General Manager	RTT	Right to Treatment
DoH	Department of Health	SB UHB	Swansea Bay University Health Board
ECAG	Equipment Cost Allowance Guide	SDCP	Site Development Control Plan
EQA	External Quality Assessment	SOC	Strategic Outline Business Case
FBC	Full Business Case	SOP	Standard Operating Procedure
GEM	Generic Economic Model	TAT	Turn Around Time
HB	Health Board	VATS	Video-assisted thoracoscopic surgery
HBCA	Health Board Cost Adviser	VfM	Value for Money
HBPM	Health Board Project Manager	WAST	Welsh Ambulance Service NHS Trust
HCSE	Health Care Systems Engineering	WGov	Welsh Government
HDU	High Dependency Unit	(W)HBN	Welsh Health Building Note
HDUHB	Hywel Dda University Health Board	WHSSC	Welsh Health Specialised Services Committee
HIA	Health Impact Assessment	(W)HTM	Welsh Health Technical Memorandum
HMT	Her Majesty's Treasury	WTE	Whole Time Equivalent