



**CYFARFOD BWRDD PRIFYSGOL IECHYD  
UNIVERSITY HEALTH BOARD MEETING**

<b>DYDDIAD Y CYFARFOD: DATE OF MEETING:</b>	29 July 2021
<b>TEITL YR ADRODDIAD: TITLE OF REPORT:</b>	Chief Executive's Report
<b>CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:</b>	Steve Moore, Chief Executive
<b>SWYDDOG ADRODD: REPORTING OFFICER:</b>	Sian-Marie James, Assistant Director of Corporate Legal Services & Public Affairs

**Pwrpas yr Adroddiad (dewiswch fel yn addas)**

**Purpose of the Report (select as appropriate)**

Ar Gyfer Penderfyniad/For Decision

**ADRODDIAD SCAA  
SBAR REPORT**

**Sefyllfa / Situation**

The purpose of this report is to:

- Update the Board on relevant matters undertaken as Chief Executive of Hywel Dda University Health Board (the UHB) since the Board meeting held on 27<sup>th</sup> May 2021; and
- Provide an overview of the current key issues, both at a local and national level, within NHS Wales.

**Cefndir / Background**

This report provides the opportunity to present items to the Board to demonstrate areas of work that are being progressed and achievements that are being made, which may not be subject to prior consideration by a Committee of the Board, or may not be directly reported to the Board through Board reports.

**Asesiad / Assessment**

**(1) Register of Sealings**

The UHB's Common Seal has been applied to legal documents and a record of the sealing of these documents has been entered into the Register kept for this purpose. The entries at **Appendix A** have been signed by the Chair and Chief Executive or the Deputy Chief Executive (in the absence of the Chief Executive) on behalf of the Board (Section 8 of the UHB's Standing Orders refers).

**(2) Consultations**

The UHB receives consultation documents from a number of external organisations. It is important that the UHB considers the impact of the proposals contained within these consultations against its own strategic plans, and ensures that an appropriate corporate response is provided to highlight any issues, which could potentially impact upon the

organisation. A status report for Consultation Documents received and responded to is detailed at **Appendix B**, should any Board Member wish to contribute.

### **(3) Strategic and Operational Issues**

#### Transformation Steering Group (TSG)

On 23<sup>rd</sup> June 2021, the TSG met under its revised remit. The main item on the meeting centred on Planning Objective 4N: *Create and implement a process in partnership with local authorities, PSBs and other stakeholders that engages and involves representatives of every aspect of the food system. This will include growers, producers, distributors, sellers, those involved in preparation and the provision of advice to individuals & organisations and thought leaders in this field. The aim is to identify opportunities to optimise the food system as a key determinant of wellbeing. The opportunities identified will then need to be developed into proposed planning objectives for the Board and local partners for implementation from April 2023 at the latest, with Dr Phil Kloer as the Executive Lead.*

The item looked at the concept of the interlinkages between nature, food (and its production) and wellbeing in Wales. Although in its early stages, the UHB is looking to learn the lessons from such a collaboration, and is exploring how we continue to develop our involvement.

#### Strategic Enabling Group (SEG)

The SEG relaunch is planned for 28<sup>th</sup> July 2021 and, in the meantime, it is continuing its current workplan. In particular, the Improving Together work has gained pace following the Board Seminar workshops on outcome measurement. This work, alongside development of the revised Integrated Performance Report and Board Assurance Framework, is expected to come back to Board in the Autumn.

Work on our Value Based Health and Care approach has also developed, with the latest education programme being completed in the week commencing 5<sup>th</sup> July 2021. Systematic outcomes measurement is now being undertaken across Heart Failure; Trauma and Orthopaedics (hips, knees, shoulders and elbows); Ophthalmology (Age-related Macular Degeneration (AMD)); Lung cancer; and Lymphedema. This rapid progress has been noted nationally.

Work on community wealth-building and social value has also progressed. The Board has already been sighted on the Local Needs Analysis, and the principles are being incorporated into our approach on procurement. It is pleasing to note the positive support of one of our suppliers in particular, Castell Howell Foods, who are working with us to develop their own offering.

#### Urgent and Emergency Care Programme of Improvement

In July 2020, the former Minister for Health and Social Services announced a redesign of urgent and emergency care, with a focus on 'Contact First' and the emerging Welsh Access Model. Two key features of this model are:

- **Physician Triage, Assessment and Streaming (PTAS):** the UHB will recruit PTAS Physicians to its Bank workforce who will undertake physician triage, assessment and streaming of calls made to the Welsh Ambulance Services NHS Trust (WAST) Clinical Stack. These physicians will be medical doctors registered on the General Medical Council's Full, Specialist, or GP Register, and will undertake a remote clinical assessment of patients who have requested an ambulance to hospital.

Working with the WAST multi-disciplinary team, these physicians will determine whether sending an ambulance can be avoided. The PTAS physician will provide additional clinical triage and consultation, advice and support to patients to ensure that they can access the most clinically appropriate care for their urgent and emergency healthcare needs.

- Think '111 First': this system allows patients to book appointments for care that is urgent but not life threatening; it would be clinically staffed and patients would be streamed to specialities and services after a telephone triage. This will be through the 111 telephone line for our residents.

The UHB is working closely with WAST developing two Memoranda of Understanding (MoU) for each model to formalise the arrangements between the two NHS bodies, with a view to implementing the models towards the end of summer 2021. The MoU for the PTAS programme is more advanced and is attached at **Appendix C** for approval. The MoU for the 111 First will be presented to Board at a future meeting for approval.

The PTAS MoU (**Appendix C**) sets out the principles for collaboration and both corporate and clinical governance of the programme between the UHB and WAST and is supported by a more technical Standard Operating Procedure. The MoU will commence on the date it is signed and can be terminated by either party by giving 90 days' notice.

This work is being progressed as part of Planning Objective 5J, led by the Director or Primary Care, Community and Long Term Care and, as mentioned in the Recovery Plan update paper later on this agenda; a comprehensive progress report will be provided to Board in September 2021.

#### Update on the Joint Executive Team Meeting

Pre-COVID-19, members of the Executive Team and I met bi-annually with the Chief Executive NHS Wales and members of his senior team as a Joint Executive Team (JET). These meetings have resumed by Teams virtually, with the most recent meeting held on 7<sup>th</sup> July 2021. This was a positive meeting that started with an overview of the last year followed by an update on the UHB's performance during 2020/21, the key challenges ahead, our plans for 2021/22, and finally how we are planning to reset and recover our health system going forward.

As always, I was pleased with the level of discussion at the meeting and my team valued the opportunity to discuss progress and challenges on their areas of responsibility and appreciated the feedback from the Health & Social Services Group's Executive Team. The meeting allowed the UHB to demonstrate how it was learning lessons from the last unprecedented year to ensure its future was even stronger. Our aim as an Executive Team is to have a Three Year Plan and to return to routine monitoring.

The Chief Executive NHS Wales reiterated his thanks to all the UHB's staff for their unstinting commitment during the pandemic. There is confidence that the UHB will deliver its strategic plan and its recovery programme and it must ensure that it converts into a post pandemic organisation that has resilience but can still deliver Public Health within its resources.

#### **(4) National Issues**

##### All Wales Position Emission Tomography Programme Business Case

On 18<sup>th</sup> May 2021, the NHS Wales Health Collaborative Chief Executive Group (CEG) confirmed their support for the All Wales Positron Emission Tomography (PET) Programme Business Case (PBC) (attached at **Appendix D**), which has been submitted to Welsh Government.

In March 2019, the Chief Executive NHS Wales mandated the Welsh Health Specialised Services Committee (WHSSC) to host the PET Programme Board, following publication of key strategic reports on both PET and the wider imaging provision in Wales. WHSSC has adopted the HM Treasury Green Book methodology and extensive engagement to develop the All Wales PET PBC.

The preferred way forward seeks to have four Projects that will, over the course of five years, update the existing fixed facility at Cardiff, replace mobile scanners with fixed scanners at the Swansea and North Wales sites and at a fourth location (to be defined). The PBC is primarily a capital funding request business case (£24.881m) and has focused on the supporting infrastructure for PET-CT service delivery over the next ten years, ensuring deliverability and sustainability is at the heart of the overall strategic approach.

There has been wide engagement on the Programme and there is representation from each Health Board and Velindre NHS Trust on the PET Programme Board, in addition to regular updates at the National Imaging Strategic Programme Board (NIPSB). There will be no fundamental change to any referral pathways and the revenue costs required to fund the increase in PET scanning capacity in the future, set out in the business case, will be funded by the commissioning health boards through the usual Integrated Commissioning Plan process.

I am inviting Board Members to support this Programme and all Health Boards will be issuing a letter of support to accompany the PBC submission to Welsh Government.

##### Adoption of Service Specification for Hepato-Pancreato-Biliary (HPB) Surgery

The NHS Wales Health Collaborative Chief Executive Group (CEG) also commissioned the Wales Cancer Network to develop a model service specification to inform the future commissioning of HPB surgery, partly in response to a letter from the Deputy Chief Medical Officer, Welsh Government, who sought advice on the potential to bring the pancreatic and liver surgical teams together into one service, on one site. In the same May 2021 CEG meeting, the service specification was approved in principle.

The service specification is clear that there needs to be closer integration between the two services, and as agreed at the meeting I have written to the Chief Executives of Cardiff and Vale UHB and Swansea Bay UHB, to request that they establish an inter-organisation multidisciplinary task and finish group, to make recommendations on an appropriate service model, which complies with the model service specification.

CEG also agreed to formally request that WHSSC take on the commissioning of HPB Surgery, and the Hepato Cellular Carcinoma (HCC) Multi-Disciplinary Team, as a delegated responsibility. The UHB is considering what arrangements it is putting in place to formally adopt the service specification.

## Argymhelliad / Recommendation

The Board is invited to:

- **Endorse** the Register of Sealings (**Appendix A**) since the previous report on 27<sup>th</sup> May 2021;
- **Note** the status report for Consultation Documents (**Appendix B**) received/responded to;
- **Approve** the Memorandum of Understanding for the Physician Triage, Assessment and Streaming programme (**Appendix C**); and
- **Support** the Positron Emission Tomography (PET) Programme Business Case (**Appendix D**) to allow the Chief Executive to send a letter of support to WHSSC for submission to Welsh Government.

### Amcanion: (rhaid cwblhau)

#### Objectives: (must be completed)

Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol: Datix Risk Register Reference and Score:	Not Applicable
Safon(au) Gofal ac Iechyd: Health and Care Standard(s): <a href="#">Hyperlink to NHS Wales Health &amp; Care Standards</a>	All Health & Care Standards Apply
Amcanion Strategol y BIP: UHB Strategic Objectives: <a href="#">Hyperlink to HDdUHB Strategic Objectives</a>	All Strategic Objectives are applicable
Amcanion Llesiant BIP: UHB Well-being Objectives: <a href="#">Hyperlink to HDdUHB Well-being Statement</a>	Improve efficiency and quality of services through collaboration with people, communities and partners Develop a sustainable skilled workforce Support people to live active, happy and healthy lives

### Gwybodaeth Ychwanegol:

#### Further Information:

Ar sail tystiolaeth: Evidence Base:	Chief Executive's meetings (internal, external and NHS Wales wide), diary and correspondence
Rhestr Termiau: Glossary of Terms:	Included within the body of the report
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol: Parties / Committees consulted prior to University Health Board:	Not Applicable

### Effaith: (rhaid cwblhau)

#### Impact: (must be completed)

Ariannol / Gwerth am Arian: Financial / Service:	Any issues are identified in the report.
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<b>Ansawdd / Gofal Claf: Quality / Patient Care:</b>	Any issues are identified in the report.
<b>Gweithlu: Workforce:</b>	Any issues are identified in the report.
<b>Risg: Risk:</b>	<p>This report provides evidence of current key issues at both a local and national level, which reflect national and local objectives and development of the partnership agenda at national, regional and local levels.</p> <p>Ensuing that the Board is sighted on key areas of its business, and on national strategic priorities and issues, is essential to assurance processes and related risks.</p>
<b>Cyfreithiol: Legal:</b>	Any issues are identified in the report.
<b>Enw Da: Reputational:</b>	Any issues are identified in the report.
<b>Gyfrinachedd: Privacy:</b>	Not Applicable
<b>Cydraddoldeb: Equality:</b>	<ul style="list-style-type: none"> <li>• Has EqIA screening been undertaken? Not on the Report</li> <li>• Has a full EqIA been undertaken? Not on the Report</li> </ul>

**Appendix A: Register of Sealings from 11<sup>th</sup> May 2021 – 12<sup>th</sup> July**

<b>Entry Number</b>	<b>Details</b>	<b>Date of Sealing</b>
319	Lease Relating to Unit 1 and First Floor Office at Dura Business Park, Bynea Llanelli Between Tower Pension Trustees Limited as Trustee of the Curtis Banks Full SIPP for the benefit of Mr Nigel Vernon Short and Hywel Dda University Local Health Board	25.05.21
320	Lease Relating to Dental Accommodation at Cardigan Integrated Care Centre, Bath House Road, Cardigan SA43 1JD Between Hywel Dda University Local Health Board and Gower Healthcare Dental Limited	10.06.21
321	Licence for Alterations Relating to Dental Accommodation at Cardigan Integrated Care Centre, Bath House Road, Cardigan SA43 1JD Between Hywel Dda University Local Health Board and Gower Healthcare Dental Limited	10.06.21

Appendix B: Consultations Update Status Report up to 15<sup>th</sup> July 2021

Ref No	Name of Consultation (hyperlink included for online consultations)	Consulting Organisation	Consultation Lead	Received On	CLOSING DATE	Response Sent
460	<a href="#">Arthritis and long-term musculoskeletal conditions in adults</a>	Welsh Government	Dr Phil Kloer, Lisa Davies, Owain Ennis, Keith Jones, Stephanie Hire	24.03.2021	30.07.2021	
461	WHSSC: Stereotactic Ablative Body Radiotherapy (SABR) - Service Specification (CP219)	Welsh Health Specialised Services Committee	Dr Phil Kloer, Mark Henwood, Dr Alison Brewster, Jegadish Mathias, Debra Bennett, Lisa Humphrey, Gina Beard	31.03.2021	05.05.2021	04.05.2021
462	<a href="http://www.gov.uk">Protect Duty - GOV.UK (www.gov.uk)</a>	UK Government	Mandy Rayani, Andrew Carruthers, Phil Lloyd, Sam Hussell	12.04.2021	02.07.2021	04.06.2021
463	WHSSC consultation: Positron Emission Tomography (PET)	Welsh Health Specialised Services Committee	Dr Phil Kloer, Mark Henwood, Jegadish Mathias, Debra Bennett, Lisa Humphrey	13.04.2021	11.05.2021	Response not required as advised by Cancer Services Team
464	Possible WHSSC- CAR T cell therapy	Welsh Health Specialised Services Committee	Dr Phil Kloer, Mark Henwood, Jegadish Mathias, Debra Bennett	14.04.2021	11.05.2021	Response not required as advised by Cancer Services Team
465	<a href="#">Race Equality Action Plan: An Anti-racist Wales</a>	Welsh Government	Ros Jervis, Anna Bird, Helen Sullivan, Jo Wilson, Alison Gittins,	30.04.2021	15.07.2021	14.07.2021

**Appendix B: Consultations Update Status Report up to 15<sup>th</sup> July 2021**

Ref No	Name of Consultation (hyperlink included for online consultations)	Consulting Organisation	Consultation Lead	Received On	CLOSING DATE	Response Sent
			Lisa Gostling, Annmarie Thomas			

**DATED**

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**MEMORANDUM OF UNDERSTANDING**

relating to the delivery of **Physician Triage Assessment and Streaming**.

between

**HYWEL DDA UNIVERSITY LOCAL HEALTH BOARD**

and

**WELSH AMBULANCE SERVICES NATIONAL HEALTH SERVICE TRUST**

**THIS AGREEMENT** is dated

## **PARTIES**

- (1) **HYWEL DDA UNIVERSITY LOCAL HEALTH BOARD (HDUHB)** of Corporate Offices, Ystwyth Building, Hafan Derwen, St Davids Park, Jobswell Road, Carmarthen SA31 3BB
- (2) **WELSH AMBULANCE SERVICES NATIONAL HEALTH SERVICE TRUST** of Trust Headquarters, Ty Elwyn, Unit 7, Ffordd Richard Davies, St. Asaph Business Park, St Asaph, Denbighshire, Wales, LL17 0LJ (**WAST**).

## **1. BACKGROUND**

- 1.1 HDUHB and WAST have agreed to work together on the Operational Model detailed in Annex A (Operational Model).
- 1.2 The parties wish to record the basis on which they will collaborate with each other on the Project. This Memorandum of Understanding (**MoU**) sets out:
  - (a) the key objectives of the Operational Model;
  - (b) the principles of collaboration;
  - (c) the governance structures the parties will put in place; and
  - (d) the respective roles and responsibilities the parties will have during the Project.

## **2. KEY OBJECTIVES FOR THE OPERATIONAL MODEL**

- 2.1 The parties shall undertake the Operational Model to achieve the key objectives set out in Annex A to this MoU (**Key Objectives**).

## **3. PRINCIPLES OF COLLABORATION**

The parties agree to adopt the following principles when carrying out the Project (**Principles**):

- (a) collaborate and co-operate. Establish and adhere to the governance structure set out in this MoU and read in conjunction with the Physician Triage Assessment and Streaming (PTAS) standard operating procedure to ensure that activities are delivered and actions taken as required;
- (b) be accountable. Take on, manage and account to each other for performance of the respective roles and responsibilities set out in this MoU;
- (c) be open. Communicate openly about major concerns, issues or opportunities relating to the Project;

- (d) learn, develop and seek to achieve full potential. Share information, experience, materials and skills to learn from each other and develop effective working practices, work collaboratively to identify solutions, eliminate duplication of effort, mitigate risk and reduce cost;
- (e) adhere to appropriate and NHS statutory requirements and best practice as defined in the SOP. Comply with applicable laws and standards including applicable procurement rules, data protection and freedom of information legislation;
- (f) act in a timely manner. Recognise the time-critical nature of the Project and respond accordingly to requests for support.

#### **4. GOVERNANCE**

##### **4.1 Overview**

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

##### **4.2 Guiding principles**

The following guiding principles are agreed:

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

##### **4.3 Hywel Dda University Local Health Board Patient Triage Assessment and Streaming Board.**

- (a) The PTAS Board will provide overall strategic oversight and direction to the Operational Model, and will consist of representatives from both HDUHB and WAST.

- (b) The PTAS Board will provide strategic management at workstream level and shall have shared responsibility for the creation and execution of the plan and deliverables, and therefore it can draw technical, clinical and communications resources as appropriate from each respective representative.
- (c) The PTAS Board shall meet regularly to review and assure the following areas of shared responsibility:
  - Operational updates;
  - Governance report;
  - Regular Clinical Performance Indicators (CPI) and Key Performance Indicators (KPI) updates; and
  - Regular updates on any concerns, complaints, compliments, investigations and adverse incidents.

#### 4.4 **Clinical Governance**

- (a) All HDUHB and WAST employees contributing to the Operational Model agree to be bound by and comply with the Clinical Governance reporting and requirements established by each organisation that are applicable to the role they undertake.
- (b) Both organisations will adhere to existing internal procedures, policies, and clinical guidelines appropriate to the tasks undertaken.
- (c) Both organisations will adhere to all guidance given in relation to adverse incident reporting, safeguarding and Health and Safety aspects as stipulated by both parties' requirements.

#### 4.5 **Training**

- (a) All PTAS physicians must ensure that they work only within their scope of practice as set out within the standards of their professional body (GMC, HCPC, NMC).
- (b) PTAS staff will only be suitable and appropriate to work for the PTAS service if HDUHB consider they have significant experience in telephone/remote assessment and maintain a level of clinical competency congruent with this type of practice (regular out of hours triage, for example).
- (c) The PTAS service may not be used as a formalised mentorship or training period for any junior member of clinical staff; even under the direct supervision of a competent physician. Informal shadowing may be explored on a case by case basis – subject to data sharing agreements. Mentorship of PTAS suitable physicians as part of PTAS related work is appropriate (such as new PTAS staff induction / training).

- (d) The PTAS service may not be used as an alternative duty for a physician subject to restrictions upon their clinical practice.
- (e) WAST is responsible for providing system based training to PTAS clinicians. This may include C3 remote worker, Toxbase, Directory of Service use, and Clinical Response Model familiarisation.

#### 4.6 **Documentation**

- (a) It is the responsibility of the PTAS physicians to ensure that their clinical documentation (of assessment, rationale, advice, and outcome) is of sufficient quality. This documentation should be consistent with expectations set out by both the GMC and the RCGP Urgent and Emergency Care Clinical Audit Toolkit.
- (b) Documentation should be consistent with the requirements set out within the PTAS Standard Operating Procedures (SOP) also. WAST is not responsible for any documentation added to or stored on external databased used by HDUHB (Examples include Aadastra or Emis).
- (c) PTAS physicians must comply with the All Wales Safeguarding Adult and Children reporting / referring procedures. If unsure about such procedures, advice must be sought from a clinical contact centre clinician, health board clinical lead, or duty control manager.

#### 4.7 **Audit**

- (a) It remains the responsibility of HDUHB and individual PTAS physicians themselves to ensure that they regularly undertake and receive random clinical call audits. To do so, it is imperative that HDUHB ensures that robust call recording technology is utilised during the delivery of the PTAS service. Where the call has occurred within an agreed WAST site and telephony location, WAST will cooperate in providing call recordings for random clinical call audits.
- (b) The PTAS physician will comply with the RCGP Urgent and Emergency Care Clinical Audit Toolkit, and the results of these audits will be shared with the PTAS Board. .

### 5. **ACCOUNTABILITY AND RESPONSIBILITY FOR PATIENTS**

- 5.1. WAST will remain responsible for each patient who presents to the 999 service until the point, either before or following secondary telephone assessment by the remote physician.
- 5.2 Following secondary telephone assessment, where the PTAS physician decides to delay or downgrade an ambulance response, and an adverse incident occurs or claim is received, the accountability and responsibility will be determined on the individual facts of each case, as to where liability rests.

- 5.3 If following secondary telephone assessment, the PTAS physician decides to upgrade the patient's disposition and that an ambulance response is still required, responsibility remains with WAST.
- 5.4 If following secondary telephone assessment, the PTAS physician decides that that no ambulance response is required, and/or an alternative end disposition has been achieved, and the case is closed from the C3 incident stack, the responsibility for the patient passes to HDUHB.

## 6. CONCERNS, COMPLAINTS AND COMPLIMENTS

- (a) Both parties are a '*Welsh NHS body*' as defined pursuant to the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ('the Regulations'), the provisions of which are applicable to all Health Boards, Trusts, independent providers in Wales providing NHS funded care and primary care practitioners in Wales.
- (b) The term 'concern' is used to define any complaint, claim or reported patient safety incident. Almost anyone can raise a concern and a Responsible Body is under a duty to consider whether it can be investigated.
- (c) A concern can be raised about any service, decision and/or care and treatment provided by a Responsible Body in Wales (unless excluded under Regulation 14).
- (d) Each party will be responsible for the investigation and handling of any concerns or complaints arising from the actions of, or advice given by, their respective staff.
- (e) If such complaints or concerns regarding the other party are received then each party undertakes to pass them on to the other party immediately upon receipt and in any event within 1 working day to enable the relevant party to provide its acknowledgement within 2 working days of its receipt.
- (f) Each party agrees to support these investigations by providing relevant incident details, statements from attending clinical staff, or other information as may be deemed necessary at the time for the purpose of that investigation.
- (g) Concerns received by either party involving the other may fall under Regulation 17, being concerns that involve or may involve more than one Responsible Body.
- (h) In such cases, upon receipt of a Concern, a determination should be made following consultation between the parties as to which party should be the agreed lead Responsible Body.

The agreed Lead Responsible Body will:

- Act as the lead in co-ordinating and investigating the concern in accordance with the Regulations
- Communicate with the person who raised the concerns and keep them updated
- Prepare and agree a joint response as the lead Responsible Body
- Agree the sharing of information relevant to the concern (subject to consent)
- Agree appropriate representation of both Responsible Bodies at any relevant meetings

Both parties agree to:

- Co-operate fully in relation to the investigation
- Provide all relevant documentation and statements within the timescales indicated in each concern
- Agree the draft response
- Attend any relevant meetings in connection with the concern
- Ensure compliance with the provisions of the Regulations

## **7. ESCALATION**

- 7.1 If either party has any issues, concerns or complaints about the Operating Model, or any matter in this MoU, that party shall notify the other party and the parties shall then seek to resolve the issue by a process of consultation as part of the PTAS Board.
- 7.2 If either party receives any formal inquiry, complaint, claim or threat of action from a third party (including, but not limited to, claims made by a supplier or requests for information made under the Freedom of Information Act 2000) in relation to the Operating Model, the matter shall be promptly referred to the PTAS Board (or its nominated representatives). No action shall be taken in response to any such inquiry, complaint, claim or action, to the extent that such response would adversely affect the Project, without the prior joint approval of the PTAS Board (or its nominated representatives).

## **8. INTELLECTUAL PROPERTY**

- 8.1 The parties intend that any intellectual property rights created in the course of the Operating Model shall vest in the party whose employee created them (or in the case of any intellectual property rights created jointly by employees of both parties in the party that is lead for the part of the project that the intellectual property right relates to).

**9. TERM AND TERMINATION**

9.1 This MoU shall commence on the date of signature by both parties and shall expire at any time following ninety days prior written notice from either party to the other.

9.2 Both parties reserve the right to cease providing support for the PTAS service at any point; however, professional communication and courtesy is expected in relation to the provision of sufficient notice, and reasoning. Any communication relating to the cessation of support should comply with section 9 of this agreement.

**10. FREEDOM OF INFORMATION**

(a) Both parties are subject to the requirements of the Freedom of Information Act 2000 (FoI) and may be legally required under this Act to release information which relates to, or includes reference to each other in relation to this MoU.

(b) In the event such a circumstance arises in respect of such a request received by either party, in accordance with its procedures for releasing information under the FoI, each party will notify the other setting out:

- What details about them the requested information includes; and
- Any exemptions that potentially apply will be explained.

The relevant party will be invited to reply with any comments or concerns about the release of this information but it remains the responsibility of the receiving party to determine whether it is required under the Act to release the information. The other party will be advised of the final decision where any concerns have been raised.

**11. CONFIDENTIALITY AND SECURITY OF INFORMATION**

(a) Each of the parties of this MoU hereby indicates its intention to keep the terms of the MoU and any related documentation confidential, and will take all necessary action to ensure that all persons associated with the MoU, whether employees, agents or consultants, likewise keep confidential any information regarding the provisions of this MoU or either of the parties to this MoU.

(b) Each party also agrees that any information received for the purpose of the project is only to be used for the purpose for which it is provided and will ensure that it is not used for any other purpose and is only accessible to those who need access to it for that purpose.

(c) All agencies involved with the delivery of PTAS services agree to sign a Data Processing Impact Assessment (DPIA).

- (d) The DPIA has been written in accordance with the national principles contained within the Wales Accord on the Sharing of Personal Information (WASPI).
- (e) This DPIA intends to help partner organisations understand what data can be disclosed. It also assures that the partners have considered the requirements of data protection legislation.
- (f) All PTAS physicians are to maintain normal patient and information confidentiality expected from both current legislation and the expectations of their professional bodies.
- (g) Any adverse incidents involving breaches in data protection should be reported immediately using the Datix system and should confirm to the process outlined within the next section.

**12. INDEMNITY PROVISIONS AND MANAGEMENT OF LEGAL AND REDRESS CLAIMS**

- (a) Both parties are Health Bodies in NHS Wales and as such are members of the NHS Wales Risk Pooling Scheme, and consequently NHS Indemnity covers any negligent acts or omissions of individuals engaged to undertake the activities under this agreement.
- (b) Each party will co-operate with the other in relation to any concerns, complaints or legal claims which arise out of or from the Project and this MOU
- (c) Claims or Redress matters received in relation to the activities under this agreement will be investigated collaboratively.
- (d) Redress matters will be investigated and managed in accordance with the process adopted by each party having regard to the outcome of the concerns investigation under under paragraph 6 above.
- (e) Each party will refer any indemnity issue or legal claims to Legal & Risk Services and Welsh Risk Pool Services as appropriate and required under the current Legal & Risk Services Referral Protocol and/or Welsh Risk Pool Reimbursement Procedures.
- (f) Each party will manage any request for records by way of Subject Access Request or under the Access to Health Records Act received by it and notify the other party of the request.

- (g) In the event of the receipt of a Pre-Letter of Claim or a Letter of Claim, or any of the events which would trigger a referral to Legal & Risk Services under their referral protocol, each party will instruct Legal & Risk Services requesting that a single solicitor be instructed to act for both parties (assuming that there is no conflict of interests or any such conflict can be resolved).
- (h) Neither party will make any admissions (in respect of facts, breach of duty or causation) on the part of the other nor agree to pay any compensation on the part of the other, save unless this has been expressly agreed in writing in advance of the making of any such admission
- (i) Each party will indemnify each other in respect of damages and legal costs and disbursements on the conclusion of a claim in such proportions as may be agreed between the parties and in default of agreement to be determined by mediation undertaken by NHS Wales Legal & Risk Services.

### **13. VARIATION**

This MoU, including the Annexes, may only be varied by written agreement of the PTAS Board and both parties.

### **14. CHARGES AND LIABILITIES**

- 14.1 Except as otherwise provided, the parties shall each bear their own costs and expenses incurred in complying with their obligations under this MoU.
- 14.2 Both parties shall remain liable for any losses or liabilities incurred due to their own or their employee's actions and neither party intends that the other party shall be liable for any loss it suffers as a result of this MoU.

### **15. STATUS**

- 15.1 This MoU constitutes an NHS Contract under section 7 of the National Health Service (Wales) Act 2006. As such, it does not give rise to contractual rights or liabilities and is not intended to be enforceable through the courts.
- 15.2 Nothing in this MoU is intended to, or shall be deemed to, establish any partnership or joint venture between the parties, constitute either party as the agent of the other party, nor authorise either of the parties to make or enter into any commitments for or on behalf of the other party.
- 15.3 This MOU should be reviewed by key stakeholders (or their replacement/deputies) from each agency and shared with respective legal services yearly. If any changes are made to the MOU, the above review should take place before the annual review date; which may be restarted.

**16. COMMUNICATION**

- 16.1 Any communication relating to PTAS, for example, including but not limited to, social media, press releases, and/or reports to commissioners/or government agencies, needs a prior agreement between both parties before release.
- 16.2 Should an out-of-hours press request be received from either agency (perhaps in response to an adverse incident, coronial case, or in response to a report being published); both agencies on-call communications and press office should agree on a joint response before any communication is release.
- 16.3 Any academic publication resulting from work undertaken as part of PTAS and or service evaluations needs a prior agreement between both agencies before the peer review process and before any final draft is accepted. Such work is encouraged.

**17. DISPUTE RESOLUTION**

- 17.1 In the case of a Dispute arising out of or in connection with this MoU the parties shall make every reasonable effort to communicate and cooperate with each other with a view to resolving the Dispute as the first stage in the Dispute Resolution Procedure.
- 17.2 If any Dispute arises out of the MoU, either party may serve a notice on the other party to commence formal resolution of the Dispute. The parties shall first seek to resolve the Dispute by escalation to the respective Chief Executives.
- 17.3 If the procedure set out in Clause 17.2above has been exhausted and fails to resolve such Dispute, the Dispute shall be referred to the Welsh Ministers for determination under section 7(6) of the National Health Service (Wales) Act 2006.
- 17.4 The parties agree to comply in full with any such determination under Clause 17.2.

**18. WELSH LANGUAGE**

- 18.1 The parties warrant that they will not act in such a way as to render either party in breach of the Welsh Language Obligations.

**19. GOVERNING LAW AND JURISDICTION**

- 19.1 This MoU, and any Dispute or claim arising out of or in connection with it or its subject matter, shall be governed by, and construed in accordance with, the laws of England and Wales, as applied in Wales.

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

Signature: .....  
Name: .....  
Position: .....  
Date: .....

Signed for and on behalf of **WELSH  
AMBULANCE SERVICES NATIONAL  
HEALTH SERVICE TRUST**

Signature: .....  
Name: .....  
Position: .....  
Date: .....

**CONTACT POINTS  
H DUHB**

Name: .....  
Office address: .....  
.....  
Tel No: .....  
E-mail Address: .....

**WAST**

Name: .....  
Office Address: .....  
.....  
Tel No: .....  
E-mail Address: .....

## **Annex A. The Operational Model**

### **Overview**

The Welsh Ambulance Services NHS Trust (WAST) Emergency Medical Service (EMS) Clinical Contact Centres (CCC) operate out of three sites across Wales. 999 cases are received and queued on a virtual computer-aided dispatch system (CAD) known as C3. This system facilitates nurses, paramedics, mental health professionals, and other allied health professionals undertaking Secondary Telephone Triage.

WAST is committed to providing an efficient, effective, appropriate and safe service for the people of Wales. Underpinning this commitment is the clinical model (CM), of which Secondary Telephone Triage is a vital function in ensuring that the right care is delivered to patients at the right time in the right place.

WAST recognises the expertise, and different skill sets that physicians (Typically but not limited to General Practitioners) bring to the remote assessment of some patients and the contribution they bring to ensuring positive outcomes and experience for patients presenting to 999 services. The telephone assessment of patients by a physician is not a new concept. It is delivered nationally through primary care, out of hours' services, NHS advice services such as NHS 111, and other existing UK ambulance services models.

The term Physician Telephone Assessment and Streaming Services (PTAS) refers to a registered medical doctor undertaking a remote clinical assessment of patients. Such telephone assessments usually take place as part of the delivery of Out of Hours clinics, Ambulance Services responses, and NHS Direct/111 responses.

The term PTAS refers only to those medical doctors registered on the General Medical Councils Full, Specialist, or GP Register. Those working on a provisional registration are not considered suitable for undertaking PTAS within the context of this memorandum.

The streaming element of these often physician led services refers to a range of allied health professions such as paramedics, nurses, and advanced practitioners proactively reviewing patients' details to determine if they can be directed to the most appropriate destination, clinic, or care service within the community. This has formerly been known as a single point of clinical access type model.

PTAS physicians will identify 999 cases, from the live C3 stack (from their geographical/health board area) that they consider would benefit from additional remote/telephone clinical assessment, management, and streaming.

The principal role of the PTAS physician is to provide additional clinical triage and consultation, advice and support to patients to ensure that they can access the most clinically appropriate care for their urgent and emergency healthcare needs.

# **Programme Business Case** for an All Wales Positron Emission Tomography (PET) Service

May 2021



**GIG**  
CYMRU  
**NHS**  
WALES

Pwyllgor Gwasanaethau Iechyd  
Arbenigol Cymru (PGIAC)  
Welsh Health Specialised  
Services Committee (WHSSC)

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## Document control

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## Glossary of Abbreviations and Acronyms

ABUHB	Aneurin Bevan University Health Board
AML	Alliance Medical
ARSAC	Administration of Radioactive Substances Advisory Committee
AWPET	All Wales PET Advisory Group
BCUHB	Betsi Cadwaladr University Health Board
CRB	Cash Releasing Benefit
CSFs	Critical Success Factors
CT	Computerised Tomography
CUBRIC	Cardiff University Brain Research Imaging Centre
CTMUHB	Cwm Taf Morgannwg University Health Board
CVUHB	Cardiff and Vale University Health Board
DHCW	Digital Health and Care Wales
EA	Environment Agency
EPSRC	Engineering and Physical Sciences Research Council
FBC	Full Business Case
HDUHB	Hywel Dda University Health Board
GDNF	Glial cell-derived neurotrophic factor
GIRFT	Getting It Right First Time
GMP	Good Manufacturing Practices
HCA	Health Care Assistant
HEIW	Health Education and Improvement in Wales
IMP	Investigational Medicinal Product
IPEM	Institute of Physics and Engineering in Medicine
LSHW	Life Sciences Hub Wales
MA	Marketing Authorisation
MDT	Multi-Disciplinary Team
MHRA	Medicines and Healthcare Products Regulatory Agency
MPE	Medical Physics Expert
MRC	Medical Research Council
MRI	Magnetic Resonance Imaging
NCRI	National Cancer Research Institute
NIAW	National Imaging Academy Wales
NIPSB	National Imaging Strategic Programme Board
NRW	National Resources Wales
OBC	Outline Business Case
ONS	Office for National Statistics

PACS	Picture Archive System
PBC	Programme Business Case
PET	Positron Emission Tomography
PET-CT	Positron Emission Tomography combined with Computerised Tomography
PETIC	Positron Emission Tomography Imaging Centre
PTHB	Powys Teaching Health Board
QA	Quality Assurance
RCR	Royal College of Radiologists
RCP	Royal College of Physicians
RD&I	Research, Development and Innovation
RIS	Radiology Information System
RISPP	Radiology Information System Procurement Programme
RPA	Radiation Protection Adviser
RWA	Radioactive Waste Adviser
SLA	Service Level Agreement
SOC	Strategic Outline Case
SBUHB	Swansea Bay University Health Board
SPB	Strategic Programme Board
SPECT	Single-Photon Emission Computerised Tomography
SRO	Senior Responsible Officer
SWOT	Strengths Weaknesses Opportunities Threats
UHB	University Health Board
VUT	Velindre University NHS Trust
WSAC	Welsh Scientific Advisory Committee
WHSSC	Welsh Health Specialised Services Committee
WTE	Whole Time Equivalent
18F-DOPA	Fluoro-3,4-dihydroxyphenylalanine - radiopharmaceutical
18F-FDG	Fluorodeoxyglucose – radiopharmaceutical
18PSMA	Prostate-specific membrane antigen – radiopharmaceutical

# Executive Summary

## Introduction

PET-CT has become a central diagnostic tool in the management of cancer, and increasingly in many non-cancer conditions. Its role and the evidence base continue to evolve. Although it is a relatively expensive investigation, when used appropriately, PET-CT can significantly improve clinical decision making, particularly with respect to the appropriate use of complex and expensive specialist treatments.

This is supported by an increasing body of high-quality evidence outlining the contribution of PET to improved patient outcomes. There are many studies that demonstrate the role PET-CT has in accurately determining the staging of certain cancers and subsequent treatment plans, which enables reduction of inappropriate patient management and allows for best prognosis and patient care.

Demand for PET-CT is growing with England realising an approximate 18% rise in demand per annum. However, in Wales, scanning activity levels are low compared with the rest of the UK. It is estimated that in 2020 Wales was performing approximately 33% of the PET scans per head of population compared to England. In addition, NHS Wales has a list of funded indications for PET-CT which is limited compared to England and Scotland. The picture becomes bleaker when comparing performance with the rest of Europe and beyond.

Continuing to meet growing demand by relying on external providers is likely to cost an additional £25.6 million p.a. revenue by 2031/32. This approach would not only prove expensive but would deliver no improvements to the existing service structure. Indeed, without investment, the PET service in Wales would likely be served by expensive external providers, using mobile scanners, and the Welsh NHS would miss the opportunity to build a future-proofed network of centres of excellence.

Shortly after the Welsh Government published the Imaging Statement of Intent (March 2018), the All Wales PET Advisory Group (AWPET) and the Welsh Scientific Advisory Committee (WSAC) produced a report "Positron Emission Tomography (PET) in Wales – Overview and Strategic Recommendations" (November 2018). One of its five key recommendations was that WHSSC should be commissioned to produce a Programme Business Case for PET-CT capacity in Wales that considers increased demand projections, estates, staffing requirements and research.

These reports clearly demonstrates that much like other imaging modalities in Wales, there is an obvious and clear need to address the multifactorial issues facing the PET service including staffing, equipment age, facilities and research, development and innovation (RD&I).

In March 2019, the Director General, Health and Social Service/NHS Wales Chief Executive, Welsh Government endorsed the 2018 AWPET/WSAC report recommendations and outlined the expectations for NHS Wales to collaborate on their implementation. As there was recognition that additional capital investment would be required to develop the service, the Director General requested that WHSSC develop the PBC, with support from the National Imaging Strategic Programme Board (NIPSB), to guide the development of future service provision for the whole of Wales.

WHSSC has led the All Wales PET Programme development and produced this Programme Business Case (PBC) which justifies the rationale to invest in the All Wales PET service.

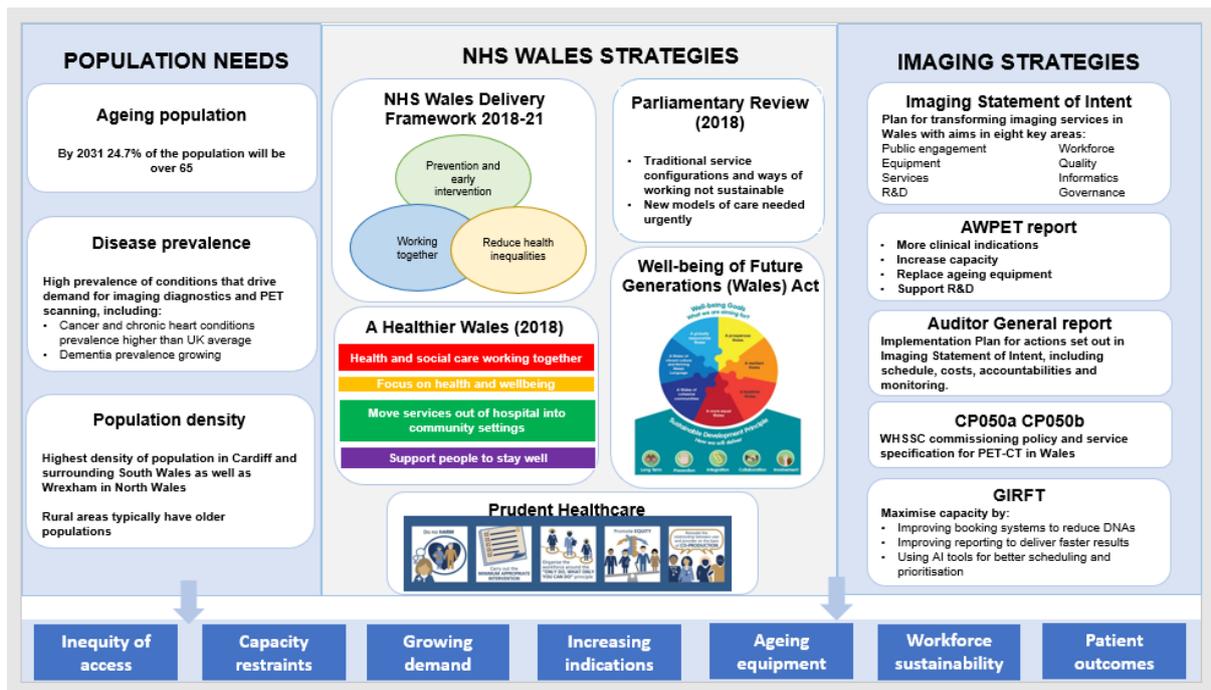
The resulting PBC assesses future Welsh PET scanning demand needs and focuses on the surrounding infrastructure of PET scanning delivery. As such, it provides a ten-year strategic view of service delivery, in addition to describing the business change and technical aspects of implementation.

Following a robust assessment of options, the PBC identifies the preferred way forward which involves investing in four fixed PET-CT scanners which will reduce the cost pressure by £6.8 million p.a. by providing sufficient capacity for NHS Wales and PETIC to meet demand. WHSSC therefore seeks capital funding of £24.881 million from Welsh Government over five years to invest in equipment and building works required to deliver the preferred way forward.

## The Strategic Case

### The Strategic Context

There are multiple strategic drivers for this Programme of work, which have been summarised in the figure below.



## The Case for Change

The programme has run workshops and set up specific task and finish groups with subject matter experts to fully understand business requirements from clinical and operational perspectives. These have allowed the Programme to identify its core Spending Objectives and has defined programme implementation plans.

### Spending Objectives

The Programme identified five spending objectives which articulate what the programme is seeking to achieve.

- **SO1** - To improve the quality of PET service provision for Welsh patients by delivering better patient outcomes.
- **SO2** - To ensure a sufficient workforce to deliver a high-quality service.
- **SO3** - To improve delivery of the All Wales PET Service by efficient use of PET-CT scanners, facilities, processes and infrastructure.
- **SO4** - To ensure that the future All Wales PET service provides a cost-effective service for patients and NHS Wales.
- **SO5** - To widen the scope of the All Wales PET service, to meet recognised international best practice.

## Current Service provision

WHSSC commission and approve funding of PET scans for the population of Wales in line with the criteria presented in commissioning policy CP50a and service specification CP50b (which covers requirements for both fixed site and mobile scanners). WHSSC is committed to regularly reviewing and updating all of its clinical commissioning policies based upon the best available evidence of both clinical and cost effectiveness.

NHS Wales currently has three providers delivering PET-CT services:

- A fixed site at the University Hospital of Wales in Cardiff (the Wales Research and Diagnostic Positron Emission Tomography Imaging Centre; PETIC).
- A mobile service at Wrexham Maelor Hospital (2 days per week).
- A mobile service at Singleton Hospital, Swansea (2 days per week).

Patients are referred for a range of PET-CT scans by members of the relevant multi-disciplinary team (MDT).

## Business Needs

Continuing with existing arrangements is not feasible because there are some significant business needs which will result in deterioration of the service, growing costs and impact on clinical outcomes and patient experience. Specifically, these include:

- There is a growing and aging population, thus the demand for PET-CT is increasing substantially in countries across the world. Critically, in his 2020 report 'Diagnostics: Recovery and Renewal', Professor Sir Mike Richards indicated that between 2014/15 and 2018/19 demand for PET-CT in England increased by 18.7% per annum in England. He recommended that scanning equipment should, as a minimum, be expanded in line with current growth rates and that all imaging equipment older than 10 years be replaced.
- However in Wales, scanning activity levels are low compared with the rest of the UK. It is estimated that Wales is currently performing approximately 33% of the PET scans per head of population compared to England (2020). In addition, NHS Wales has a list of commissioned indications for PET-CT which is limited compared to England and Scotland. Furthermore, Wales has just 0.6 scanners per million population versus ~1.0 scanners per million population in other devolved nations. The picture becomes bleaker when comparing performance and infrastructure with the rest of Europe and beyond.
- Several other significant considerations for this programme are:

- there are patient experience and quality issues associated with mobile scanners that are currently used in South West and North Wales,
- the analogue fixed scanner at PETIC is older than its useful life, causing a significant service delivery risk,
- there are critical workforce issues facing the wider imaging and nuclear medicine professions, with staffing levels low and many core personnel being close to retirement,
- there are issues facing the assurance of radiopharmaceutical supply across Wales, with some but not all radiopharmaceuticals being produced at PETIC in Cardiff and the production facility requiring investment to update equipment, and
- there is a clear need for equitable patient access to research, development and innovation activity in Wales.

The spending objectives are therefore not achievable under current arrangements. Problems with the existing arrangements are described in relation to each of the spending objectives in the figure below.

SO1 Improve the quality of PET service provision for Welsh patients by delivering better patient outcomes	SO2 Ensure a sufficient workforce to deliver a high-quality service	SO3 Improve delivery of the All Wales PET Service by efficient use of PET-CT scanners, facilities, processes and infrastructure	SO4 Ensure that the future All Wales PET service provides a cost-effective service for patients and NHS Wales	SO5 Widen the scope of the All Wales PET service, to meet recognised international best practice
<b>Problems with existing arrangements</b>				
Wales currently under-performs: <ul style="list-style-type: none"> <li>• PET-CT scans per head of population</li> <li>• Density of PET scanners</li> <li>• Wider PET-CT infrastructure</li> <li>• Unable to meet growing demand and increasing number of indications in the future</li> </ul>	Challenges recruiting and retaining highly skilled staff required to deliver high quality service due to: <ul style="list-style-type: none"> <li>• Working environment</li> <li>• Constrained capacity</li> <li>• Limited development opportunities</li> </ul>	Reliance on mobile units impacts directly on: <ul style="list-style-type: none"> <li>• Quality</li> <li>• Patient experience</li> <li>• Planning</li> <li>• Research capacity and capability</li> <li>• Reliability</li> <li>• Access</li> <li>• Flexibility of booking</li> <li>• Analogue scanners</li> </ul>	Reliance on mobile units and external suppliers for radiopharmaceuticals results in increased cost per scan. Limited opportunities to: <ul style="list-style-type: none"> <li>• Reduce inefficiencies associated with duplication and downtime</li> <li>• Generate income</li> </ul>	Scanning facilities and infrastructure limit opportunities to explore: <ul style="list-style-type: none"> <li>• Expanding Research &amp; Development capability</li> <li>• Achieving Gold standard</li> <li>• Innovation, such as AI</li> </ul>

Addressing the business needs and delivery of the spending objectives will deliver a range of benefits including:

- Improved quality and reduction in patient harm
- Workforce resilience
- Improved efficiency and economy
- Improved access reducing patient travel time
- Cost effective service supported by income generation
- Provide capacity that meets population needs in line with international best practice
- Increased opportunities for Research and Development
- Increased opportunities for innovation

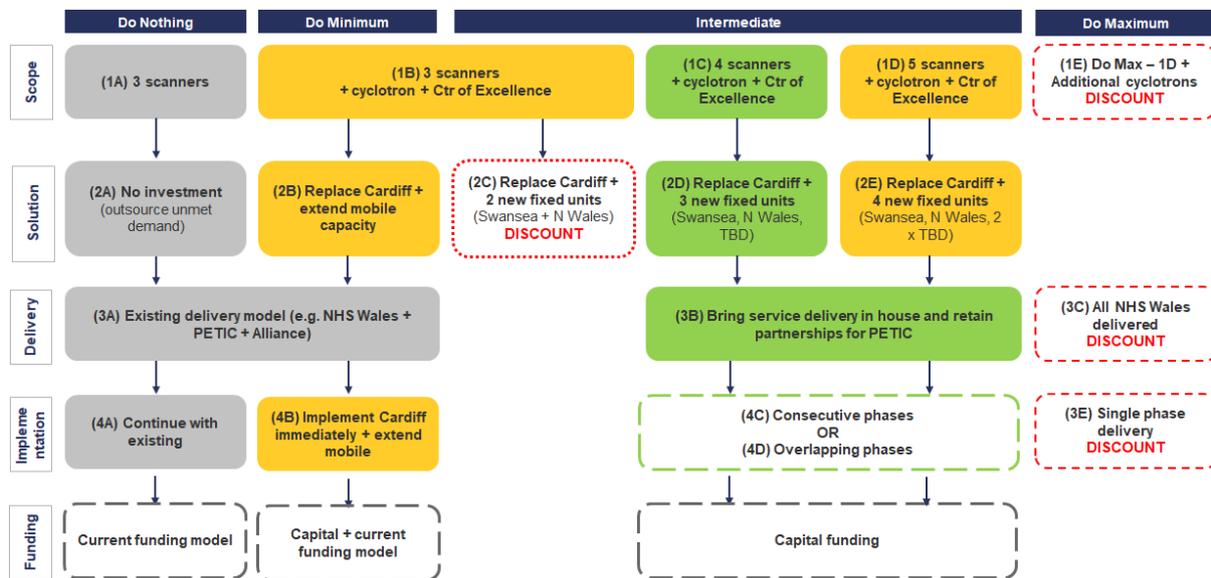
The PBC has a detailed benefits log as part of its appendices.

## The Economic Case

In accordance with HM Treasury’s Green Book 2020 (A Guide to Investment Appraisal in the Public Sector) and Better Business Case guidance, a wide range of options have been considered that could deliver the agreed spending objectives for the following five categories of choice:

- Scope (service and geographical coverage)
- Solution (including services and required infrastructure)
- Service delivery (who will deliver the required services)
- Timing and phasing of delivery
- Funding of the investment

Stakeholders identified a long list of options for each of these categories and assessed them in relation to how well each meets the agreed spending objectives and critical success factors. An overview of the long list is shown in the diagram below.



The results of this were aggregated into a shortlist of options as shown in the table below.

Options	Option 1 Business as Usual	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
Scope	<b>3 Scanners (Core scope)</b> • Access to 3 PET-CT scanners in Cardiff, Swansea, North Wales	<b>3 Scanners (Core + Desirable scope)</b> • Access to 3 PET-CT scanners in Cardiff, Swansea, North Wales • Cyclotron co-located Cardiff • Centres of Excellence facilities (with new scanners)	<b>4 scanners (+Desirable)</b> • Access to 3 PET-CT scanners in Cardiff, Swansea, North Wales • Cyclotron co-located Cardiff • Centres of Excellence facilities • 1 additional PET-CT or PET-MR scanner (aligned to clinical model/demand)	<b>5 scanners (+Optional)</b> • Access to 3 PET-CT scanners in Cardiff, Swansea, North Wales • Cyclotron co-located Cardiff • Centres of Excellence facilities • 2 additional PET-CT or PET-MR scanner (aligned to clinical model/demand)
Solution	No investment (Outsource unmet demand to mobile scanners)	Replace Cardiff equipment + extend mobile capacity in Swansea and North Wales	Replace Cardiff equipment + 3 new fixed units (Swansea, North Wales, 1 location to be determined)	Replace Cardiff equipment + 4 new fixed units (Swansea, North Wales, 2 locations to be determined)
Delivery	Existing delivery model (e.g. NHS Wales + PETIC + Alliance)	Existing delivery model (e.g. NHS Wales + PETIC + Alliance)	Bring service delivery in house and retain partnerships for PETIC	Bring service delivery in house and retain partnerships for PETIC
Implementation	Continue with existing arrangements	Deliver Cardiff replacement + extend mobile provision	<b>Phased approach</b> • Cardiff 2021/22 • North Wales 2023/24 • Swansea 2023/24 • 4 <sup>th</sup> scanner 2025/26	<b>Phased approach</b> • Cardiff 2021/22 • North Wales 2023/24 • Swansea 2023/24 • 4 <sup>th</sup> scanner 2025/26 • 5 <sup>th</sup> scanner 2028/29
Funding	Current funding model	Capital and revenue	Capital funding	Capital funding

The following shortlist was therefore carried forward to the economic appraisal to evaluate the costs, benefits and risks in order to identify the option that is most likely to offer best public value for money:

- Option 1 – Business as Usual: Do nothing.
- Option 2 – Do Minimum: Retain 1 fixed scanner and extend capacity of 2 mobile scanners.
- Option 3 – Preferred Way Forward: Provide 4 fixed scanners (10-year programme).
- Option 4 – More Ambitious: Provide 5 fixed scanners (10-year programme).

At Project business case stage, the development of detailed designs which will determine patient flows and resource requirements will allow costs, benefits and risks to be estimated with a greater degree of certainty. For the purposes of the PBC, indicative capital costs have been estimated by Specialist Estates Services and indicative revenue costs, benefits and risks have been estimated based on high-level assumptions which are outlined in detail in the Economic Case.

Based on these assumptions, the Comprehensive Investment Appraisal (CIA) model has been prepared to estimate the Net Present Social Value (NPSV) and Benefit Cost Ratio (BCR) for each option. An overview of the results is presented in the table below.

	<b>Option 1 Business as Usual (BAU)</b>	<b>Option 2 Do Minimum</b>	<b>Option 3 Preferred Way Forward</b>	<b>Option 4 More Ambitious</b>
<b>Description</b>	Do nothing	Retain 1 fixed and extend capacity of 2 mobile scanners	Provide 4 fixed scanners (10-year programme)	Provide 5 fixed scanners (10-year programme)
<b>Incremental NPSV</b>	-	£4.4m	£54.0m	£68.3m
<b>Benefit Cost Ratio</b>	-	0.00	2.30	2.38
<b>Average cost per scan (10 year period)</b>	£935	£898	£729	£708
<b>Sensitivity and risks</b>	Consistently ranks as worst value for money even with significant changes in assumptions	Consistently ranks as second worst value for money even with significant changes in assumptions	Ranks as best value for money if demand growth is lower than 17.5% year on year	If demand growth is lower than predicted 5th scanner will be significantly underutilised

The analysis concluded that although Option 4, which involves a programme to provide five fixed scanners within the next 10 years, results in the highest NPSV and Benefit Cost Ratio, this is relatively sensitive to changes in the demand growth assumptions. Option 3, which involves a programme to provide four fixed scanners within the next 10 years, delivers the second highest NPSV and Benefit Cost Ratio, while providing greater flexibility to review requirements as more evidence emerges about demand growth in the future.

It is therefore recommended that Option 3 is carried forward as the preferred way forward for delivering the programme and the potential need for a fifth scanner assessed at a later date.

## The Commercial Case

The Programme will look to acquire four fixed, digital (Artificial Intelligence enabled) PET-CT scanners and install these key items of equipment at four locations across Wales. This procurement includes ancillary equipment, radiotherapy adaptations, in addition to an ion source and hot cell replacement for the cyclotron at the Cardiff site.

In line with clinical demand and workforce availability, the implementation of the Programme will need to be carried out in a phased manner. Dependent upon the timings of the phases and or the available funds, it may be possible to aggregate NHS Wales' purchasing requirements so as to generate additional value.

There are multiple procurement routes that can be followed, however all of the major items of equipment are available on a compliant pre-approved framework. NHS Wales has direct access to this framework and at the time of writing it is thought that Cardiff University can, through its own procurement department, access this same agreement.

Given the scale and impact on current Welsh NHS services that the All Wales PET Programme will deliver, it is imperative to ensure appropriate governance is in place for procurement. As such we propose that a multidisciplinary team will make up membership of a Procurement Workstream that will support the Programme.

The Procurement Workstream will be made up of specialist colleagues from both NWSSP-SES and NWSSP-PS, in addition to local procurement and estates and facilities teams to ensure that expertise and information is shared effectively and efficiently.

## The Financial Case

Delivery of the preferred way forward, which involves implementing a programme that will deliver four fixed digital scanners in Wales requires capital investment of £24.881m for which funding is sought from Welsh Government.

As well as delivering a wide range of non-financial benefits in relation to service improvements and patient experience and outcomes, this will enable three of the scanners to reduce the average cost per scan to £572, compared with an average cost from external providers of £935. This will result in an overall average cost per scan for all four scanners over a 10-year period to £729.

Indicative modelling suggests that revenue costs could increase by £25.6m per annum by 2030/31 based on predicted demand growth. This investment will contribute to mitigating the ongoing cost pressure associated with growing demand including:

- Reduction in average cost per scan resulting in £6.6m annual financial benefit by 2030/31.
- Opportunities to deliver system-wide financial benefits due to increased PET-CT scanning reducing the need for high-cost late stage interventions. There is insufficient detail available on specific demand by patient pathway to calculate this at this stage.
- Opportunities for income generation from RD&I activities which, based on 7% of predicted demand, is estimated at around £3.3m by 2030/31.

Revenue funding for PET scanning is currently provided via WHSSC on a price-per-scan basis, with existing service providers charging WHSSC an agreed price for each scan carried out. WHSSC has

included projected growth in PET scanning demand within the WHSSC ICP plan. It is expected that each local organisation that will host a PET-CT scanner will make clear how they, as service providers commissioned by WHSSC, will incorporate the additional revenue implications i.e. staff and running costs, into the price-per-scan that they charge WHSSC.

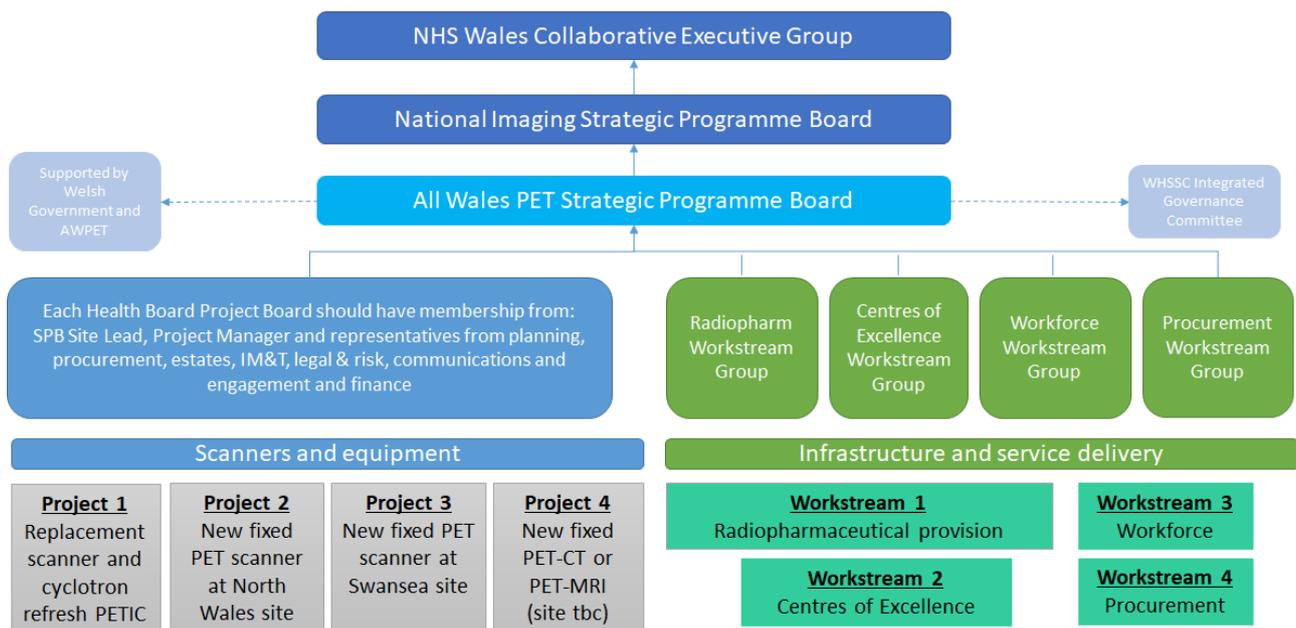
## The Management Case

### Programme structure

The All Wales PET Programme is a strategic Programme that is hosted by WHSSC and sits within the “Strategic Resource Planning” category of the National Imaging Programme Strategic Board (NIPSB). The NIPSB is hosted and supported by the NHS Wales Collaborative and the NHS Wales Collaborative Executive Group (CEG).

The All Wales PET Strategic Programme Board (SPB) is the formal decision making forum for the programme, and is chaired by the NHS Senior Responsible Officer (SRO), the Managing Director of WHSSC, Dr Sian Lewis.

The Programme structure as set out below ensures clear accountability and also deploys mechanisms to facilitate decision making, escalation, communication and alignment.



The scope of this Programme is limited to procurement of the following list of equipment:

- Four digital PET-CT Scanners (Artificial Intelligence enabled; one scanner at each site);
- Ancillary equipment and phantoms (robotic radiotracer dispenser);
- Radiotherapy adaptations (laser bridge, flat table top).

The equipment is to be located at Cardiff (replacement scanner), Swansea (new scanner) and North Wales (new scanner). The fourth scanner (new) placed at a location to be defined at a later date will be based upon clinical demand and population density. Associated build works for the PET site

facilities are also within scope. Furthermore, refresh of equipment connected with the cyclotron at Cardiff is within scope of this Programme, thus requiring procurement of:

- Ion source replacement within the cyclotron
- Hot cell replacement and associated GMP build.

Supporting infrastructure to PET has been identified as an essential consideration to the success of the PET Programme delivery, including workforce and research and development. As such, these elements have been considered as within scope and are addressed in the Programme structure, with a series of sub projects for implementation works and supporting workstreams.

### Programme Plan

Programme implementation will be phased so that sufficient time is given to scrutinise supporting business cases for Projects. This will ensure supporting infrastructure requirements are solved at appropriate timings, in order to optimise delivery and ultimately PET service provision.

Business Case (BC)	Proposed date of Welsh Gov. BC approval	Proposed "go live" date	
<b>Tranche 1</b>			
<b>Project 1</b>			
BJC	July 2021	PET Scanner	March 2022
		Ion Source replacement	March 2022
		Hot Cell replacement	March 2023
<b>Tranche 2</b>			
<b>Project 2</b>			
SOC1	July 2021	January 2024	
OBC/FBC	March 2022		
<b>Project 3</b>			
OBC2	November 2021	November 2023	
FBC2	July 2022		
<b>Tranche 3</b>			
<b>Project 4</b>			
Appraisal Process	April 2023	June 2026	
OBC3	January 2024		
FBC3	December 2024		
<b>Tranche 4</b>			
January 2027			

Further to endorsement of the PBC, the programme will expand to provide the capacity to procure, prepare and implement the programme solution. At the time of writing, the NHS Wales Collaborative

fund a programme manager that is hosted by WHSSC on a fixed-term basis. This role forms the core of the All Wales PET Programme Management arrangements and is funded until March 2022.

The anticipated annual staffing cost of the Programme Implementation is £115k and will consist of a national programme manager and administrator, providing a total cost of £575k over the five year total implementation and evaluation period. Local organisations that will host a PET-CT scanner will need to source a project manager from within their existing resource for the duration of local implementation and these arrangements should be outlined in subsequent project business cases.

### External Programme Review and Assurance

This Programme has clearly defined internal governance arrangements and will be subject to the OGC Gateway™ Review processes. The Programme will also be subject to audit by the NWSSP (Audit and Assurance Services).

### Benefits realisation

A detailed Benefits Register is included in the Appendices, alongside detailed Benefits Maps in in the full Management Case. On endorsement of this PBC, the baselining of these benefits will begin in advance of implementation of scanners.

### Risk Management

The All Wales PET Programme will utilise its governance structure and arrangements to ensure the effective management of risk. The governance structures allow for risks to be escalated from Project boards and Workstream groups, through to the Strategic Programme Board and/or the Health Board/Trust, as appropriate.

### Post Programme Evaluation

The All Wales PET Programme is committed to ensuring that a thorough Post-Programme Evaluation (PPE) is undertaken after the Programme has concluded, to ensure that positive lessons can be learnt. This is noted in tranche 4 of the Programme Plan.

The All Wales PET Programme is also committed to ensuring that lessons are learned at all key stages during implementation, so these can be fed into the wider Programme.

As such, there will be two Evaluation sessions held after each Tranche:

- **Lessons learned and post tranche review** – to be held two to three months post tranche completion.
- **Evaluation of benefits, outcomes & spending objectives** – to be held six to twelve months post tranche completion.

# 1 Strategic Case

## 1.1 Introduction

### 1.1.1 Purpose

The purpose of the Programme Business Case (PBC) is to set out the case for an All Wales Positron Emission Tomography (PET) Programme with sufficient capacity to meet the projected increased demand for PET scanning over the next ten years. It considers the requirements in terms of infrastructure, workforce, and research, development and innovation (RD&I).

This introductory section of the PBC provides an overview of:

- The context of the proposed investment.
- The governance arrangements for the programme.
- The structure and the content of the PBC.

### 1.1.2 Context of proposed investment

A PET-CT scan is where Positron Emission Tomography is combined with Computerised Tomography (CT) to produce a highly detailed image. This combination is the most commonly used approach in PET scanning and as such, scanning may be referred to as either PET or PET-CT throughout this document.

PET-CT scanning services in Wales are commissioned by the Welsh Health Specialised Services Committee (WHSCC) [1, 2]. NHS Wales currently has three providers delivering PET-CT services, and the respective University Health Board (UHB) where these are located are responsible for managing the service:

- A fixed site at the University Hospital of Wales in Cardiff (the Wales Research and Diagnostic Positron Emission Tomography Imaging Centre; PETIC) (Cardiff and Vale UHB).
- A mobile service at Wrexham Maelor Hospital (2 days per week) (Betsi Cadwaladr UHB)
- A mobile service at Singleton Hospital, Swansea (2 days per week) (Swansea Bay UHB).

PET-CT has become a central diagnostic tool in the management of cancer, and increasingly in many non-cancer conditions. Its role and the evidence base continue to evolve. Although it is a relatively expensive investigation, when used appropriately PET-CT can significantly improve clinical decision making, particularly with respect to the appropriate use of complex and expensive specialist treatments.

There is an increasing body of high-quality evidence to demonstrate the contribution of PET to improved patient outcomes. There are many studies that have demonstrated the role PET-CT has in accurately determining the staging of certain cancers and subsequent treatment plans, which enables reduction of inappropriate patient management and allows for best prognosis and patient care [3, 4, 5].

Demand for PET-CT is growing, however in Wales, scanning activity levels are lower compared with the rest of the UK. It is estimated that in 2019 Wales was performing approximately 33% of the PET scans per head of population compared to England. In addition, NHS Wales has a list of funded

indications for PET-CT which is limited compared to England and Scotland. The picture becomes bleaker when comparing performance with the rest of Europe and beyond.

In November 2018, the All Wales PET Advisory Group (AWPET) and the Welsh Scientific Advisory Committee (WSAC) produced a report “Positron Emission Tomography (PET) in Wales – Overview and Strategic Recommendations” [6].

A detailed summary of this report is available in section 2.11. One of its five key recommendations was that WHSSC should be commissioned to produce a PBC for PET-CT capacity in Wales that considers increased demand projections, estates, staffing requirements and research.

In March 2019, the Director General, Health and Social Service/NHS Wales Chief Executive, Welsh Government endorsed the report recommendations and outlined the expectations for NHS Wales to collaborate on their implementation. As there was recognition that additional capital investment would be required to develop the service, the Director General requested that WHSSC develop the PBC, with support from the National Imaging Strategic Programme Board (NIPSB), to guide the development of future service provision for the whole of Wales.

This document sets out the PBC which:

- Explores the case for change in terms of the gap between existing arrangements and future business needs.
- Describes the appraisal undertaken to identify a preferred option for the future service model that will address this gap and deliver optimum public value for money.
- Assesses alternative procurement routes available to deliver the preferred way forward.
- Determines the overall capital and revenue requirements and assesses affordability.
- Sets out the programme management arrangements to deliver the preferred way forward.

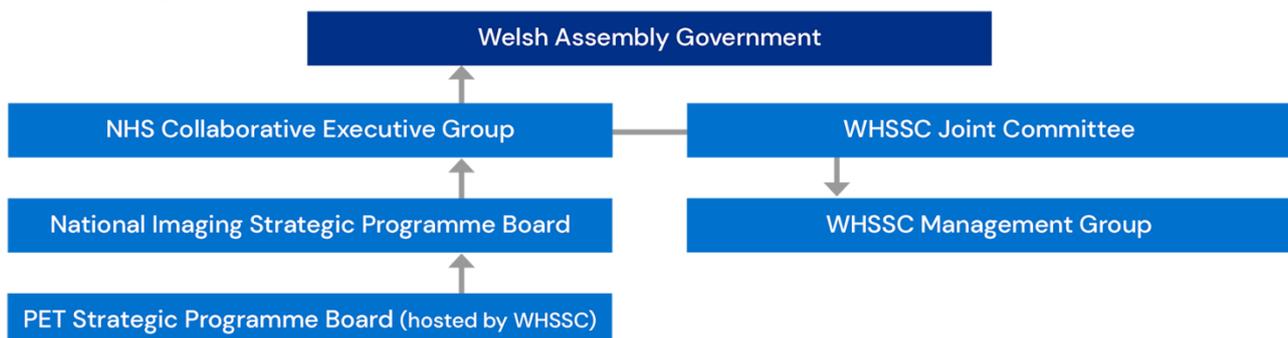
### 1.1.3 Programme governance

The PET Strategic Programme Board (SPB) was established to develop and implement the recommendations from the AWPET report (see section 1.3.8).

The Senior Responsible Officer (SRO) of the Programme Board is Dr Sian Lewis, Managing Director, WHSSC and Deputy SRO is Dr Andrew Champion, Assistant Director, Evidence Evaluation and Effectiveness, WHSSC.

The SPB is accountable to the National Imaging Strategic Programme Board (Figure 1).

Figure 1: Programme governance structure



### 1.1.4 Structure and content of the PBC

This PBC follows the Five Case Model in line with HM Treasury Green Book and Welsh Government best practice guidance as set out in 'Better Business Cases: Guide to Developing the Programme Business Case'<sup>1</sup>. The structure of the PBC is outlined in the table below.

*Table 1: Structure of the Programme Business Case*

Case	Section	Purpose	
Strategic Case	1.1	Introduction	Sets out the background and programme governance.
	1.2	PET Scanning Context	Provides context for the proposals by describing what PET is, the steps involved in a PET-CT scan, an overview of the production of radiopharmaceuticals and specialist workforce.
	1.3	Strategic Context	Provides an overview of current services and explains how the programme is strategically placed to contribute to the delivery of organisational goals.
	1.4	Case for Change	Establishes the case for change by outlining the spending objectives, existing arrangements and business needs.
	1.5	Potential Scope	Identifies the potential scope of the programme in terms of the operational capabilities and service changes required to satisfy the identified business needs.
	1.6	Benefits and Risks	Identifies the benefits, risks, constraints and dependencies for the project.
Economic Case	2.1	Options Identification	Explores the preferred way forward by agreeing critical success factors (CSFs), determining the long list of options, and undertaking a SWOT analysis to identify a shortlist of options.
	2.2	Economic Appraisal	Appraises the economic costs, benefits and risks for the shortlisted options. Identifies the preferred way forward by reviewing the outputs of the economic appraisal, as well as consideration for the benefits and risks of each of the three shortlisted options to determine which option offers the best value for money
Commercial Case	3	Procurement Arrangements	Outlines the procurement strategy and the contractual arrangements for development of the deal that is required to deliver the preferred solution for the programme.
Financial Case	4	Financial Appraisal	Sets out the forecast financial implications of the preferred way forward.
Management Case	5	Management Arrangements	Sets out the arrangements put in place to manage the programme to successful delivery.

<sup>1</sup> <https://gov.wales/better-business-cases-investment-decision-making-framework>

## 1.2 PET scanning Context

### 1.2.1 Introduction

This section of the PBC provides context to the All Wales PET Programme by providing an overview of PET including:

- A description of PET.
- The steps involved in PET-CT scans.
- The production of radiopharmaceuticals.
- Specialist workforce for PET scanning.

### 1.2.2 What is PET?

Positron emission tomography (PET) is a scanning technique that produces detailed 3-dimensional (3D) images of the inside of the body. The images can clearly show the part of the body being investigated, including any abnormal areas, and can highlight how well certain functions of the body are working.

A PET-CT scan is most commonly used where PET is combined with Computerised Tomography (CT) to produce an even more detailed image. The main clinical benefit of using PET-CT scanning lies in its ability to link changes in metabolic activity (PET), with anatomical imaging (CT), allowing for more accurate identification of the location, size and shape of tumours through identifying abnormal cellular activity. PET can also be used alongside Magnetic Resonance Imaging (MRI).

PET-CT scans are particularly helpful for investigating cases of cancer, for example to determine how far the cancer has spread and how well it is responding to treatment. As PET is a functional technique, it can detect tumours and metastatic spread of cancer much earlier than other anatomical imaging techniques such as CT or MRI. Indeed, PET is more sensitive than either CT or MRI in the detection of cancer and results in more accurate staging and typically changes patient management in 30-40% of patients that are scanned.

The breadth of application of PET-CT scanning is expanding and it is increasingly being used to help plan operations, such as a coronary artery bypass graft or brain surgery for epilepsy. Some specific scanning can assist in the diagnosis of conditions such as dementia, Alzheimer's or Parkinson's disease.

PET scanners work by detecting the radiation given off by a substance that has been injected into the body as it is metabolised in different parts of the body. This substance is called a radiopharmaceutical. Radiopharmaceuticals consist of two components: a radionuclide and a biological molecule or "carrier". The radionuclide is chosen on the basis of the radioactive decay characteristics.

Positron emitting radionuclides decay via emission of positrons (particles with the mass of electrons but with a positive charge). Positrons interact with surrounding electrons in the body. This electron and positron interaction causes the annihilation of both particles, releasing energy in the form of two 511keV gamma photons which travel in opposite directions. The resulting gamma rays are detected by a ring of detectors - the PET camera - that surround a patient during a scan. The ring of detectors feeds into computer software that creates a 3D image of the radiopharmaceutical presence in the body.

The carrier molecule, for example glucose, is chosen to match a particular function within the body. Therefore, altering the carrier molecule means that clinicians are able to target specific organs, tissues or cells within the human body. In most PET scans a radiopharmaceutical called

fluorodeoxyglucose (18F-FDG) is used. The 18F is the radionuclide and the DG (deoxyglucose) is the carrier.

The deoxyglucose is metabolised by the human body in a similar manner to glucose. Tumours often demonstrate increased metabolism and as a result will show up as areas of increased 18F-FDG uptake on the PET scan.

By analysing the areas where the radiopharmaceutical is metabolised, it is possible to visualise how well certain body functions are working and identify any abnormalities. For example, a concentration of 18F-FDG in the body's tissues can help identify cancerous cells because cancer cells use glucose at a much faster rate than normal cells.

### 1.2.3 Steps involved in a PET-CT scan

Before the scan, the radiopharmaceutical is injected into a vein in the patient's arm or hand. The patient needs to wait quietly and keep warm for about an hour to give the radiopharmaceutical time to be absorbed by the cells in the body, a process known as 'uptake'. It is important to relax while waiting because moving and speaking can affect how and where in the body the radiopharmaceutical is absorbed.

Figure 2: a PET-CT scanner



During the scan, the patient lies on a flatbed that is moved into the centre of the scanner.

The duration of a scan depends on which part of the body is requested for imaging, and which radiopharmaceutical is being used.

On average and in general, scans typically take between 30 minutes for an 18F-FDG scan and 45 minutes for an 18F-PSMA scan.

Following the scan, a patient is asked to make use of a "hot toilet" where any radioactive material that may be present in the patient's body, may be safely expelled and managed.

For more details on the steps involved, please see Appendix 1: Service Operating Model.

### 1.2.4 Production and management of radiopharmaceuticals

Approximately 95% of PET-CT scans are currently performed using a radiopharmaceutical called fluorodeoxyglucose or 18F-FDG. Many other radionuclides are under development and are likely to see widespread use, both in the clinic and for research, within the next five years.

The decay of a radioactive substance is termed "half-life" and this refers to when the unstable radioactive nuclei has decayed. Typical half-life is a matter of hours, some are within minutes, and such preparations therefore have very short "shelf-lives". 18F has a two-hour half-life and, as a result, radiopharmaceuticals labelled with 18F require manufacture and use on the same day. Furthermore, the shelf-life of a radiopharmaceutical is dependent on the radiochemical stability and impurities

within the preparation. For example,  $^{18}\text{F}$  based preparations such as  $^{18}\text{F}$ -FDG and  $^{18}\text{F}$ -PSMA are normally intended to be used within 10 hours of preparation.

As a result of this short half-life, radiopharmaceuticals must be produced immediately prior to use in patients. This is a significant factor for consideration when planning the location of a PET scanner as it needs to be easily accessible for delivery of the radioactive material, to ensure that a sufficient dosage arrives in time for a patient's scan.

Radionuclides for PET radiopharmaceuticals are produced in cyclotrons. A cyclotron is a particle accelerator, an electrically powered machine which accelerates charged particles in a spiral path and produces a beam of charged particles. These particles are then processed in a clean room and combined with a pharmaceutical molecule to produce a radiopharmaceutical for use in patients.

The proximity of the PET-CT scanner to the cyclotron has a bearing on 'recovery' plans should the cyclotron or scanner fail at a given session. If a scanner is located near to a cyclotron, the more feasible it is for a rapid second delivery of radiopharmaceutical should the first batch be wasted due to scanner delays or faults or should the cyclotron fail to manufacture a first batch of suitable quality.

The production of radiopharmaceuticals is strictly controlled. Production centres must have a licence from the Medicines and Healthcare Products Agency (MHRA) to manufacture and supply radiopharmaceuticals for PET-CT imaging for both clinical and clinical trial use. There are three types of license:

- **Marketing Authorisation (MA):** supplying the product commercially. For example,  $^{18}\text{F}$ -FDG.
- **Investigational Medicinal Product (IMP):** supplying the product to sites carrying out a research trial (cannot be administered to a patient outside of a clinical trial)
- **Specials License<sup>2</sup>:** this is where a production centre can manufacture to a specification, satisfy itself of the quality and supply other sites where a marketing authorisation is not in place. For example,  $^{68}\text{Ga}$  or  $^{18}\text{F}$ -PSMA and  $^{18}\text{F}$ -DOPA.

The handling of radioactive materials and disposal of radioactive waste is also strictly controlled and is an important consideration in the planning and design of PET-CT facilities.

The radiological installation or operator organisations that use radioactive substances will inevitably produce such waste following the administration of PET radiopharmaceuticals to patients.

The keeping and use of radioactive materials, and the accumulation and disposal of radioactive waste or activities will be detailed in site-specific permits issued by the Environment Agency (EA) (Natural Resources Wales (NRW) in Wales). Radiological risk assessments will be required as part of the permit application process. An overarching procedure for managing PET radioactive waste at a radiological installation should describe the best available techniques to minimise the impact on the public and the environment from the use and disposal of such waste.

Operators who accumulate, dispose or manage radioactive waste must appoint a suitable radiation protection expert. Radioactive Waste Advisors (RWA) are specialists in radioactive waste management and environmental radiation protection. In particular, a designated 'hot' toilet is required for PET patients and a lockable shielded safe is required to decay-store PET radioactive waste.

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<sup>2</sup> The Medicines Act 1968 allows a GMP facility to produce and sell unlicensed radiopharmaceuticals as 'specials' if they are not licensed in the jurisdiction of the UK. If they are licensed (have a MA) they can be made for local use but cannot be sold (or given) to another institution. All 'specials' radiopharmaceuticals can furthermore be subjected to a MA which (once granted) would preclude existing facilities to manufacture the product for sale

### 1.2.5 Specialist workforce for PET scanning

PET-CT is a complex imaging modality (sub-speciality of nuclear medicine) that requires a specialist skill mix for a service to run. The reasons that necessitate such a specialist skill mix include the handling and administration of radioactive material, dealing with radioactive waste and operating highly technical equipment. As such, it is a tightly regulated field of work (note IR(ME)R 2017, IRR17, Environmental Permitting Regulations 2016). These regulations govern the practice of PET-CT as well as the rest of nuclear medicine. Given the level of specialisation within PET-CT, most staff members start their careers in general SPECT nuclear medicine and specialise later in PET-CT. Therefore there is transferability of skills between PET and nuclear medicine.

It is a legal requirement under IR(ME)R 2017 for employers to hold an Administration of Radioactive Substances Advisory Committee (ARSAC) licence at each medical radiological installation (hospital, etc.) where radioactive substances are to be administered to humans, and additionally for practitioners to hold individual ARSAC licences in order to justify the administration of those substances. A nuclear medicine service cannot therefore operate without these licences in place.

It is the ARSAC who provides advice to the relevant licensing authority on the issue of these licences. Practitioners who wish to apply for a licence to enable them to support a comprehensive diagnostic nuclear medicine imaging service should have satisfactorily completed the Royal College of Radiologists (RCR) Radionuclide Radiology Subspecialty Training Programme, the Royal College of Physicians (RCP) Nuclear Medicine Speciality Training Programme or demonstrate an equivalent level of training.

## 1.3 Strategic Context

### 1.3.1 Introduction

This section of the PBC outlines the strategic context for the All Wales PET Programme by providing an organisational overview and explaining how the proposals are strategically placed to support the delivery of organisational goals. It includes:

- An overview of the lead organisation and stakeholders.
- An analysis of population needs including demographic growth and disease prevalence.
- An outline of how the programme is essential to achieving the overall business strategies and aims of NHS Wales.
- A description of how the programme contributes to strategic goals within the context of the Imaging service.
- An overview of interdependencies with other relevant programmes and strategies.

### 1.3.2 Organisation overview

The All Wales PET Programme is led by Welsh Health Specialised Services Committee (WHSSC). WHSSC is responsible for the joint planning of Specialised and Tertiary Services on behalf of local health boards in Wales.

WHSSC Commissioning policies define the specialised services commissioned by WHSSC on behalf of the seven Welsh Health Boards and the criteria that must be met for Welsh patients to access the treatment.

WHSSC Service specifications are important in clearly defining what WHSSC expects to be in place for providers to offer evidence-based, safe and effective services and importantly, sets equitable access to services for Welsh patients.

WHSSC supports NHS Wales and the Health Boards by ensuring that there is equitable access to safe, effective, and sustainable specialist services for the people of Wales, as close to patients' homes as possible, within available resources. WHSSC has an established Prioritisation Process and Risk Management Framework to help identify the priorities for the WHSSC Integrated Commissioning Plan (ICP) [7].

WHSSC must ensure that any new investment decisions are affordable, offer value for money and are supported by convincing evidence of safety and effectiveness. To do this WHSSC runs an annual prioritisation process to determine the relative prioritisation of new interventions within specialised services. The process is facilitated by the WHSSC Clinical Impact Assessment Group (CIAG) and their recommendations (or priorities) are subsequently presented in the WHSSC ICP.

The WHSSC ICP 2020-23, which was approved by Joint Committee in February 2021, included investment in a number of new key clinical areas recommended by CIAG. This included a recommendation to support 20 new or updated PET indications across six disease areas that will account for an additional 679 scans per year across Wales.

Other stakeholders for the programme are:

- All Health Boards in NHS Wales;
- Velindre University NHS Trust;
- Cardiff University;
- PET providers in NHS England commissioned by WHSSC;
- National Imaging Strategic Programme Board (NIPSB);
- Welsh Government;
- Imaging Workforce and Education Group (IWEG);
- NHS Health Collaborative;
- Wales Cancer Network and other relevant specialist groups or organisations (e.g. Royal College of Radiologists);
- National Imaging Academy Wales (NIAW);
- Health Education and Improvement Wales (HEIW);
- Digital Health and Care Wales (DHCW; formerly the NHS Wales Information Service).

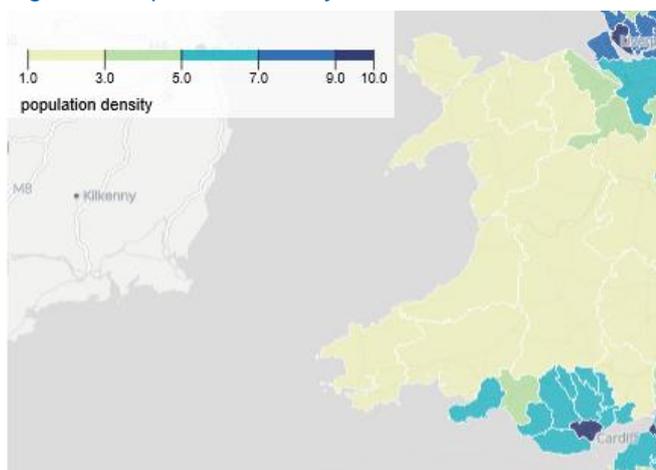
Collaboration with:

- Consultant Radiologists;
- Nuclear Medicine;
- Medical Physics;
- Cancer MDTs and non-cancer MDTs;
- Planning and Estates departments.

### 1.3.3 Population needs: Demographic growth

The mid-2019 population of Wales was 3,152,879 (1,554,678 males at 49.3%, and 1,598,201 females at 50.7%) (Dataset: Estimates of the population for the UK, England and Wales, Scotland and Northern Ireland, ONS, June 2020).

Figure 3: Population density



Map sourced from Dataset: Estimates of the population for the UK, England and Wales, Scotland and Northern Ireland, ONS, June 2020

Predicted population growth for Wales over the next 10 years is 0.25% p.a. (“Stats Wales: Population projections by local authority and year”, 2018), which suggests that the population of Wales is likely to be 3.2 million by 2031.

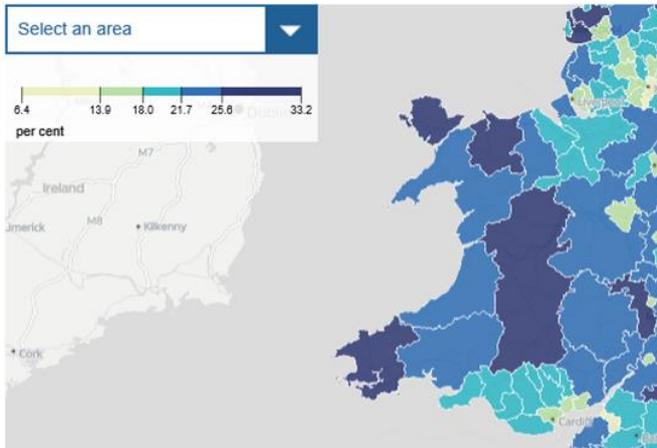
This is a modest growth and is in line with the 2018 National Population Projections by the Office of National Statistics.

The 2020 population density across Wales can be seen in Figure 3, where Cardiff and the surrounding South Wales areas have the highest density of people. The highest density of Welsh citizens in North Wales is centred on Wrexham.

The population aged 65 years and over experienced the highest level of growth of any broad age group in 2019 (ONS, Dataset: Estimates of the population for the UK, England and Wales, Scotland and Northern Ireland). There was a relatively uniform increase in the number of people aged 65 years and over in the year to mid-2019 across the constituent countries of the UK, with England

(1.7%), Scotland (1.8%), Wales (1.6%) and Northern Ireland (2.1%) all experiencing a similar proportion of growth.

Figure 4: Proportion of population 65 or older



Map sourced from Dataset: Estimates of the population for the UK, England and Wales, Scotland and Northern Ireland, ONS, June 2020

The 2019 ONS Dataset critically demonstrated how Welsh rural areas typically have older populations than cities. This is an important consideration in service provision and access to key clinical services (Figure 4).

More detail on population growth estimates can be found in Appendix 2.

### 1.3.4 Population needs: Disease Prevalence

Although Welsh population growth over the next 10 years will be modest, Wales is projected to realise growth in the 65+ population of around 130,000 by 2031, which is a significant demographic shift. An aging population will mean increased overall demand for health and care services (Future of an Ageing Population, Government Office for Science, 2016).

Population ageing will mean a greater prevalence of age-related conditions, such as dementia and chronic conditions affecting the heart, musculoskeletal and circulatory system. Data from Cancer Research UK correlates increased incidence of cancer with age at diagnosis (Cancer Research UK, <https://www.cancerresearchuk.org/health-professional/cancer-statistics/incidence/age#heading-Zero>, Accessed January 2021).

Wales has a higher prevalence of cancer and chronic heart disease than the UK average. Although dementia in Wales is at a slightly lower prevalence to the UK average, projections are for a substantial increase in the overall number of cases from 822,000 to 940,000 by 2031 in the UK, and more than 1.7 million by 2051 (Alzheimer's Society (2014) Dementia UK: Update, <https://www.alzheimers.org.uk/dementiauk>, Accessed January 2021). Therefore dementia rates in Wales will likely rise in line with the rest of the UK, and as a marker of an aging population of Wales.

This disproportionate demand on services will include increased requests for imaging diagnostics, which is an important consideration when looking to predict future demand for PET-CT scans. In particular, conditions such as cancer, chronic heart disease and dementia are believed to be the biggest drivers for future PET scanning.

### 1.3.5 NHS Wales business strategy and aims

The proposals outlined within this PBC are aligned with the national strategic context, supporting a broad range of national strategies and policies. An analysis of these is provided in the table below, showing how the programme will support their delivery.

Table 2: Programme alignment with national strategies

Strategy/Policy	Summary	How the All Wales PET Programme supports this
The NHS Wales Planning Framework 2020-23 [8]	The Framework sets high quality as a key priority which underpins all aspects of services, settings and contacts with the NHS in Wales. It states the need for health organisations to focus on the populations for which they are responsible, with an emphasis on prevention and early intervention, reducing health inequalities, timely access to care and working with wider partners to deliver the best possible services for citizens in Wales.	Patients across Wales will have equitable access to PET-CT services. There will be sufficient capacity within the service to cope with anticipated demand for PET-CT. High-quality, detailed scanning will lead to more accurate diagnosis, improved treatment planning and improved outcomes for patients.
The Parliamentary Review of Health and Social Care in Wales. Final Report. (January 2018) [9]	The Parliamentary Review set out a vision for the future, to include health and social care moving forward together and developing primary care services out of hospitals. The Review's recommendations focus on key themes around seamless care, a great place to work and maximising the benefits of technology and innovation.	Providing seamless care. Improving facilities. Providing greater opportunities in order to attract a highly skilled workforce Maximising the benefits of technology and innovation.
A Healthier Wales: Our Plan for Health and Social Care (June 2018) [10]	'A Healthier Wales' is the Welsh Government's response to the Parliamentary Review. It sets out the vision of a 'whole system approach to health and social care' which is focused on health and wellbeing, and on preventing physical and mental illness. It focuses on 'providing more joined-up services, in community settings', and shifts the emphasis from treating illness to prevention and supporting people to stay well and lead healthier lifestyles.	Addressing the recommendations set out in the Parliamentary Review as described above Focusing on improving access to services that will enable earlier interventions.
The Wellbeing of Future Generations (Wales) Act 2015 [11]	The Wellbeing of Future Generations Act is about improving the social, economic, environmental, and cultural wellbeing of Wales. It makes the public bodies listed in the Act think more about the long-term, work better with people and communities and each other, look to prevent problems and take a more joined-up approach.	Deliver a sustainable service that focuses on Addressing health inequalities Improving outcomes for patients Attracting and developing a highly skilled workforce.

### 1.3.6 Imaging Service strategic aims

There are a range of strategic aims related specifically to Imaging services that are relevant to the programme including:

- Positron Emission Tomography (PET) in Wales - Overview and Strategic Recommendations, All Wales PET Advisory Group (AWPET) and the Welsh Scientific Advisory Committee (WSAC) (November 2018) [6].
- Imaging Statement of Intent, Welsh Government (March 2018) [12].
- Radiology Services in Wales, Auditor General for Wales (November 2018) [13].

- Specialised Services Commissioning Policy: CP50a Positron Emission Tomography, WHSSC and Specialised Services Service Specification: CP50b Positron Emission Tomography - Fixed and Mobile Site [1, 2].

An overview of each of these is provided in sections 1.3.7-10 below.

### 1.3.7 Imaging Service strategic aims: Imaging Statement of Intent

Imaging services in Wales face a number of significant challenges, for example:

- Increasing demand for non-invasive and accurate imaging modalities.
- Workforce issues related to recruitment, training, and retirement.
- The need to diagnose conditions quicker.
- New imaging techniques and technologies.

Such challenges can lead to unnecessary delays in diagnoses and treatment and there is compelling evidence of the need to transform the provision of imaging services in Wales. To respond to these challenges, it is essential that a coordinated implementation plan for imaging services in NHS Wales is developed. To prepare the ground for this, a Welsh Government-led Imaging Taskforce prepared a strategic, forward looking, Statement of Intent [12].

The table below shows how the All Wales PET Programme supports some of the Statement’s key priorities.

Table 3: Programme alignment with Imaging Statement of Intent priorities

Statement of Intent Priority	How the All Wales PET Programme supports this
<b>Workforce development</b>	Makes the case for a well-trained and highly qualified PET-CT workforce, which is flexible and has the correct skill mix. Ensures that the PET-CT service in Wales can attract, retain and develop staff.
<b>Equipment</b>	Sets out the case for new, state-of-the-art equipment to replace ageing facilities, including latest generation digital PET-CT scanners to meet forecast demand for services and a new cyclotron to support the supply of radiopharmaceuticals.
<b>Quality</b>	Improves access to services that will enable earlier interventions and improve clinical outcomes. Provides, through new digital scanners, high quality, detailed images leading to more accurate diagnosis, improved treatment planning and improved clinical outcomes.
<b>Services</b>	Ensures that patients across Wales will have equitable access to PET-CT services. Increases capacity to meet the forecast growth in demand for scanning services.
<b>Research, development and innovation</b>	Provides modern and updated facilities that will create centres and a network of RD&I excellence for staff and will ensure that patients have equitable access to participate in clinical trials.

### 1.3.8 Imaging Service strategic aims: the AWPET Advisory Group ‘PET in Wales’ report

The AWPET report [6] provided the strategic vision for Welsh PET Services and outlined, in broad terms, a strategic plan for PET development in Wales. The table below shows how the All Wales PET Programme supports some of the report’s recommendations:

Table 4: Programme alignment with AWPET report

Recommendation	How the All Wales PET Programme supports this
Indication list should be expanded based on best clinical evidence	Increases capacity to meet the forecast growth in demand for scanning services, which comes partly from a growing list of clinical indications.
Provide an outline business case (OBC) for the replacement of the end of life machine at PETIC	Sets out the case for new, state-of-the-art equipment to replace ageing facilities, including latest generation digital PET-CT scanners to meet forecast demand for services and a new cyclotron to support the supply of radiopharmaceuticals.
Produce a Programme Business Case for PET-CT capacity in Wales	This PBC forecasts capacity based on increased demand projections, and also considers the requirements for estates, staffing and research and innovation. It also ensures patients across Wales will have equitable access to PET-CT services.
Review the licensing of radiopharmaceuticals	Describes the need for an expanded supply chain for radiopharmaceuticals to support the expansion of PET-CT facilities in Wales. Sets out the case for the replacement of the cyclotron at PETIC. Provides a radiopharmaceutical enabling workstream that will fully assess requirements for the programme, including needs to contractually assure supply outside of PETIC remit, potential MA licensing of the cyclotron at PETIC, horizon scanning of the future of radiopharmaceuticals.
Establish a Welsh PET innovation strategy to support RD&I	Provides modern and updated facilities that will create centres of R&D excellence for staff and will ensure that patients have equitable access to participate in clinical trials. Provides an RD&I enabling workstream and group to lead and support implementation of the programme.

### 1.3.9 Imaging Service strategic aims: Radiology Services in Wales, Auditor General

Given the challenges facing imaging services in Wales, the Auditor General began a review of radiology services at all health boards in late 2016. The work examined each Health Board’s arrangements to meet demand for radiology examinations and made recommendations for service improvements.

Table 5: Programme alignment with Auditor General – Key findings

Key findings	How the All Wales PET Programme supports this
Despite increasing demand, diagnostic radiology examination waiting time targets are currently largely being met, however, some patients wait a long time for their examination results.	Providing the appropriate capacity to meet growing demand for PET-CT services
Recruitment, retention and an ageing workforce are threatening the sustainability of the service and limiting Health Boards’ ability to train staff	Developing a PET-CT service and development opportunities that will attract and retain highly skilled staff
Ageing and underutilised equipment are making it harder for health boards to meet demand and health boards do not have the staffing resources to extend opening hours.	Replacing ageing equipment and mobile scanners with new generation digital scanners that can meet the growing demand for PET-CT services

Key findings	How the All Wales PET Programme supports this
Wales-wide radiology IT system challenges and weaknesses in local IT infrastructures inhibit radiology services' efficiency.	Replacing ageing equipment with new generation digital scanners that are enabled for future IT developments.

### 1.3.10 Imaging Service strategic aims: PET commissioning policy

WHSSC commission and approve funding of PET scans for the population of Wales in line with the criteria presented in commissioning policy CP50a [1] and specification CP50b [2] (which covers requirements for both fixed site and mobile scanners). This defines the requirements and standard of care essential for delivering PET-CT for people of all ages who are resident in Wales.

WHSSC is committed to regularly reviewing and updating all of its clinical commissioning policies based upon the best available evidence of both clinical and cost effectiveness. In September 2016, WHSCC established the multidisciplinary All Wales PET Advisory Group (AWPET). This Group is tasked to review the evidence base for PET-CT and advise WHSSC on the introduction of new indications (including non-oncological indications), ensuring that all decisions are made following a systematic review of the available evidence.

The All Wales PET Programme aligns directly with the objectives of the commissioning policy by seeking to deliver a sustainable high-quality PET service for the people of Wales, ensuring there is equitable access to PET-CT and improving outcomes for those accessing PET-CT services.

### 1.3.11 Interdependencies and other relevant programmes and strategies

In developing the proposals within this PBC, a number of other relevant programmes and strategies were considered. These are summarised in the table below.

Table 6: Other relevant strategies and considerations

Strategy Summary	How the All Wales PET Programme supports this
<p><b>Diagnostics: Recovery and Renewal – Report of the Independent Review of Diagnostic Services for NHS England, Professor Sir Mike Richards (December 2020) [14]</b></p> <p>Demand for PET-CT scanning in England grew by 18.7% per annum between 2014/15 and 2018/19. Major expansion and reform of diagnostic services is needed over the next five years to facilitate recovery from the COVID19 pandemic and to meet rising demand for all diagnostic services. The review recommends:</p> <ul style="list-style-type: none"> <li>• scanning equipment should, as a minimum, be expanded in line with growth rates prior to the pandemic and all imaging equipment older than 10 years should be replaced;</li> <li>• a major expansion in the workforce with an additional 2000 radiologists and 4000 radiographers [in England];</li> <li>• improving connectivity and digitisation to deliver seamless care across traditional boundaries and facilitate remote reporting.</li> </ul>	<p>Increases capacity to meet the forecast growth in demand for scanning services.</p> <p>Sets out the case for new, state-of-the-art equipment to replace ageing facilities, including latest generation digital PET-CT scanners and a new cyclotron to support the supply of radiopharmaceuticals</p> <p>Ensures that the PET-CT service in Wales can attract, retain and develop staff.</p>

Strategy Summary	How the All Wales PET Programme supports this
<b>The Single Cancer Pathway, Next Steps To Achieve Earlier Diagnosis In Wales, Cross Party Group on Cancer (November 2020) [15]</b>	
<p>Inquiry into cancer waiting times in Wales to consider how the new Single Cancer Pathway was being implemented during its first year, as well as develop recommendations to identify next steps for cancer diagnosis in Wales. The report made a series of recommendations including:</p> <ul style="list-style-type: none"> <li>• developing a comprehensive cancer strategy to support the Cancer Delivery Plan;</li> <li>• re-starting reporting against the Single Cancer Pathway, which was paused during the Covid-19 pandemic;</li> <li>• increasing the amount of diagnostic equipment to ensure adequate capacity to manage rising demand for diagnostic services.</li> </ul>	<p>Increases capacity to meet the forecast growth in demand for scanning services.</p> <p>Sets out the case for new, state-of-the-art equipment to replace ageing facilities, including latest generation digital PET-CT scanners to meet forecast demand for services and a new cyclotron to support the supply of radiopharmaceuticals</p>
<b>Rapid Diagnostic Centres [16]</b>	
<p>Following a study tour to Denmark to investigate their initiatives to improve cancer diagnosis, Wales is now testing the Danish model by piloting access to rapid diagnostic centres. The centres take referrals for patients who present to primary care with serious but non-specific symptoms, where the GP suspects this could be due to cancer and needs further investigation.</p>	<p>The Programme will engage with this initiative.</p>
<b>Radiology Informatics System Procurement Programme (RISPP) [17]</b>	
<p>The Radiology Informatics System Procurement (RISP) Programme is supporting the modernisation of imaging services across Wales. From 2020 to 2024 the Programme aims to procure an innovative system that will provide a seamless end-to-end electronic solution, from receipt of a referral to the delivery of a radiology report. This will include:</p> <ul style="list-style-type: none"> <li>• a Picture Archive System (PACS) - storing all diagnostic imaging files;</li> <li>• a Radiology Information System (RIS) - allowing users to track patient records</li> </ul>	<p>Will be considered in developing the Programme and in implementation.</p> <p>The All Wales PET Programme will engage with the RISPP where appropriate and required.</p>
<b>The National Imaging Academy Wales (NIAW)</b>	
<p>Established in 2018, the Academy is Wales' flagship purpose-designed, state-of-the-art facility which will meet the increasing need to train radiologists and imaging professionals across the UK.</p>	<p>The Programme supports the aims of the National Imaging Academy by creating centres of excellence to attract and retain highly trained and qualified staff.</p>
<b>Heart Conditions Delivery Plan 2017, Welsh Government [18]</b>	
<p>Plan to both minimise the incidence of preventable heart disease and ensure patients have timely access to high quality pathways of care, irrespective of where they live.</p> <p>Diagnostic tests should be provided as early (within 8 weeks) and as locally as possible.</p> <p>Health Boards should ensure that diagnostic procedures, technologies, treatment and techniques are in line with the latest evidence.</p>	<p>Range of clinical indications may be in scope of PET scanning. Will be considered when developing the Programme.</p>

Strategy Summary	How the All Wales PET Programme supports this
<b>Dementia Delivery Plan 2018-2022, Welsh Government [19]</b>	
Currently only around 53% of individuals in Wales with dementia have a diagnosis. The plan therefore sets targets for health boards to increase diagnosis rates by at least 3% a year.	Range of clinical indications may be in scope of PET scanning. Will be considered when developing the Programme further.
<b>Neurological Conditions Delivery Plan 2017, Welsh Government [20]</b>	
There are around 100,000 people with a neurological condition in Wales. All GPs should have direct access to a range of diagnostic tests and procedures where a neurological condition is suspected. Health Boards should ensure research findings result in service change to improve clinical practice and patient outcomes so patients get quicker access to innovative new diagnostic tools, treatments and medical technologies.	Range of clinical indications may be in scope of PET scanning. Will be considered when developing the Programme further.
<b>Getting it Right First Time Programme National Speciality Report, Radiology (2020) [21]</b>	
The GIRFT report examines ways of meeting the ever-increasing demand on radiology units in England at the same time as shaping a better service for those who use it.	Provides examples of the ways in which existing capacity can be maximised and services expanded. Suggests patient-centred measures that are of interest to the All Wales PET Programme.

### 1.3.12 Relevant regional issues

There are a number of initiatives taking place across the Welsh Health Boards and other organisations that will have an impact on the Programme.

#### Betsi Cadwaladr UHB

Initiatives to be considered by the programme:

- The restructure of nuclear medicine in north Wales.
- The Nuclear Medicine service in north Wales, which includes gamma cameras and the mobile PET service, is being consolidated. Currently the service is provided utilising three gamma cameras - one on each of the three main acute hospital sites - and one mobile PET-CT, which is located in Wrexham for two days a week. A Strategic Outline Case (SOC) was submitted to Welsh Government in October 2020 and identifies a series of issues with the Nuclear Medicine service configuration which make it unsustainable in the short and long term, in particular:
  - difficulties in staffing three separate services;
  - obsolete equipment;
  - falling demand for the gamma camera service; and
  - increasing demand for PET-CT.
- The SOC notes that there is an opportunity to improve the quality of the service, make it more resilient and reduce revenue costs.
- The preferred way forward identified in the SOC is to consolidate services in a single Centre of Excellence for Nuclear Medicine at one of the three acute sites across North Wales. The Centre would consist of two gamma cameras and one permanent fixed PET-CT scanner, and would be housed by a combination of new building and refurbishment work. The gamma camera and PET-

CT service would be run by the same radiographers and administrative staff. The programme is currently out to public consultation and the outcome of this is a clear interdependency to delivering this All Wales PET Programme.

### Velindre NHS Trust

Initiatives to be considered by the programme:

- Re-provision of the Velindre Cancer Centre on a new site in Cardiff may affect the patient flow to PETIC and may offer opportunities to the All Wales Programme.

### Swansea Bay UHB

Initiatives to be considered by the programme:

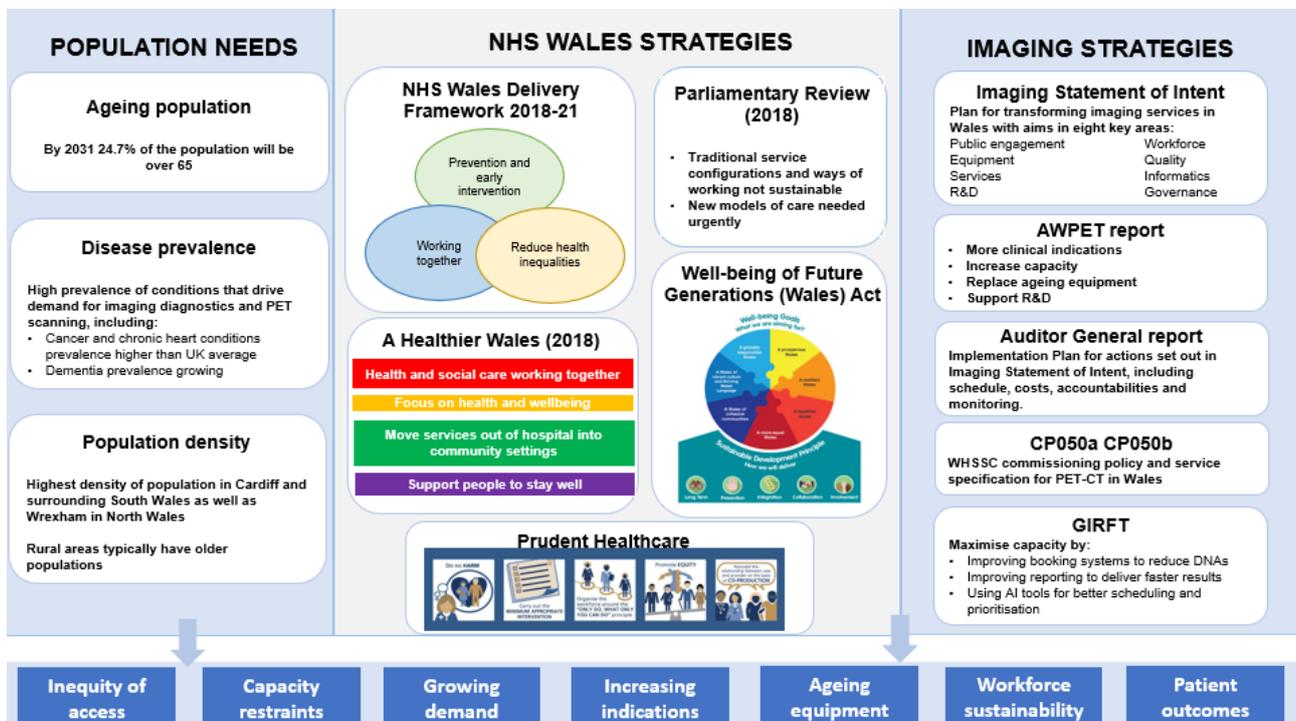
- Currently has an active project that is putting in place two new SPECT cameras and associated facilities.

## 1.3.13 Summary

The All Wales PET Programme seeks to address population needs while aligning with the strategic direction of Wales and addressing specific strategic issues within the Imaging service. Other relevant strategies and interdependencies with related programmes have been considered in developing these proposals.

An overview of the overall strategic context is provided in the illustration below (Figure 5).

Figure 5: Strategic context



## 1.4 The Case for Change

### 1.4.1 Introduction

This section of the PBC establishes the case for change that is driving the All Wales PET Programme, providing a clear understanding of:

- The spending objectives (what the programme is seeking to achieve).
- Existing arrangements (what is currently happening).
- Business needs (what is required to close the gap between existing arrangements and where the service needs to be in the future).

### 1.4.2 Spending objectives

Spending objectives describe what the programme is seeking to achieve and provides a basis for post-programme evaluation.

The spending objectives were partly informed through early engagement with service providers. A clinical questionnaire was sent to healthcare professionals at all PET providers in Wales and asked the following questions:

- In general terms, what are we not doing now that we should? This could include additional clinical indications for a PET scan, more research, further investment in infrastructure, education and training etc.
- What would you perceive to be the main clinical areas where the demand for PET scans (new indications) will change over the next 5 years, for example cardiology, dementia etc. and to what extent?
- What are the likely technical developments in the pipeline we need to be aware of and factor into future PET imaging services? This maybe to do with advances in technology (more efficient machines, all body PET, more sensitive/specific isotopes etc.)
- Considering the existing PET service across Wales, Is there anything we should not be doing/stop doing?

The questionnaire was sent to 23 clinicians, 12 of whom responded (six Medical Physicists, six PET Consultant Radiologists). The responses were also used to inform the clinical demand model. A summary of the responses is included in Appendix 3.

The final spending objectives were discussed as part of a workshop and subsequently approved by the PET Strategic Programme Board in February 2021 and these are outlined below.

- **SO1** - To improve the quality of PET service provision for Welsh patients by delivering better patient outcomes.
- **SO2** - To ensure a sufficient workforce to deliver a high-quality service.
- **SO3** - To improve delivery of the All Wales PET Service by efficient use of PET-CT scanners, facilities, processes and infrastructure.
- **SO4** - To ensure that the future All Wales PET service provides a cost-effective service for patients and NHS Wales.
- **SO5** - To widen the scope of the All Wales PET service, to meet recognised international best practice.

### 1.4.3 Existing arrangements

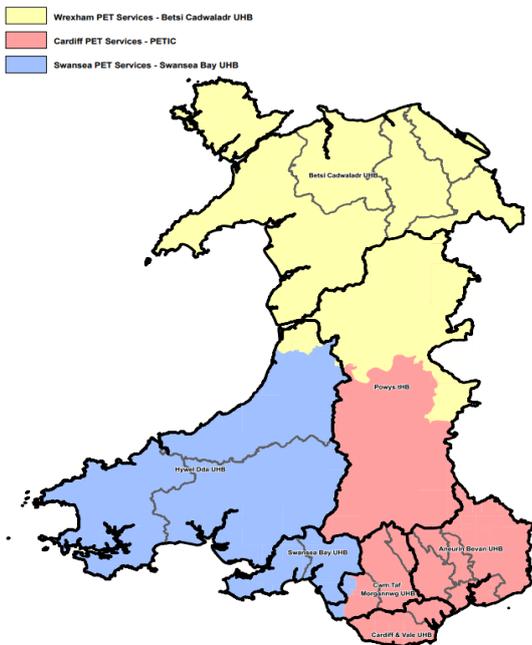
There are currently three PET-CT service providers in Wales, each with an analogue scanner:

- A full-time fixed site and cyclotron in Cardiff at the Wales Research and Diagnostic Positron Emission Tomography Imaging Centre (PETIC). This is a Cardiff University owned PET-CT scanner, which is situated at University Hospital Wales Cardiff site.
- A mobile service at Wrexham Maelor Hospital (2 days per week), provided by Alliance Medical.
- A mobile service at Singleton Hospital in Swansea (2 days per week), provided by Alliance Medical.

#### Referral routes

Patients are referred for a range of PET-CT scans by consultants or other members of the multi-disciplinary team (MDT).

Figure 6: PET services catchment areas, Wales



Patients in South East Wales (excluding Swansea Bay, Hywel Dda and West Bridgend) and parts of Mid Wales are referred to the Wales Research and Diagnostic PET Imaging Centre (PETIC) Cardiff. Patients in South West Wales, and parts of Mid Wales are referred to the mobile PET-CT service at Singleton Hospital, Swansea.

Patients in North Wales and parts of Mid Wales are referred to Nuclear Medicine, Wrexham Maelor Hospital, Wrexham. The patient flow for mid Wales generally follows the pattern for cancer referral to the north and south Wales specialist centres. Patients from mid Wales who would otherwise be referred to the Royal Shrewsbury Hospital for specialist treatment are referred to north Wales for PET scans.

#### Clinical indications

PET-CT scans are offered in line with the WHSSC Commissioning policy [1]. When treatments are not routinely available, patients who might get particular benefit can still access the treatment through a process called Individual Patient Funding Requests (IPFR).

Funding requests are considered by the all Wales IPFR Panel. The purpose of the Panel is to act as a Sub Committee of WHSSC and hold delegated Joint Committee authority to consider and make decisions on requests to fund NHS healthcare for patients who fall outside the range of services and treatments that a Health Board has agreed to routinely provide.

Each year the AWPET Advisory Group review evidence and advise WHSSC on new clinical indications that may be commissioned for PET scans. When considering requests for new indications, the AWPET Advisory Group will also review the list of recent IPFR applications and assess any trends in requests when advising WHSSC.

## Activity levels

For Wales overall, under the current commissioning policy, 3,865 scans were completed in 2020-21, which equates to approximately 1,246 scans per million population. There was a significant drop in PET referrals during the period March-June 2020, related to the first wave of the COVID-19 pandemic, but this activity had returned to 'normal' levels by the end of 2020.

The table below shows current activity levels for each of the three individual PET-CT centres. Please note that Swansea PET scanning went "live" in July 2020, so the table includes just nine months of activity for 2020-2021. The annual equivalent would be 1,061 scans.

Table 7: Current and forecast activity levels

Year	PETIC, Cardiff (South East)		Wrexham (North Wales) 2 days per week		Swansea (South West) 2 days per week		Total no. PET scan
	NHS Scans	Growth	NHS Scans	Growth	NHS Scans	Growth	
2010-11	675	n/a					675
2011-12	1,285	90%					1,285
2012-13	1,417	10%					1,417
2013-14	1,619	14%					1,619
2014-15	1,920	19%					1,920
2015-16	2,119	10%	794	N/A			2,913
2016-17	2,263	7%	784	-1%			3,047
2017-18	2,318	2%	763	-3%			3,081
2018-19	2,667	15%	771	1%			3,438
2019-20	2,939	10%	819	6%			3,758
2020-21	2206	N/A*	891	9%	768 <sup>#</sup>	N/A	3,865

The figures for this table have been submitted to WHSSC by the service providers at each site. South East Wales are provided by Prof Chris Marshall, for South West Wales by Professor Neil Hartman, and for North Wales from Dr Mark Elias. \*Fall in activity due to Covid-19 and provision of new capacity at Swansea from July 2020. #Scanner at Swansea was opened in July 2020.

## Commissioning beyond Wales

A very small number of patients from South Wales currently travel to London centres for Gallium DOTA-PET imaging (approximately 50 per year). Some patients from North Wales have PET scans in English centres but this number is low.

## Supply of radiopharmaceuticals

All three Welsh sites offer 18F-FDG and 18F-PSMA PET scans. However, as PETIC benefits from an onsite cyclotron, it is able to offer a wider range of scans to patients.

The cyclotron at PETIC Cardiff is producing 18F-FDG, 18F-PSMA, 18F-Fallypride, 18F-DOPA and 18F-FMZ. PETIC is supplying 18F-FDG, 18F-PSMA, 18F-Fallypride, 18F-DOPA and 18F sodium fluoride to external providers and industry.

Under the Specials Licence, PETIC is supplying 18F-PSMA to Swansea, Bath, Poole, Plymouth and Bristol and 18F-DOPA to Manchester and London.

Under licensing rules, as PETIC does not hold Marketing Authorisation for 18F-FDG, it is currently unable to sell this product commercially to other sites within Wales. Instead, PETIC has a contract with Alliance Medical meaning PETIC can only supply other sites when/if Alliance Medical is unable to meet demand. Under the Specials License, PETIC is able to provide other UK sites products such as 18F-PSMA, 18F-DOPA and 18F-Fallypride.

### Summary of current PET-CT facilities in Wales

The table below (Table 8) summarises PET-CT infrastructure, staffing and radiopharmaceutical position across each site.

Table 8: PET-CT centres summary

	PETIC	Wrexham	Swansea
Population served	1,661,810	711,946	777,008
Date site was established	2010	2015	July 2020
PET sessions per week (a session is considered to be half a day of scanning)	Nine - Two extended days (Tues and Wed), half day Fri	Four to five	Four
Cyclotron present (Y/N)	Y	N	N
Fixed or mobile	Fixed	Mobile (Alliance)	Mobile (Alliance)
Research activity undertaken at site (Y/N)	Y	Y (limited)	Y (limited)
Staffing	Onsite Clinical Radiologists from C&V, in addition to hub and spoke model for radiologists from Aneurin Bevan, Velindre and Cwm Taf (in discussion). Radiographers from C&V, Medical Physics staff from Cardiff University, radiopharmaceutical production staff from Cardiff University	Alliance staffing – comes with mobile scanner Local BCUHB team (Nuclear Medicine Dept.) undertake booking PET appointments and liaising with referrers, patients and Alliance Medical. Justification of the medical Exposures, reporting of the images and requisition of the PET Tracer from Cyclotron	Alliance staffing – comes with mobile scanner Swansea Bay UHB provides its own booking staff, clinical scientists, RPA, reporting, waste management, financial management.
Scan types offered / radiopharmaceuticals used	18F-FDG, 18F-PSMA, 18F-DOPA, 18F-Fallypride, 18F-FMZ	18F-FDG, 18F-PSMA	18F-FDG, 18F-PSMA
Sources of radioisotopes	Manufacture own 18F-FDG and 18F-PSMA External supply of 18F-FDG and 18F-PSMA as back up and cover for 4 service weeks per annum. Only site in UK manufacturing 18F-DOPA supporting specialised paediatric insulinoma clinical services in Manchester and London. Only site in UK manufacturing 18F-Fallypride and 18F-FMZ currently for research only. 18F-Fallypride also supplied for research purposes to London. Not possible to supply 18F-FMZ at moment but developing new production method in conjunction with commercial partner. Manufactures and supply 18F-sodium fluoride to a number of research institutions.	18F-FDG supplied by Alliance Medical as part of package with scanning 18F-PSMA sourced from PETNET and delivered from Nottingham	18F-FDG sourced from Alliance Medical and delivered from Guilford, London 18F-PSMA sourced from Alliance Medical, however manufactured and delivered by PETIC

	PETIC	Wrexham	Swansea
Referral pathways	WHSSC CVUHB ABUHB Mid and South Powys Mid and East CTMUHB Epilepsy service commissioned by C&V epilepsy service Epilepsy service commissioned by Bristol epilepsy service Paediatric Cancer for SW England commissioned by NHS England	WHSSC BCUHB & North Powys  The following external referrers who see BCUHB / North Powys Patients on behalf of Welsh NHS: North Powys Shropshire (RJAH / SaTH NHS Trust) Countess of Chester Hospital Liverpool Heart & Lung Hospital Clatterbridge Cancer Centre	WHSSC Hywel Dda Swansea Bay West CTUHB
Site issues / strategic considerations	Several significant items of equipment are 11 years old and in need of replacement. Business Justification Case is in preparation.	Consolidation of Nuclear Medicine is underway across North Wales. SOC has been submitted to WG and is out to public consultation. One site is proposed to include Nuclear Medicine (SPECT-CT) and PET-CT and no site selection at time of writing this PBC.	

### Information Technology

The existing arrangements in relation to the processing of referrals are as follows:

- Referrals are currently made using paper forms that are printed out and sent to the relevant PET site using email or fax.
- Administrators or “booking clerks” at each site need to manually update local data systems to make and track appointments and order materials for scanning, including radiopharmaceuticals. Booking clerks liaise with referrers directly via email or phone to clarify referral needs, where forms are not completed fully.
- In addition, the gatekeeping for referrals carried out by consultant radiologists is done manually and “off line”.
- Where relevant, administrators spend time retrieving previous scans from other sources to best inform clinical decision making.
- Post scan, a radiographer then sends scan data to the PACS system for the clinical radiologist to subsequently report on the PACS system.
- A frequent operational issue is the failure of data transfer from the mobile scanning units via a data cable to PACS for reporting which results in having to manually import studies from DVD which is slow and delays reporting.

### Facilities

The fixed scanner and cyclotron at the PETIC site are now beyond their recommended useful age and urgently require replacing. Replacement parts for the PETIC scanner are no longer manufactured hence the site is currently functioning “at risk”.

The sites at Wrexham and Swansea make use of mobile scanners which also have significant limitations and issues (see Table 15: Mobile vs fixed scanners).

## Workforce

The imaging workforce is in a critical situation across the UK. There is an increasing clinical demand across all imaging modalities, and capacity issues are exacerbated by difficulties in recruiting consultant radiologists<sup>3</sup>, radiographers<sup>4</sup>, radio pharmacists and other nuclear medicine staff - the level of difficulty varies according to geographical location [12, 13]. Clinical imaging remains a popular specialty for medical trainees but training capacity does not match current workforce deficits.

According to the Clinical radiology Wales workforce summary published by the Royal College of Radiologists (RCR; 2019) [22], “there are still not enough consultant radiologists to deliver safe and effective care”, with this report further noting regional variation in staffing across Wales and shortages in clinical radiology specialists being areas of concern.

Wales has 7.8 consultant clinical radiologists per 100,000 population [22], compared to a European average of 12.8. Wales has the oldest demographic of consultant radiologists in the United Kingdom; based on a retirement age of 62 years, 26% are anticipated to retire by 2020 [12]. The number of ARSAC practitioners is reducing with retirement.

Indeed the situation facing the imaging workforce has been further highlighted in the recent RCR Clinical Radiology UK Workforce Census 2020 report (2021) [23]. This report clearly outlines how the demand for diagnostics is increasing faster than the demand for NHS services as a whole, how waiting times have lengthened due to the pandemic with 58% of Clinical Directors reporting insufficient Clinical Radiology consultants. Specifically, this report notes that how £8.1 million was spent by NHS Wales on outsourcing reporting (of all imaging modalities) to the independent sector and ad-hoc locums.

Critically, the RCR 2020 census [23] notes that over the past five years there has been an 11% decline in ARSAC license holders, with many professionals approaching retirement age or have retired and returned. Many service providers are soon to be reliant on contractual agreements with other trusts or health boards and the report highlights that “health boards must ensure succession plans are in place for ARSAC license holders”.

The situation for radiographers and clinical scientists is no better. According to a 2019 workforce survey carried out by the Institute of Physics and Engineering in Medicine (IPEM), 33% of UK centres stated their current staffing provision was sufficient. 57% of UK centres felt their staffing provision was not sufficient. The IPEM report noted “the precarious nature of staffing this specialism, with most services stretched to capacity, and concerns were expressed of potential increase in demand or area of coverage”. The report also highlighted the concerns expressed over future workforce supply, and the just-about-managing description of the workforce is not future-proof, and while safe, does not have sufficient capacity to research, develop, and implement new technologies.

As a result of the Imaging Statement of Intent the National Imaging Academy Wales (NIAW) was established in 2018 to “develop a sustainable and flexible imaging workforce to deliver a modern, responsive diagnostic imaging service for Wales”. In addition, Health Education and Improvement Wales (HEIW) were tasked with facilitating the development of an integrated workforce training strategy for radiologists, radiographers, sonographers, advanced practitioners, assistant practitioners and other imaging healthcare professionals in Wales, including Medical Physics.

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<sup>3</sup> Also refers to Consultant Nuclear Medicine Physician throughout this document

<sup>4</sup> Also refers to Nuclear Medicine Technologists throughout this document

Further information on the training routes for all professions included in PET scanning can be found in Appendix 7.

The three current PET sites in Wales are set up differently, so there is some variance in how staffing is currently structured.

PETIC makes use of a pool of 15 radiographers/nuclear medicine technologists in CVUHB, currently deemed competent and entitled to perform PET scans. These are typically cross trained from the nuclear medicine pool. Having a large pool of staff competent to scan in Cardiff provides some resilience with regard to service expansion.

A similar model is employed for administrative staff. There is currently a pool of three booking clerks who can book PET-CT scans at PETIC, again providing resilience. In addition, PETIC has several consultant radiologists, one clinical scientist and a business manager. As the site at PETIC consists of a cyclotron, there are multiple technical posts associated with radiopharmaceutical production. In addition, several research posts are at this site.

The appointment of researchers also provides an additional route for clinical scientist accreditation. Students who obtain a PhD in a suitable subject can obtain state registration as clinical scientists through the equivalence route (<https://www.ahcs.ac.uk/equivalence/>). In addition, researchers may also obtain practical skills in radiochemistry which can translate into technical posts supporting the production of radiopharmaceuticals in Wales, another area with significant staffing issues. The active PhD programme in PETIC offers another pool of staff that may be utilised to meet the increasing demands of the clinical service.

For the mobile scanning sites in South West and North Wales, Alliance Medical (AML) provide the mobile scanner and three scanning operators per scanner (two to three imaging technologists/radiographers, and one healthcare assistant) and the RPA (radiation protection advisor). The local "host hospital" then provides the booking staff, waste management, governance, management of the PET-CT service, consultant radiologist reporting of scans and finance business partner for the fiscal aspects. The Swansea site has a clinical scientist for dosimetry, however Wrexham does not. Dosimetry is part of the Medical Physics Expert (MPE) role, which is contractually provided by Alliance Medical in North Wales. Additionally, the RPA role is externally contracted by AML and the RPA is rarely on site, but available by phone to the mobile van staff.

Swansea has just written and agreed an SLA with Alliance Medical to allow existing local nuclear medicine staff (technologists/radiographers and clinical scientists) to gain experience/shadowing on the mobile PET scanner, with a view to ensure that staff are partially trained and developed for future needs, and to ensure a degree of resilience when an AML staff member is absent (sickness, etc.). Wrexham has a clause within the contract with AML to facilitate training of BCUHB staff when required.

Currently BCUHB (North Wales) has a Strategic Outline Case which is going through a consultation stage with the aim of consolidating Nuclear Medicine and converting the existing mobile PET-CT service to a fixed scanner, based at the consolidated site. It is expected that the workforce model will have staff working in both conventional gamma camera and PET-CT, and supplementary training will be required.

For further detail on existing arrangements for the PET workforce, please see Appendix 7.

### 1.4.4 Business needs

There are a number of challenges within existing arrangements that mean over the long term it will prove increasingly difficult to deliver a sustainable high-quality PET service for the people of Wales that ensures equitable access to PET-CT and improves outcomes.

The main challenges include:

- Insufficient capacity to improve the quality of provision and deliver better patient outcomes since:
- The service underperforms in relation to UK and international best practice in terms of number of funded indications, number of scanners and supporting infrastructure.
- Demand is growing and the list of indications is expanding.
- Challenges in training, recruiting and retaining the highly skilled workforce required to deliver a high-quality sustainable service.
- Limited ability to improve delivery by efficient use of scanners, facilities, processes infrastructure, due to the use of ageing analogue scanners and reliance on mobile units and outsourcing arrangements.
- Reliance on external suppliers which limits opportunities to reduce costs and improve efficiencies and deliver a service for patients and NHS Wales that offers best value for money.
- Current facilities and the reliance on mobile units which limit the ability to broaden RD&I opportunities.

These business needs are explored in greater detail in relation to each of the five spending objectives below.

### 1.4.5 SO1: To improve the quality of PET service provision for Welsh patients by delivering better patient outcomes

When compared to the devolved UK nations, Europe and the developed world, Wales significantly underperforms in terms of PET-CT scans per head of population, density of PET scanners and the wider PET-CT infrastructure.

Although the situation has improved in the last three years, with an expansion of funded indications [1] and the opening of a second WHSSC-commissioned mobile PET unit for two days per week in Swansea in the summer of 2020, there is still significant progress to be made.

#### Patient View on accessing a PET scan at Swansea

“ Before the scan the patient said ‘I don’t want to drive to Cardiff’ and his daughter said ‘getting elderly patients to Cardiff is unsafe and unacceptable in these times’.

The table below provides a comparison of Wales to the number of scans carried out in England, per million of population. It is clear that Wales is currently carrying out significantly lower numbers (approximately 33%) of PET scans per head of population compared to England, despite having a higher prevalence of cancer and other chronic diseases (see Section 1.3.3 and 1.3.4, and Table 9). There are various reasons for this difference, including:

- fewer commissioned indications in Wales compared to England;
- lack of geographic access to PET-CT for North Wales and South;
- historic under-referral; and

- tighter gatekeeping in Wales compared to England.

Table 9: Number of PET-CT scans per million population

Country	2015/16	2016/17	2017/18	2018/19	2019-20
England	1,849	2,100	2,600	3,150	3,533
Wales	922	975	985	1,100	1,192

Welsh actual number of scans sourced from WHSSC. England number of scans sourced from [Diagnostic Imaging Dataset Annual Statistical Release 2019/20](#) \*Number of scans divided by population numbers from ONS.

In the Royal College of Radiologists (RCR) 2005 strategy document “PET-CT in the UK: a strategy for development and introduction of a leading-edge technology within routine clinical practice” [24] the working party recommended initially, one PET-CT per 1.5 million population is planned to reflect the current role in cancer management.

Progress has been made in other devolved nations since 2005, and according the NCRI and local intelligence, there are now 1.05 PET scanners per million population in England (Table 10).

Table 10: Comparison of number of scanners within the UK

Country	Fixed PET CT	Mobile PET CT	PET MR	Scanners per million
England	37	20	1	1.05
NI	2	0	0	1.05
Scotland	6*	0	1	1.27
<b>Wales</b>	<b>1</b>	<b>0.8</b>	<b>0</b>	<b>0.60</b>

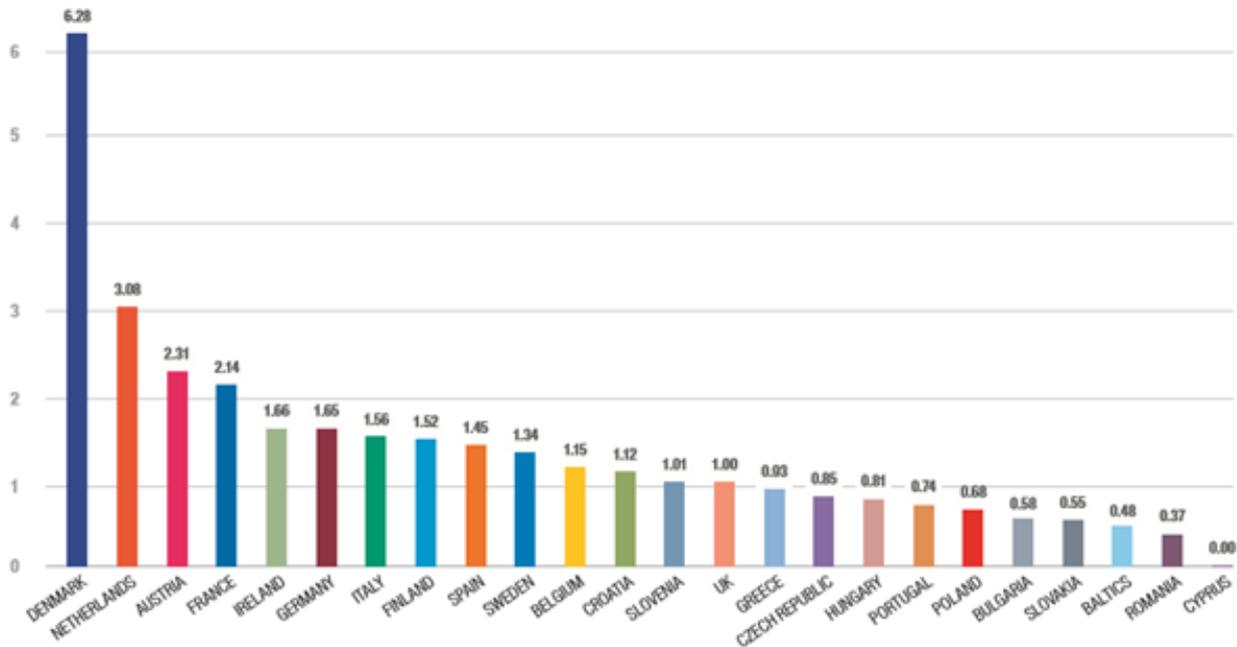
Data sources from: [http://www.ncri-pet.org.uk/pet\\_scanning\\_and\\_cyclotron\\_facilities.php](http://www.ncri-pet.org.uk/pet_scanning_and_cyclotron_facilities.php) and informal communication between Clinical Programme Board Chairs and Regional Chairs for Scotland, Northern Ireland and England. \*5 NHS PET-CT. 1 research PET CT

In the rest of the UK, PET-CT has moved out of specialist commissioning and tertiary centres to become a routine part of the equipment available in nuclear medicine departments of teaching hospitals and large District General Hospitals.

It is clear from Table 10 that the number of scanners per head of population in Wales is significantly lower than the rest of the UK. The picture becomes worse when comparing the number of scanners in Wales to the rest of Europe and beyond.

The 2016 edition of the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry report on “Medical Imaging Equipment Age Profile and Density” [25] shows the UK position to be a density of 1 PET-CT scanner per million. Welsh provision is 0.60 scanners per million population, which is comparable to Bulgaria and Poland (Figure 7).

Figure 7: Density of PET-CT scanners in the EU (scanners per million population)



According to “Healthcare resource statistics - technical resources and medical technology” (Eurostat, 2020) [26], there has been “a notable increase in the number of positron emission tomography (PET) scanner units” across Europe, with France increasing its number of PET-CT scanners from 9 in 1998 to 156 in 2018. According to this publication, the number of PET-CT scanners ranged from 0.0 per 100,000 population in countries such as Liechtenstein, Romania and Serbia, to 0.8 per 100,000 population in Denmark (Figure 8).

A more recent publication explored PET-CT services across 21 jurisdictions in seven countries (Australia, Denmark, Canada, Ireland, New Zealand, Norway and the UK). It assessed service provision to better understand the impact any variation may have upon cancer services. The authors found that the number of PET-CT scanners per 100,000 population in Wales was the lowest (0.04 per 100,000 in 2017 with 1.2 scanners) (Lynch et al., 2020) [27]. Following the introduction of a mobile scanner in Swansea in 2020, the figure has risen to 1.4 scanners equating to 0.047 scanners per 100,000 population, which would still see Wales at the lowest ranking in this comparison (

Figure 9).

Lynch et al., (2020) noted that the growth in PET-CT in Denmark is likely to be reflective of changes brought about by the 2007 National Danish Invitation to Tender for Delivery of Cancer Scanners, as well as the introduction of national integrated pathways for cancer care [28]. Lynch et al., (2020) went on to highlight that recent ICBP research demonstrated improvements in cancer survival in Denmark, for example from 27.5% 1-year lung cancer survival (1995-1999) to 46.2% (2010–2014) [29].

This will have been influenced by a multitude of factors, one of which may well be the increase in capacity of PET-CT services based on more accurate cancer staging and treatment planning [27, 30].

Figure 8: Availability of imaging equipment – PET scanners 2013 and 2018 (per 100,000 inhabitants)

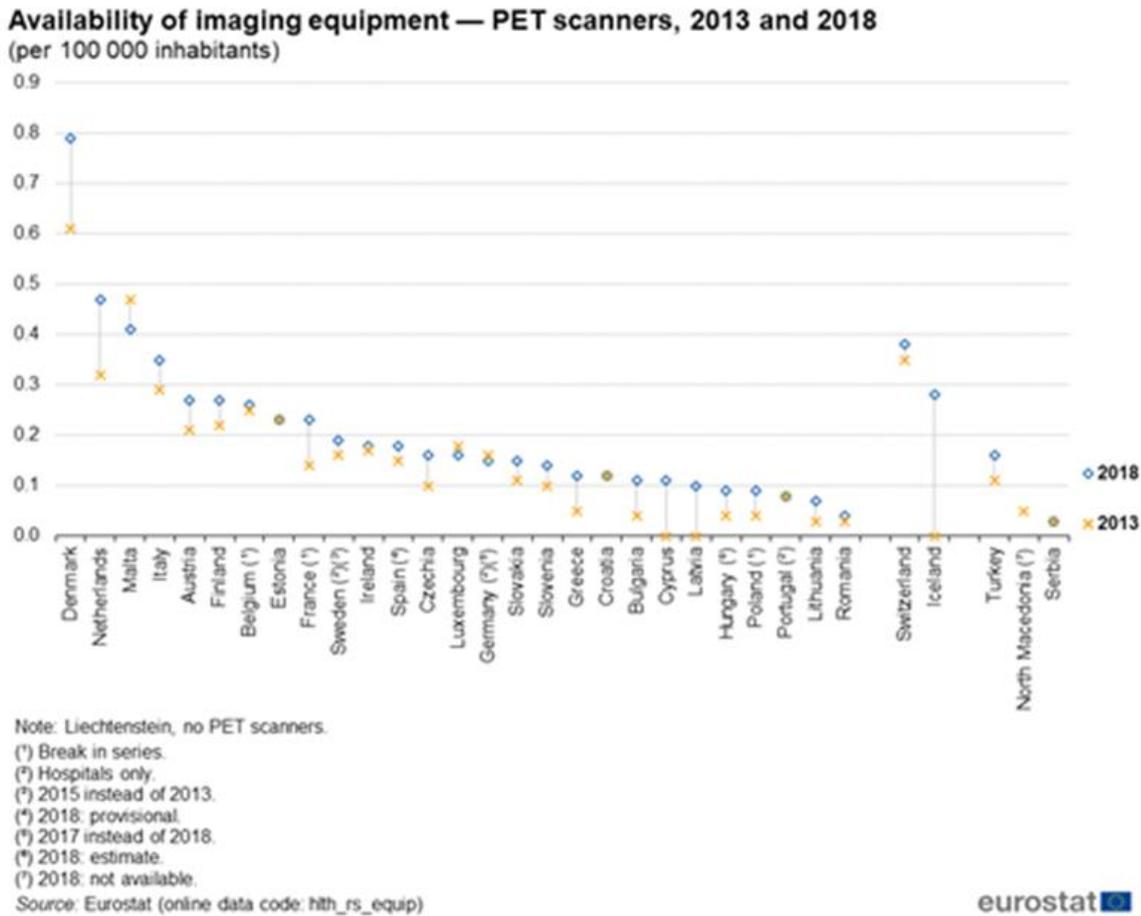
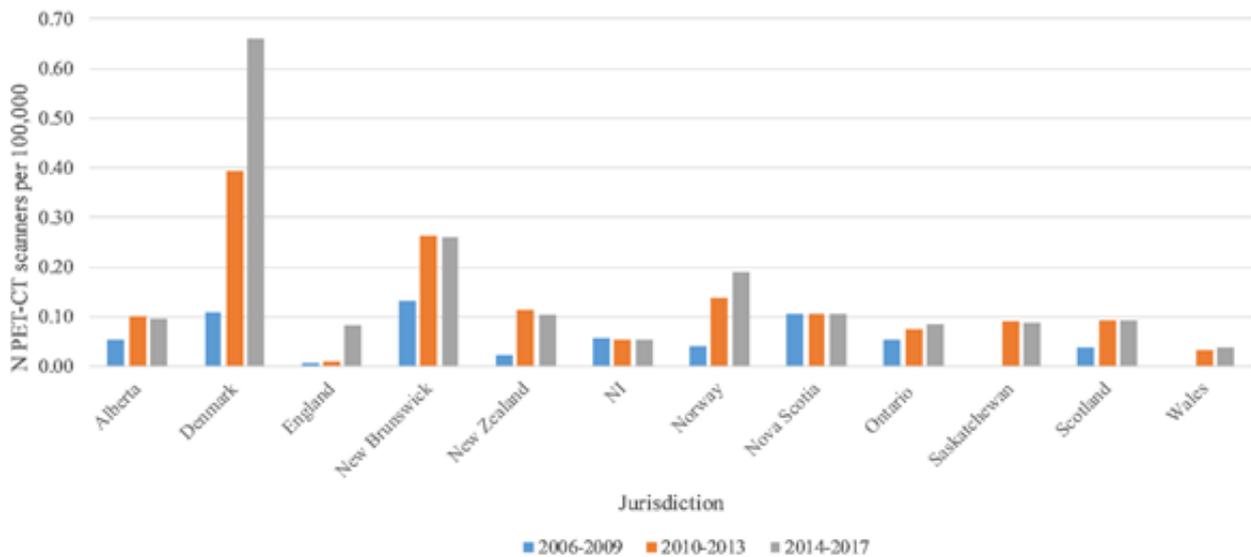


Figure 9: Comparative analysis



A comparative analysis: international variation in PET-CT service provision in oncology—an International Cancer Benchmarking Partnership study <https://academic.oup.com/intqhc/advance-article/doi/10.1093/intqhc/mzaa166/6030987>

### Provide capacity to meet growing demand

As well as addressing the business need for provision of scanning capacity to meet the growing clinical demand for PET scans, there is also a need to increase and secure capacity of the wider infrastructure.

### Expanded list of clinical indications

The number of clinical indications commissioned in Wales has historically lagged behind other devolved UK nations and comparable international healthcare systems. However, this discrepancy is improving and more indications have been funded and commissioned by WHSSC every year since 2016 (Table 11). Please see Appendix 5 and 6 for a full description.

Whilst the number of commissioned indications in Wales is increasing, greater progress still needs to be made.

It appears that tighter ‘gatekeeping’ or reviewing of referrals in Wales compared with England may be an additional factor. The necessary widening scope of commissioned indications will undoubtedly add to the scanning capacity issues that face PET provision across Wales.

Table 11: Comparison of UK PET commissioning indications

		England	Wales (2016)	Wales (2018)	Wales (2020)	Wales (2021)
FDG Oncology	Brain	Covered	None	None	None	None
	Head and Neck	Covered	Some	Most	Covered	Covered
	Thyroid	Covered	None	Covered	Covered	Covered
	Lung	Covered	Some	Covered	Covered	Covered
	Pleura	Covered	Some	Some	Some	Some
	Thymus	Covered	None	None	None	None
	Oesophagogastric	Covered	Most	Most	Covered	Covered
	GIST	Covered	None	None	None	Covered
	Breast	Covered	None	Covered	Covered	Covered
	HPB	Covered	None	None	Some	Most
	Colorectal	Covered	Most	Most	Most	Most**
	Urology	Covered	None	None	Some	Most
	Gynaecology	Covered	Some	Most	Covered	Covered
	Testicular	Covered	None	None	None	None
	Anal and penile	Covered	Some	Some	Some	Some
	Lymphoma	Covered	Most	Most	Most	Most **
	Myeloma	Covered	Some	Most	Most	Most
	Skin	Covered	None	None	None	None
	Musculoskeletal	Covered	None	Most	Most	Most
	Paraneoplastic	Covered	Some	Some	Some	Most
	Carcinoma unknown primary	Covered	Some	Some	Some	Some
	Neuroendocrine	Covered	None	Covered	Covered	Covered
	Rare childhood	Covered	None	None	Most	Most
	Pre SABR	Not specifically covered	None	None	Covered	Covered
Neurology	Covered	Some	Some	Some	Most	

		England	Wales (2016)	Wales (2018)	Wales (2020)	Wales (2021)
<b>Non oncology FDG</b>	Cardiology	Covered	Some	Some	Some	Some
	Vasculitis	Covered	None	None	Covered	Covered
	Sarcoid	Covered	None	None	Most	Most
	Infection	Covered	None	None	Covered	Covered
	PUO	Covered	None	None	Covered	Covered
<b>Non FDG</b>	Methionine/ FET	Covered	None	None	Some	Some
	Ammonia	Covered	None	None	None	None
	Choline/ PSMA	Covered	None	Some	Most	Covered
	11 C Acetate	Covered	None	None	None	None
	Ga 68 DOTA	Covered	Most	Most	Covered	Covered
	F-DOPA	Covered	None	None	None	None
	18 F Fluoride	Covered	None	None	None	None
	Amyloid	None	None	None	None	None

Table 12 summarises the new indications that AWPET has recommended for inclusion within the revised WHSSC commissioning policy from May 2021. These indications have been selected based on careful assessment of the evidence base. Behind each overarching indication, specific criteria have been agreed to define the clinical circumstances in which patients should be referred (Appendix 5). Table 12 also shows the estimated annual volumes of referral for each indication (all Wales).

Table 12: New indications for PET-CT 2021: Estimated volume per annum (All Wales)

Indication	Volume
Colorectal cancer	40
Cholangiocarcinoma	24
Dementia	250
Gastrointestinal stromal tumours (GIST)	45
Lymphoma	40
Prostate cancer	280
<b>TOTAL</b>	<b>679</b>

### Patient views on accessing a PET scan for the diagnosis of Alzheimer's

“ My wife had her PET Scan at the beginning of September last year. Her memory problems had been ongoing for sometime and the doctor had suspected the onset of Alzheimer's Disease.

The PET Scan results gave a definite diagnosis of Alzheimer's which was a relief, in a strange way, to know what we were dealing with. Reading the Scan report and seeing which areas of her brain showed reduced activity, has been a great help to me in understanding her memory loss and other symptoms.

Following the diagnosis the doctors have been able to persuade my wife to start on medication which has already had a positive effect. Her mood has improved and she is less anxious and agitated.

All in all, the PET Scan has been of real benefit to us and I am so grateful that the doctors were able to refer my wife for it. I hope many more people will be able to gain from this amazing technology.

”

“ My husband had been having problems with his memory for some time before the scan but no diagnosis was given. He had a course of CAT therapy as they thought his problems might have been due to anxiety. During this time my husband became increasingly anxious.

I was sure there was something else wrong with him, so when the diagnosis of Alzheimer's was given, it was a relief to me, even though I understood the terrible implications that were carried with the diagnosis. It enabled me to prepare for the future and to be more understanding of my husband's problems.

I would strongly recommend the PET scan as it brought clarity to a situation which until then had been quite unclear and very disturbing.

”

### Future projections for scanning demand in Wales

The NHS England report “[Diagnostic Imaging Dataset Annual Statistical Release 2019/20](#)” shows PET-CT scanning in England increasing year-on-year with a large proportional increase in 2019/20 (12.6%). The dataset also shows that PET-CT scanning is dominated by the 60-74 year old age group, accounting for 45% of total activity.

Critically, in his December 2020 report ‘Diagnostics: Recovery and Renewal’ [14], Professor Sir Mike Richards indicated that between 2014/15 and 2018/19 demand for PET-CT in England increased by 18.7% per annum. He recommended that scanning equipment should, as a minimum, be expanded in line with current growth rates and that all imaging equipment older than 10 years be replaced.

This is an exceptional consideration when estimating growth demand for PET-CT for Wales as scanner numbers, scans per population and commissioned indications are currently markedly below other UK devolved nations and Europe. In addition, Wales faces an increasing proportion of older people in the population and an associated increase in disease prevalence by 2031.

Essentially, Welsh PET-CT scanning provision first needs to “catch up” with developed world country comparators, then look to align with the estimated growth demand.

### Developing the Welsh PET-CT demand model

The demand model has been developed by the Clinical Programme Board based on:

- The population growth estimates included in section 1.3.4.
- An expanded list of commissioned clinical indications in line with comparator countries;
- Feedback from the clinical questionnaire (see section 1.4.1 and Appendix 3).

Table 13 demonstrates the various aspects of growth and scenarios that were considered by the PET Programme Clinical Board.

A full range of modelled scenarios can be found in Appendix 4 and a full narrative in Appendix 6.

The Clinical Board presented all model scenarios to the Strategic Programme Board in August 2020. In consideration of the need for international benchmarking or “levelling-up”, alongside the predicted expansion of commissioned clinical indications and the potential for additional modalities of use, a 20% activity growth model per annum for the next ten years was proposed as an appropriate figure that would fully account for the inputs noted above. This figure of 20% was agreed and confirmed by all members of the Strategic Programme Board as the most likely real-time demands, based on figures from the Richards report and anecdotal growth in England to date.

As well as cancer diagnostics, the demand model is inclusive of the expert consideration for the probable widening scope of indications such as dementia and scanning for modalities such as radiotherapy planning and generic cardiology. It also includes the additional scans that are estimated to result from the widened commissioning policy that will be in place from May 2021 (679 additional scans).

The Strategic Programme Board also considered the role and function of RD&I in their review of the activity growth in the clinical demand model. Advice from expert membership is that a PET scanning facility could dedicate no more than 10% of its annual scanning capacity to RD&I. Indeed, in the recent quarterly report from PETIC, it stated that 7% scans were associated with RD&I. As a result, RD&I scanning activity is included in all projected activity data and as part of the annual 20% estimates for growth.

*Table 13: Summary of likely clinical demand for PET scans across Wales based on 20% underlying growth*

Year	South East Wales	South West Wales	North Wales	Projected All Wales
2021	2629	1434	1144	5207
2022	3155	1721	1373	6249
2023	3786	2065	1647	7498
2024	4543	2478	1976	8998
2025	5452	2974	2372	10789
2026	6542	3569	2846	12957
2027	7851	4282	3415	15548
2028	9421	5139	4098	18658
2029	11305	6167	4918	22390
2030	13566	7400	5902	26868
2031	16279	8880	7082	32241

Modern digital PET-CT machines are capable of performing up to 5,500 times scans per annum. Assuming that a scanner is functional 50 weeks of the year (allowing two weeks for maintenance etc.) then a total of 5,288 scans per annum can be achieved.

The current analogue scanners that are in place within Wales (mobile and fixed at PETIC site) are capable of 2,884 scans per annum, when active for ten sessions per week (50 weeks per year, with

3,000 maximum annual capability). Based on a 20% growth model, it is possible to identify the years in which demand for PET scanning can no longer be met by existing service models and facilities. See Section 5.

The above information will assist in timing the installation of any approved PET-CT scanner and the associated building of any supporting facilities. However, the run-up time for writing and seeking approval of an OBC and FBC for each site should be factored into planning, in addition to ensuring sufficient workforce is present to run the facilities (see section 5). Indeed, in line with the Richards Report (2020), “expansion of the imaging workforce (combined with improvements in productivity will be vital in meeting the increasing demand, but very challenging. Actions will be needed on multiple fronts and by several organisations”. In Wales this will include NHS Wales Improvement, HEIW, NIAW, DHCW and higher education institutions and professional bodies.

### Radiopharmaceutical supply

It is clear from the clinical demand model that the projected increase in scanning activity will lead to a significant increase in demand for radiopharmaceuticals over the coming years. This step change in demand needs to be carefully considered to ensure this essential resource is available and does not prove to be a limiting factor to roll-out.

The possibility of the cyclotron facility at PETIC obtaining an MA license should be considered, as there is merit in having an assured, Welsh resource for radiopharmaceutical supply.

Furthermore, the contractual arrangements with Alliance Medical should be further considered to mitigate against the fact that Swansea needs to purchase supply from Alliance Medical, despite a local Welsh-funded cyclotron manufacturing radiopharmaceuticals in close proximity to the Swansea site.

- The demand needs to be met in the most cost effective, rational and secure manner.
- Safeguarding provision and prices through long-term contracts with suppliers may be needed for sites where on-site production cannot be secured.
- Securing partnerships and political agreement in provision from within and from outside of Wales is needed.
- Critically, horizon scanning of new isotopes, pending MA for those currently considered under Specials license and identifying new ways of using existing isotopes should become part of an annual consideration for commissioners and clinicians.
- An All Wales Strategy for Research and Development should be developed so that all sites in Wales can be considered for research activity (in partnership with one another, and further afield) in a way that ensures radiopharmaceutical supply does not hinder patient access to clinical trials.

### Information Technology

There is a clear and urgent need to update the way in which referrals, appointments and reporting is managed through the PET service.

### Improve clinical outcomes

The superiority of PET-CT scanning in diagnosing and staging particular cancerous lesions, evaluating metastatic spread, optimising and evaluating treatment, and assessing prognosis has been well documented. 18F-FDG PET can upstage patients with cancer and can result in patients avoiding unnecessary surgical intervention. It can also downstage a cancer diagnosis and facilitate

a patient accessing more appropriate treatment. PET-CT is also being used in the diagnosis and treatment planning of an increasing range of other diseases.

However, the under referral of patients in Wales to PET-CT services means that these benefits are not being realised, and clinical outcomes are not as good as they could be.

Clinical outcomes could be further improved by the introduction of new generation digital scanners and new radioisotopes, both of which will increase diagnostic accuracy. Extending the range of clinical indications for PET-CT will also ensure patients receive the most clinically effective interventions.

#### 1.4.6 SO2: To ensure a sufficient workforce to deliver a high-quality service

As noted in Section 1.4.3 (page 40), the imaging workforce is in a critical situation across the UK. There is increasing clinical demand across all imaging modalities, and capacity issues are exacerbated by difficulties in recruiting consultant radiologists, radiographers and sonographers. Clinical imaging remains a popular specialty for medical trainees but training capacity does not match workforce deficits. There is a clear and substantial need to attract, train and develop appropriate staff to the All Wales PET service to ensure deliverability.

PET-CT is not a stand-alone provision, and radiology services will typically not have staff solely dedicated to PET. Instead, staff typically work across several imaging modalities. This is certainly beneficial for skill mix and resilience in a workforce. However, this needs to be considered when planning workforce for future PET-CT services as the needs have to be fed in to wider radiology service on site.

The location of a PET-CT scanner is critical when considering the use of radiopharmaceuticals. A PET-CT scanner would ideally be co-located close to other nuclear medicine services and the specialist medical physics workforce.

The various reviews and reports on this topic suggest a variety of approaches that could facilitate skill-mixing and future-proofing of the PET-CT workforce. One possibility is for radiographers/technologists/physicists to train and become adept at reporting, thus facilitating/reducing consultant radiologist reporting tasks.

Indeed, clinical reporting (interpretation), by non-medical professionals, is established practice in conventional nuclear medicine imaging and other imaging modalities. It is likely that radiographers, clinical scientists and nuclear medicine technologists (with the necessary training/qualification in clinical reporting) can facilitate some limited PET-CT reporting capacity in future, by supplementing the role of the radiologist/nuclear medicine physician, by freeing up medical time for PET-CT reporting. This would be limited to reporting on site only under the guidance of the PET (IR(ME)R) practitioner in possession of an ARSAC licence. Therefore there is a potential route to building some additional resilience within a site team, which will undoubtedly be an interesting prospect for non-medical staff wishing to expand their skill-set.

There is potential for Artificial Intelligence to play a role and assist in many areas that could facilitate more efficient working practices (see Appendix 8). Some of this is being considered and is in scope of the RISP Programme.

The IT infrastructure supporting imaging in Wales requires further development and there is a programme now addressing these issues: the Radiology Informatics System Procurement (RISP)

Programme. It is anticipated (and considered necessary) for these developments to enable the reporting of PET-CT remote from the PET-CT sites. This would facilitate a potential shift toward a “hub and spoke” service model of reporting radiologists in Wales, where perhaps a consultant radiologist based in Hywel Dda could tele-report on scans carried out at Swansea without leaving their office. This must not be to the detriment of adequate on-site support. It is noted that ARSAC does not encourage remote practitioners, so a practitioner would still be expected to regularly attend the PET centre for which they provide primary support. However, this could be an attractive prospect for consultant radiologists looking to live and work in more rural areas of Wales, and still access the interesting field of PET-CT. This is in line with the 2019 RCR [22] recommendation to provide “innovative delivery models” and is dependent on the RISP Programme.

There is a potential risk to the surrounding radiology workforce in that new PET-CT sites could attract vital staff away from other sites. However, the added benefit of retaining and attracting high quality specialists may outweigh the potential risk. This would need to be considered in regional and local plans.

The PET-CT Workforce Board have made a set of recommendations regarding the ideal staffing state for a PET-CT scanning service and have listed their professional roles and WTE, see Table 14. Descriptions of each role and responsibilities are contained in Appendix 7.

As workforce provision is a clear constraint to implementation of this Programme, it is essential that the All Wales PET Programme works closely with existing training and education organisations, Health Boards and other groups to ensure that workforce needs are appropriately considered and planned for in the near and distant future. The PET Programme Workforce Board may be best placed to adjust into an advisory role/group in the future, to maintain expertise and momentum and continue to share and learn from one another.

A fixed, state of the art PET scanning site that has an active RD&I presence is likely to prove an attractive place to work, making it easier to recruit and retain staff from all professional groups and imaging modalities outside of PET.

*Table 14: Professional roles required to run a PET-CT scanning service (based on a single scanner)*

Role	Band	WTE (up to 6 patients per session)	WTE (7-12 patients per session)	Scalability with increased demand
Booking clerk / Administrator / Reception staff	3 or 4	1.5	2.5	In consideration of the patient interaction involved in this role, an increased throughput of patients will result in a need for additional staff members.
Radiographer / Technologist	6-8a	3.0	4.0	Increase in patient throughput is thought to be sufficiently covered by one additional post.
HCA/Clinical Support Staff	4	1.0	2.0	TBC
Clinical Scientist (physics) / Medical Physics Expert	8a-8c	2.0 (includes RWA & RPA roles)	(2.5 for >12 patients)	The scalability for this post is not linear, but there is a small increment per patient which will need to be considered, alongside increased patient throughput.
Finance Business Partner	6-8a	0.2	0.2	Post is not felt to be scalable to patient numbers.

Role	Band	WTE (up to 6 patients per session)	WTE (7-12 patients per session)	Scalability with increased demand
Consultant Radiologist	Consultant pay scale	1.5	3.0	RCR literature denotes consultant radiologist reporting a range from 3.75 - 7.5 reports per session. Agreement from this group is that 5 reports is reasonable.*
PET-CT Manager	8a-8c	0.4	(0.8 for >12 patients)	There will be increased demand for management and HR support to the increased staffing numbers when PET sessions have 7-12+ patients.

\* Comments from consultant radiologist workforce are: 1) a full time consultant will typically be at work 42 weeks of the year, to allow for necessary leave. 2) A full time consultant works 10 sessions on a 7:3 split in line with the National Consultant Contract in Wales. 3) An average of 5 PET-CTs would be reported per DCC session. A Royal College of Radiologists document of 2012 discussing clinical radiology workload and a Royal College of Physicians document of 2013 detailing the duties, responsibilities and practice of physicians both suggest 1-2 per hour i.e. 3.75 to 7.5 per session. 4) Studies won't routinely be double read or reported. 5) A full-time consultant would not devote all of their time to PET-CT duties, but most likely 2 to 4 sessions per week. The clinical lead(s) for a service may well provide more than 4 sessions. 6) If there are sufficient consultants to meet the reporting needs of the service then there are sufficient to meet the non-reporting duties. 7) MDT meeting commitments are to be funded separately.

For future consideration: non-certificated support staff to supplement the radiographer/technologist role (1 WTE).

### 1.4.7 SO3: To improve delivery of the All Wales PET Service by efficient use of PET-CT scanners, facilities, processes and infrastructure

To achieve this spending objective there is a need to provide modern, up to date and high quality PET-CT scanners and supporting facilities in order to improve processes and infrastructure.

#### Replace analogue scanners with digital PET-CT scanners

Scanning technology has advanced significantly over the last 10 years which has led to markedly improved scan image quality, shortening of scan time and lower radiation doses. Although digital scanners are significantly more expensive, they offer the following additional benefits:

- significant gain in sensitivity;
- improved resolution;
- significantly reduced radiation dose or significantly reduce scan time: in practice, a combination of both; and
- faster scans – increasing patient throughput.

All three scanning sites in Wales currently have analogue scanners.

The analogue scanner at PETIC is now 11 years old and is beyond the end of its recommended life. In order to maintain access to a scanner for the population of South East Wales and provide service continuity, the scanner will need to be replaced. A business case to progress this is in preparation.

#### Replace inadequate mobile facilities with fixed ones

The two mobile centres provide access to North and South West Wales respectively and population modelling shows an ongoing need for geographical access to patients in these areas. In the short

term, this could be continued on the mobile fleet but there are significant issues associated with mobile scanners, as described in Table 15 below.

When considering the number of scans that can be carried out by a digital scanner, their use will permit the service reaching full capacity requirements. Reaching this capacity will also require additional investment in the physical infrastructure to account for additional patient numbers. For instance, a digital scanner will scan between 7 and 12 patients in one session, compared to 6 in a typical analogue session. Therefore provision is required for more uptake rooms and more automation in dispensing to obtain greater yield per vial, for example the Tracis system. The same is true for workforce capacity (see Section 1.4.6).

### Patient experience at a mobile PET scanner

“

In autumn 2019, I had a PET scan, prior to my lung operation to make sure all areas affected by that particular cancer were visible. While I was delighted to be able to have such an expensive and useful procedure, it had its pros and cons.

The actual procedure was painless, but I had no idea until I got the paper work that the radio isotope is so unstable. It only has a life of a few hours and sometimes a batch fails in the laboratory. The nearest labs to Wrexham are in Keele and Preston. Several batches are made each day and rushed to the places with the PET scanners. I find the theory fascinating, but the practicalities aren't so much fun.

My appointment was in the morning at the mobile unit at Wrexham Maelor Hospital. Although I live in Wrexham, I arrived in plenty of time (i.e. very early) to avoid taxi problems at school times. Unfortunately, this meant I missed the phone call, saying that that morning's batch had failed.

The nurse suggested that I went home and waited for a call in the afternoon to let me know if the next batch had been successful. I never met the other patient, who had travelled 3 hours to get to their appointment. There was no point in either of us saying we would come back another day because exactly the same thing could happen multiple times.

I went home with my book and bag of warm clothes for the cold of the scanning lorry. I was hungry as I'd been fasting from the night before, but at least I could snuggle up on my sofa in my own misery. I wondered how the other poor patient was doing somewhere in the bowels of the hospital.

I was fortunate, a phone call came to say that the isotope was on its way and when to come in to the hospital. I was torn between disappointment that I couldn't eat and delight that I wouldn't have to repeat the experience another day.

It was damp and dusk when I went up the mesh stairs into the lorry. I was led into a large bright heated cupboard, mainly filled with a recliner chair and blankets. My warm clothes were redundant. I found a way to squeeze the bag beside my legs. I'm not small and I wondered how people larger than I am manage in the space.

I was given the isotope and had to stay still for a certain length of time for it to work. I was very warm and comfortable in the recliner chair. I think I snoozed a bit to allay the gnawing hunger.

To be honest, I can't remember much about the scan itself. I think it was well past five by the time I was being scanned. It wasn't uncomfortable. My main memory is of eating after an 18 hour fast!

”

“

You're asked to stay warm but you could get rather cold on your way to the scanner.

I really needed to go to the toilet after my scan so I had to be rushed to the toilet which was some distance away... having a toilet nearby would be better.

There is space restriction on board the van. I use a wheelchair so had to use the lift to gain access to the van.

”

Patient view of a fixed PET scanner and updated facilities in North Wales

“

Discussions around a static PET scan in North Wales have suggested that people coming a distance could have their appointments in the afternoon, so they can be contacted if the appointment is cancelled.

I don't drive. If I had to travel from Bangor or the Lleyon to Wrexham or vice versa, for instance, I would probably have started my journey before I could be contacted. At least, if I had made a wasted journey, it would be nice to be greeted with a comfortable seat and a bite to eat before my return journey.

Cafés aren't always open when one wants them. Similarly, mobile phone reception can be bad on some journeys. Someone with a long road trip might well miss the call cancelling their appointment.

I don't want to denigrate Wrexham Maelor Hospital at all. It's accessible, a huge bonus in this age of building hospitals at the back of beyond and it has been absolutely brilliant for me. It's just that I can see so much more potential for a modern, static PET scan facility in North Wales.

”

Table 15: Mobile vs fixed scanners

Issue	Mobile scanner	Fixed scanner
<b>Quality</b>	Manufacturers will not guarantee CT and PET alignment to <2.5mm on a mobile (i.e., that the couch movement is guaranteed linear throughout travel), as fundamentally these complex machines are not designed to be bounced around. Radiotherapy requires alignment of 0.2mm.	Fixed site scanner can be maintained, therefore offers fundamentally higher quality for all scans.
<b>Patient experience</b>	Cold, restricted space. Cannot accommodate patients on trolleys. A patient (possibly inpatient) would have to go outside to reach the mobile unit.	All facilities are co-located with the PET scanner, which means the patient does not need to leave the building until the scan is completed.
<b>Maintenance considerations</b>	Mobile units are serviced 3 monthly +/- when they break. This is often outside the control of the service provider.	A fixed site with pro-active medical physics will monitor and fine-tune performance frequently, continually maintaining the rigorous demands required for optimised clinical and research scans.
<b>Future needs</b>	Radiotherapy planning cannot be done on a mobile unit, nor can respiratory and cardiac gating. Diagnostic CT, with iv contrast, requires multiple phases. The staff are not trained or permitted by the mobile provider. This prevents 'one-stop shops' whereby patients can attend a hospital a single time for all required PET-CT, CT +/- radiotherapy planning, all fully integrated rather than multiple visits with associated time delays.	Fixed site scanner can be maintained to a standard to provide radiotherapy planning scans. Potential creation of a "one-stop shop" is possible with a fixed scanner.
<b>Research</b>	Very limited on mobile units due to quality assurance (QA) issues.	Accreditation for research is more easily obtained.

Issue	Mobile scanner	Fixed scanner
<b>Uptake facility</b>	Brown fat activation is triggered by exposure to cold temperatures. This impacts on uptake of FDG and could hinder interpretation in lymphoma and breast cancer patients, in particular. This is a significant issue in winter months.	Fixed sites generally have more uptake rooms available than mobiles, this facilitates a longer FDG uptake period, improving scan quality.
<b>Reliability</b>	Mobiles which are not 'static' mobiles suffer far more failures, often only discovered during warm-up when the first patients have arrived. Couch problems are a particular issue. This leads to patient delays.	
<b>Access</b>	Patient access is more difficult to mobile units compared to fixed sites. Space is limited for disabled patients who require a hoist. Scans on general anaesthetic patients cannot be performed on a mobile.	
<b>Hospital/Staff Benefits</b>	Staff radiation dose is higher on a mobile unit, where space is problematic.	Staff radiation dose is less within a static facility. A fixed unit helps with staff recruitment throughout nuclear medicine.
<b>Booking flexibility</b>	A mobile unit can only use contracted days with the mobile provider.	A fixed site can schedule patients over any days of the week. This not only permits more flexibility when booking patients, it allows for rebooking if there is an issue e.g., with radiopharmaceutical supply. This can also increase the range of radiopharmaceuticals that can be sourced i.e. Wrexham can only get PSMA on 3 out of 7 days. The scanner only on site for one of those days. This restricts access to that day.

## Patient view of improved facilities

“

I needed a biopsy that was more easily performed in Liverpool Heart and Chest Hospital in Broad Green, than at Wrexham, simply because they have more patients with cancers in odd places than Wrexham does. It is a new hospital with new day care facilities, which they find improves patient safety and care. The new day unit at Liverpool HCH is the Holly Suite. Because I needed to fast and had to wear hospital clothes, I only saw the Atrium. It was spacious with recliner chairs. The chairs were far enough apart for privacy. Each patient had a good-sized locker. There were magazines and papers, but I'd brought my own books and music. The unisex toilets were nearby, clearly marked and large. I can't remember exactly, but I think they were all suitable for disabled people, though only one might be necessary in a more specialised unit.

There was a water fountain and a light meal was provided after my procedure, before I was allowed home.

There was usually someone on duty at the desk if one had queries.

The only difference I would have made was to have individual earphones for the television, like they have on aeroplanes. It's a pet peeve of mine to be forced to watch and listen to TV shows that I don't like, in NHS facilities. I was fortunate, I attended on two full days, but the TV was only on for part of one of the days.

A whimsical detail made a painful biopsy more cheerful. The X-ray waiting room and room with the CT scanners had, I think, a sky painted on the ceiling and natural green murals on the waiting room walls. I remember remarking on them and a staff member saying, *'Well this is a new hospital.'*

I always enjoy seeing the woodland mural on the long corridor at Wrexham Maelor. I know it sounds a tiny thing and a bit daft, but it can make a difference.

”

#### 1.4.8 SO4: To ensure that the future All Wales PET service provides a cost-effective service for patients and NHS Wales

As well as the service impacts outlined above, reliance on mobile scanners under existing arrangements results in increased cost per scan. As demand continues to grow this will create an ongoing and increasing cost pressure.

Similarly, reliance on external suppliers for radiopharmaceuticals results in increased and growing costs.

In addition, the existing arrangements limit opportunities for driving out inefficiencies associated with duplication and downtime. It is also not possible to take advantage of income generation opportunities which might emerge in relation to private practice, commercial research trials and supporting other nations.

#### 1.4.9 SO5: To widen the scope of the All Wales PET service, to meet recognised international best practice

In 2018 the AWPET Advisory Group and Welsh Scientific Advisory Committee made the following recommendation in support of future PET research, development and innovation (RD&I) in Wales:

'Constitution of a Welsh PET innovation strategy to develop research, clinical, technological, and industrial collaboration within a formal framework. This will encompass horizon scanning and development of subjects such as PET in radiotherapy planning, and in novel malignant and non-malignant indications' (Recommendation 5, PET in Wales – overview and recommendations, 2018).

The aim is to enable and expand high quality RD&I using PET across Wales, whilst ensuring that every patient has the opportunity to access clinical research trials and to ultimately improve patient outcomes and clinical practice.

Internationally there is a large amount of clinical research activity involving PET currently planned or in progress. An independent literature search carried out in February 2021 by information specialists at Velindre Hospital, Cardiff on behalf of this Programme, identified a total of 812 clinical trials listed on the ClinicalTrials.gov register. Of these 352 were flagged as completed, terminated or cancelled. The vast majority of current trial activity using PET is set within oncology however there is an increasing desire to use PET in a variety of non-oncological indications.

It is clear that there is a breadth of research activity through which PET-CT scanning may be utilised:

- PET scans are being increasingly requested through oncological clinical trials as the gold-standard diagnostic tool for staging of cancer.
- PET-CT scanning is a field of research activity in its own right, with work dedicated to new radiopharmaceuticals and use of these in new clinical indications for diagnosis and even targeted treatment.
- There are studies focused on the use of PET-CT scanning in facilitation of radiotherapy planning / treatment and alternative targeted treatment of cancers.
- Currently PET-related RD&I activity is not consistently carried out across Wales, with almost all being carried out at PETIC in Cardiff. This is largely due to the differences between scanning facilities and infrastructure present at the three sites.
- Most clinical research studies involving PET-CT now require either National Cancer Research Institute (NCRI) or EANM Research GmbH (EARL) accreditation.

PETIC has a fixed scanner and a cyclotron facility. Since it was established over ten years ago, PETIC has made significant strides in the RD&I arena resulting in a dedicated research team and collaborations with high profile partners in academia and industry, such as the University of Oxford and National Physics Laboratory. PETIC has also secured funding from the Wellcome Trust, MRC, Cancer Research UK, EPSRC and Royal Society of Chemistry. Current research activity at PETIC includes:

- Six industry collaborations totalling £206,500 income per annum (2019/20);
- Providing PET-CT scans for 11 multi-centre clinical trials (2019/20);
- Running 9 Clinical Research Projects in Progress totalling income of £443,100;
- Running 12 Pre-Clinical Research Projects totalling income of £210,500;
- Running nine Chemistry and Pharmacy Research Projects totalling income of £1,136,000;
- Running six Physics Research Projects totalling income of £74,400.

There is no doubt that PETIC benefits from having a fixed scanner, on site cyclotron and ownership by an academic institution (Cardiff University). This opportunity is not apparent for Swansea and Wrexham sites, as a mobile scanner is not typically thought of as “ideal” for research PET scans, with research protocols usually highly restrictive and requiring levels of quality assurance that a mobile scanner cannot provide (See Section 1.4.7).

There is a clear link between an active research environment and attraction and retention of high quality staff. Indeed, the PETIC team recently attracted a leading UK radiologist, a radiochemist and a head of quality control as a result of the opportunities available at this site and their reputation for high quality research.

Since the Swansea PET mobile service started in August 2020 there has already some collaboration with PETIC through mentoring of PhD students and access to some clinical trials.

The AML mobile scanner at Singleton Hospital has recently achieved EARL accreditation, which is rare for a mobile scanning facility thus a significant achievement.

The Swansea site is currently open to receive patients for the SCOPE II and ADCT-402-103 studies. SCOPE II is a phase II/III trial to study radiotherapy dose escalation in patients with oesophageal cancer and the ADCT-402-103 study is an early phase trial evaluating loncastuximab tesirine and ibrutinib in patients with lymphoma.

Capacity issues of the mobile service and the specific needs of research trials means a number of studies are ineligible to open in BCUHB. This reduces BCUHB's reputation as a research organisation and denies local patients access to trial participation. This also has a negative effect on retention and recruitment of skilled staff.

There is a clear need for a pan-Wales research network, with membership spanning NHS, academia and industry to ensure that Welsh PET-CT services make the most of its population, geography and clinical expertise.

Critically, putting in place the appropriate scanners and associated facilities across Wales will not only create centres of RD&I excellence for staff retention and attraction, but ensure that patients have equitable access to participate in clinical trials. This is an important factor to consider for the needs of the service.

Over the past 10 years, PETIC has been a partner with Health Boards across Wales in 78 multi centre research studies. These studies have primarily been research into novel therapeutic agents where PET is used to monitor and assess the response of cancer and dementia patients to the novel therapeutic agent. This has also included a number of research studies in partnership with Bristol due to the fact that the private provider of PET scans in Bristol has been unwilling to support research scans.

PETIC also secured funding for a pilot study with clinicians in Aneurin Bevan UHB to investigate the use of FDG PET in the diagnosis of dementia. The result of the pilot study demonstrated that FDG PET significantly altered the differential diagnosis of dementia types and resulted in cost savings in other areas of patient management due to clearer diagnosis. Based on these data, evidence was submitted to AWPET in 2020 requesting the inclusion of new dementia indications in the WHSSC PET commissioning policy [1]. AWPET supported and recommended these new indications to WHSSC and they were subsequently approved and will be funded from June 2021. In addition, a national PET Dementia service is planned to go live in the summer of 2021.

PETIC has also led on the introduction of 18F-PSMA PET in Wales. PSMA PET is an emerging imaging modality with improved diagnostic accuracy (sensitivity and specificity) over conventional imaging for prostate cancer staging. PSMA PET identifies cancer that is often missed by current standard of care imaging techniques. Prior to 2019, PETIC offered a prostate cancer imaging service using F-Choline. Problems with the supply chain led PETIC to submit a business case to WHSSC to support an 18F PSMA scanning service. This was approved and PETIC began production of 18F

PSMA for human use in 2019. The service has proved to be hugely successful with PETIC now reliably scanning increasing numbers of prostate cancer patients in Cardiff and supplying PSMA to PET centres in Swansea, Bristol, Plymouth, Poole and Bath.

Other research interests and collaborations involving PETIC include:

- a validated method for the synthesis of 18F-DOPA in partnership with Pfizer and Bristol to investigate a potential cure for Parkinson’s disease. PETIC is the only site in the UK manufacturing 18F-DOPA and is supplying specialist centres in London and Manchester who used 18F-DOPA to diagnose and treat paediatric insulinoma;
- the development and validation of Fallypride and Flumazenil radiopharmaceuticals. Fallypride is currently being used in Cardiff to assess the effectiveness of stem cell implants in Huntingdon’s disease. Flumazenil is being used in partnership with CUBRIC to measure the neuroreceptor GABAA in epilepsy. In partnership with TRASIS, PETIC is planning to optimize the synthesis of Flumazenil with the aim of supplying Flumazenil across the UK;
- Artificial Intelligence (AI).

AI has been mentioned in many of the key documents referenced in the Strategic Context section of this PBC. Indeed, colleagues at the Life Sciences Hub Wales (LSHW) have used horizon scanning techniques to understand the possibilities of this advancing field of innovation, and ensure that the All-Wales PET service makes moves to the frontline of innovation (Appendix 9). There are clear and potential benefits of AI to PET-CT imaging ranging from improved image quality, reduced scan time, improved patient experience and improved efficiency, accuracy and insights. The key barriers to this innovation are the need for facilitation and collaboration. There are many suppliers with a range of technologies on offer.

The figure below summarises the case for change for this programme in relation to the five spending objectives.

Figure 10: Problems with existing arrangements

SO1 Improve the quality of PET service provision for Welsh patients by delivering better patient outcomes	SO2 Ensure a sufficient workforce to deliver a high-quality service	SO3 Improve delivery of the All Wales PET Service by efficient use of PET-CT scanners, facilities, processes and infrastructure	SO4 Ensure that the future All Wales PET service provides a cost-effective service for patients and NHS Wales	SO5 Widen the scope of the All Wales PET service, to meet recognised international best practice
<b>Problems with existing arrangements</b>				
Wales currently under-performs: <ul style="list-style-type: none"> <li>• PET-CT scans per head of population</li> <li>• Density of PET scanners</li> <li>• Wider PET-CT infrastructure</li> <li>• Unable to meet growing demand and increasing number of indications in the future</li> </ul>	Challenges recruiting and retaining highly skilled staff required to deliver high quality service due to: <ul style="list-style-type: none"> <li>• Working environment</li> <li>• Constrained capacity</li> <li>• Limited development opportunities</li> </ul>	Reliance on mobile units impacts directly on: <ul style="list-style-type: none"> <li>• Quality</li> <li>• Patient experience</li> <li>• Planning</li> <li>• Research capacity and capability</li> <li>• Reliability</li> <li>• Access</li> <li>• Flexibility of booking</li> <li>• Analogue scanners</li> </ul>	Reliance on mobile units and external suppliers for radiopharmaceuticals results in increased cost per scan. Limited opportunities to: <ul style="list-style-type: none"> <li>• Reduce inefficiencies associated with duplication and downtime</li> <li>• Generate income</li> </ul>	Scanning facilities and infrastructure limit opportunities to explore: <ul style="list-style-type: none"> <li>• Expanding Research &amp; Development capability</li> <li>• Achieving Gold standard</li> <li>• Innovation, such as AI</li> </ul>

## 1.5 Potential Scope

### 1.5.1 Introduction

This section of the PBC identifies the potential scope of the All Wales PET Programme including the key service requirements that should be considered in designing the future service model and developing options.

### 1.5.2 Scope of programme

The overall scope of the programme is to plan, design, build and implement an All Wales PET strategy and associated business case for services up to 2031.

The aims of the Strategic Programme Board are to:

- Produce a Welsh PET services strategy that will incorporate multi-disciplinary workforce, research, clinical, technological and industry within a formal framework.
- Produce a strategic business cases for future PET-CT services in Wales.
- Establish a framework to ensure continuity of service and safe practice.
- Produce a business case for funding to replace obsolete PET-CT infrastructure.
- Consider if it is relevant to supply radiopharmaceutical tracers to other providers within NHS Wales outside of PETIC.
- Support the development of the capacity of the indication list.
- Develop a strategic business case to inform future PET service across Wales that incorporate enhancements to the indicators list, PETIC replacement scanner and radiopharmaceutical supply in line with the recommendations of the AWPET group report [6] for PET-CT in April 2019.

Areas that are excluded from this programme are:

- Ongoing maintenance of the service
- Implementing commercial products.

### 1.5.3 Potential scope of services

By considering the range of business functions, areas and operations to be affected and the key services required to improve organisational capability, 'scope creep' can be avoided during the options appraisal stage of the project.

Coverage and services are considered on the following continuum of need:

- **Core:** Essential elements that must be included in the programme to address immediate risks and ensure service continuity.
- **Desirable:** Additional elements that should be included in the programme to enhance the service and deliver greater value for money through additional benefits.
- **Optional:** Possible elements that could be included in the programme to maximise benefits providing they can be justified on a marginal low cost and affordability basis.

The Strategic Programme Board considered and agreed the potential scope of service coverage and categorised the main elements in line with this continuum of need. The results of this analysis is provided in Table 16 below.

Table 16: Potential scope - service coverage

	Core	Desirable	Optional
<b>Number of scanners</b>			
Provide access to 1 x PET-CT scanner to meet forecast South East Wales demand	✓		
Provide access to 1 x PET-CT scanner to meet forecast North Wales demand	✓		
Provide access to 1 x PET-CT scanner to meet forecast South West Wales demand	✓		
Provide access to 4th PET-CT or PET-MR scanner (Location and type to be determined according to future demand requirements)		✓	
Provide access to 5th PET-CT or PET-MR scanner (Location and type to be determined according to future demand requirements)			✓
<b>Radiopharmaceutical provision</b>			
Cyclotron co-located with SE Wales PET-CT scanner	✓		
Contract for supply of radiopharmaceuticals	✓		
Additional cyclotrons (Number and location to be determined according to future demand requirements)			✓
<b>Additional service provision</b>			
Centres of Excellence*		✓	

\* Centres of Excellence refer to RD&I activity and state of the art facilities. Having Centres of Excellence will result in reputational gain and the ability to attract and retain highly skilled workforce in addition to RD&I income.

### 1.5.4 Key service requirements

The key requirements associated with this potential scope were also considered and agreed by the Strategic Programme Board (Table 17). These will provide the basis for developing design specifications at project stage.

Table 17: Potential scope – key service requirements

	Core	Desirable	Optional
<b>Scanner specification (where new scanners are acquired as part of the solution)</b>			
Digital scanners	✓		
Inclusion of existing technologies - Robotic radiopharmaceutical dispenser	✓		
Inclusion of existing technologies – Radiotherapy Treatment planning	✓		
AI-enabled machines	✓		
<b>Facilities requirements (where new scanners are acquired as part of the solution)</b>			
Uptake rooms (Increase rooms at Cardiff and create rooms at new facilities such as Swansea and North Wales)	✓		
<b>Dependencies (where new scanners are acquired as part of the solution)</b>			
Integrated IT to ensure quick turnaround and clear coding	✓		
Electronic requesting	✓		

	Core	Desirable	Optional
<b>Centres of Excellence</b>			
Flat bed and lasers included in scanner specification	✓		
Active R&D with clear pathways available at all sites		✓	
Access to novel radiopharmaceuticals		✓	
<b>Workforce requirements</b>			
Hub and spoke model	✓		
Skilled workforce (Ensure expansion of workforce to deliver capacity – see section 5.5)	✓		
Training and development	✓		

### 1.5.5 Demand requirements

Capacity requirements, in terms of the number of PET-CT scanners required and the timescales for acquiring them, have been estimated based on the need to meet predicted demand of 20% growth per annum described in section 1.4.5 and the supporting Figure 13.

Modern digital PET-CT scanners are capable of scanning up to 5,500 times per annum. Assuming that a scanner is functional 50 weeks of the year (allowing two weeks for maintenance, breakdowns etc.), a total of 5,288 scans per annum can be provided.

The current analogue scanners that are in place within Wales (mobile and fixed at PETIC site) are capable of 2,884 scans per annum, when active for ten sessions per week (50 weeks per year, with 3,000 maximum capability).

Based on these assumptions, it is possible to identify the years in which demand for PET scanning can no longer be met by existing service models and facilities and this is shown in the table below.

Table 18: Summary of likely clinical demand for PET scans across Wales based on 20% underlying annual growth in activity

Year	South East Wales	South West Wales	North Wales	Projected All Wales
2021	2629	1434	1144	5207
2022	3155	1721	1373	6249
2023	3786	2065	1647	7498
2024	4543	2478	1976	8998
2025	5452	2974	2372	10789
2026	6542	3569	2846	12957
2027	7851	4282	3415	15548
2028	9421	5139	4098	18658
2029	11305	6167	4918	22390
2030	13566	7400	5902	26868
2031	16279	8880	7082	32241

**Red** cells highlight where clinical demand outstrips current service provision. **Amber** cells denote where clinical demand may outstrip mobile provision at SW and N Wales and digital scanning provision at PETIC. **Purple** cells denote where clinical demand may outstrip digital scanner provision at all three sites.

Based on this analysis, it is clear that significant capacity shortfalls will emerge as follows:

- **South East Wales:** Forecast demand will begin to exceed capacity of the existing analogue scanner in Cardiff by the end of 2021. Replacing it with a digital scanner would provide sufficient capacity to meet forecast demand until at least 2025. Introducing an additional scanner at that point would provide sufficient capacity until 2029.
- **South West Wales:** Forecast demand has already exceeded capacity of the existing mobile scanner which currently operates just two days each week. Expanding capacity to the equivalent of five days per week for a mobile analogue scanner would only create sufficient capacity to meet forecast demand until 2024. And expanding capacity to the equivalent of five days per week for a digital scanner could only create sufficient capacity to meet forecast demand until 2028. Introducing an additional scanner in 2028 could provide sufficient capacity well beyond 2031.
- **North Wales:** Forecast demand has already exceeded the capacity of the existing mobile scanner which currently operates just two days each week. Expanding capacity now to the equivalent of five days per week for the analogue mobile scanner would only create sufficient capacity to meet forecast demand until 2025. And expanding capacity now to the equivalent of five days per week for a digital scanner would only create sufficient capacity to meet forecast demand until 2030.

It should be noted that this analysis is concerned with the scale of capacity requirements only and does not consider the implications of how this capacity may be provided (i.e. using a mobile or fixed scanner). These implications are considered within the options framework in the Economic Case.

It should also be noted that this analysis is inclusive of RD&I activity. It would be realistic to assume a lead time of two to three years before a new fixed digital PET scanning facility will be demonstrating RD&I activity of 10% of total annual scanning capacity.

### 1.5.6 Workforce requirements

The requirements for staffing should be considered carefully when planning the Programme, and concurrently with the clinical demand for PET scans. The information presented in the table below will need to be considered as a constraint in the phasing of the Programme plan.

If the All Wales PET Programme Business Case were to be endorsed, then the regional Project leads would be expected to work with local operational colleagues to ensure that more complex workforce planning is undertaken, so that future PET-CT scanners can be “manned” with a resilient workforce. Collaboration between IWEG, HEIW, NIAW and the Healthcare Scientist Board on this matter is essential.

Looking at the analysis of professional posts (Appendix 8), the indicative numbers of WTE posts needed on an All Wales basis to staff three analogue scanners is 28.8 WTEs, and three digital scanners is 45.0 WTEs.

As mentioned in Section 1.4.6, workforce will be a significant constraint to the successful implementation of this Programme. However, the gap analysis (Table 19) alongside the projected demand model (Table 18), provide sufficient data to form judgement and permit appropriate planning so that scanners can be installed at the right time to meet both clinical demand and workforce needs.

If fixed digital scanners were to be put at all three existing PET provider sites, Swansea would need to expand its workforce to that indicative of an analogue scanner by 2024-25 and North Wales by 2025-26. This should give sufficient time, if this PBC were to be endorsed by WG in 2021, to carry out detailed local workforce planning, train existing staff and advertise and attract staff needed for the new facility in advance. Conversely, PETIC would need to carry out local workforce planning to ensure the deliverability of the service as the demand gradually increases year-on-year.

Table 19: Professional posts gap analysis

	All Wales Current staffing (WTE)	All Wales Analogue Scanner requirements (WTE)	All Wales Analogue scanner gap (WTE)	All Wales Digital Scanner requirements (WTE)	All Wales Digital scanner gap (WTE)
Booking clerk/ Administrator/ Reception staff	4.4	4.5	0.1	7.5	3.1
Radiographer/ Technologist	6.2	9.0	2.8	12.0	5.8
HCA/Clinical Support Staff	0.0	3.0	3.0	6.0	6.0
Clinical Scientist (physics)/ Medical Physics Expert	2.1	6.0	3.9	7.5	5.4
Finance Business Partner	1.3	0.6	-0.7*	0.6	-0.7
Consultant Radiologist	3.9	4.5	0.6*	9.0	5.1
PET-CT Manager	1.6	1.2	-0.4*	2.4	0.8
<b>TOTAL WTE</b>	<b>19.5</b>	<b>28.8</b>	<b>9.4</b>	<b>45.0</b>	<b>25.6</b>

\*The current consultant radiologist, finance business partner and PET-CT manager staffing level at PETIC is 2.1WTE, 1.0WTE and 1.0WTE, respectively - which is above the proposal for an analogue scanner. PLEASE NOTE THAT LOCAL/REGIONAL CONSIDERATIONS WILL BE REQUIRED AT OUTLINE AND FULL BUSINESS CASE SUBMISSION.

It is clear from Table 19 that there will be a need for a fourth PET scanner in the South East region of Wales in 2026. This should be considered as part of the Options Appraisal and should be carefully and effectively planned. The programme should be phased in such a way that there is sufficient oversight from the SPB to review real-time scanning demand and provision for “stop/go” end of tranche reviews.

Should annual demand growth exceed 20% per annum, and this may be the case dependent on the rate of introduction of new services/indications, these timelines can be revised to an earlier date. Conversely, if the rate of growth in the next few years is not realised, the dates would be expected to be pushed back.

### 1.5.7 Radiopharmaceutical requirements

Radiopharmaceutical provision is an additional infrastructure factor for the All Wales PET Programme and this has been addressed in the Potential scope - service coverage (Table 5-1). However, during in-depth discussions at the SPB in development of the Programme, it became

evident that requirements for radiopharmaceutical provision for Wales may stretch beyond the scope of the All Wales PET Programme.

Therefore, it is possible that additional investment via a Project or Programme is identified for radiopharmaceutical provision for Wales after further horizon scanning and scope work. The Programme arrangement should allow space and structure for this work to be done and ensure that the radiopharmaceutical provision is future-proofed.

## 1.6 Benefits and Risks

### 1.6.1 Introduction

This section of the PBC identifies the benefits, risks, constraints and dependencies that should be considered in the All Wales PET Programme when developing and assessing the options for the optimal solution.

### 1.6.2 Benefits

The Preferred Way Forward should address all the business needs and achieve each spending objective identified as part of the review in order to deliver a range of benefits including:

- **Cash releasing benefits (CRB):** those that can be monetised and include improved economy (i.e. reduction in costs);
- **Non-cash releasing benefits (non CRB):** those that can be monetised and include improved efficiency (i.e. staff time released to focus on more value added tasks);
- **Quantifiable benefits (QB):** those that can be measured but not monetised (i.e. patient experience); and
- **Qualitative benefits (Qual):** those that cannot be measured or monetised.

The table below provides an overview of the main outcomes and benefits arising from achieving the spending objectives.

Table 20: Main benefits

Benefit	Description	Beneficiary	Type of benefit
Avoid high-cost late-stage interventions	Avoid surgical intervention	NHS Wales Patient	Financial
Reduction in harm	i. Increase the number of correct operations in those for whom it offers a potential cure and reduce the number of missed operations within this group. ii. Avoid the resource cost of futile operations in patients for whom it does not offer a potential cure. iii. Avoid the mortality and morbidity associated with futile operations. iv. Reduce the number of "open and close" operations for which the futility of the operation is realised during operation. v. Allow improved placement of radiation fields for curative treatment.	Patient Workforce NHS Wales	Quantitative (Unmonetised)
Reduced waiting times	Time to referral to time of scan	Patient	Quantitative (Unmonetised)
Increased certainty of treatment and planning	Increased certainty of treatment and planning through improved imaging in latest software and reduced risk of brown fat uptake in fixed units. Ensuring sufficient capacity and counter pathways.	Patient	Qualitative

Benefit	Description	Beneficiary	Type of benefit
Improved patient experience	Improved access, better facilities and greater convenience, better outcomes lead to better patient experience	Patient	Qualitative
Improved recruitment and retention	Greater ability to recruit and retain highly skilled workforce	NHS Wales Patient	Qualitative
Improved access to / uptake of training and education	Increased opportunities to provide access to training and education	Workforce	Quantitative (Unmonetised)
Improved staff satisfaction	Improved working environment, reduced stress and greater opportunities for development contribute to greater staff wellbeing	Workforce	Qualitative
Increased job opportunities contributing to Welsh economy	Ability to attract highly skilled workforce to Wales to deliver service model	Economy	Societal (monetised)
Increased capacity resulting in ability to meet demand	Ability to meet future demand - reducing cost per unit	NHS Wales	Cash releasing
Reduced downtime	Greater control of lists resulting in reduced cancellations and delays and better utilisation allowing greater throughput	NHS Wales	Non-cash releasing
Reduced reliance on mobile scanners	Reduced cost per scan due to establishing in house scanning facilities	NHS Wales	Cash releasing / cost avoidance
Reduced patient travel time - value to patients	Value to patient of reduced travel time for scans	Patient	Societal (monetised)
Reduced patient travel time - reduced greenhouse gases	Reduction in greenhouse gases as a result of reduced patient mileage	Environment	Societal (monetised)
Reduced road travel of mobile units	Reduction in greenhouse gases as a result of reduced mobile unit mileage	Environment	Societal (monetised)
Income generation opportunities	Increased opportunities to protect existing and generate additional income in relation to private practice, commercial trials, NHS England	NHS Wales	Cash releasing
Better equity of access	Increasing access in line with international best practice in terms of scanning capacity in relation to population needs ensures better equity of access which will result in improved patient outcomes	Patients	Quantitative (Unmonetised)
Increased proportion of staff research active	Centre of Excellence provides increased opportunities for staff to be involved in research and clinical trials ensuring the service is aligned with international best practice, leading to better outcomes in the long term	NHS Wales Workforce Patients	Quantitative (Unmonetised)

Benefit	Description	Beneficiary	Type of benefit
Increased proportion of patients on clinical trials	Centre of Excellence provides increased opportunities for patients to participate in clinical trials ensuring the service is aligned with international best practice, leading to better outcomes in the long term	NHS Wales Workforce Patients	Quantitative (Unmonetised)
Greater number of trials led by and participated in by PET site	Centre of Excellence provides increased opportunities for PET sites to be involved in a greater range of research ensuring the service is aligned with international best practice, leading to better outcomes in the long term	NHS Wales Workforce Patients	Quantitative (Unmonetised)
Improved access to a greater range of diagnostics to support greater range of therapeutics	Providing increased number of dedicated fixed PET-CT facilities provides opportunities to offer an increased range of diagnostics that will support more therapeutics that would not be possible using mobile units, such as <ul style="list-style-type: none"> <li>- Radiotherapy planning</li> <li>- Cardiology</li> <li>- GA</li> </ul>	NHS Wales Workforce Patients	Qualitative

### 1.6.3 Risks

Risk is the possibility of a negative event occurring that adversely impacts on the success of the future service model.

Identifying, mitigating and managing risk is crucial to successful programme delivery. The key risks are likely to be those that mean the programme will not deliver its intended outcomes and benefits within the anticipated timescales and spend.

The main risks identified are listed below.

Table 21: Main risks

Risk category	Risk
Resilience	Risk of insufficient scanning capacity to meet demand resulting in increased waiting times and impacting on patient outcomes
	Risk of cancellations and downtime of service
Demand	Risk that demand and capacity requirements have been under or over-stated
Workforce	Risk of insufficient workforce available to provide high quality service
	Risk of challenges recruiting workforce
Implementation	Risk of programme delays resulting in insufficient capacity during transition period
	Risk of programme delays resulting in increased programme costs
Funding and finance	Risk of insufficient capital funding available to deliver programme
	Risk of increasing revenue costs
	Risk that programme costs have been understated

### 1.6.4 Constraints

Constraints relate to the parameters that the programme is working within and any restrictions or factors that might impact on the delivery of the programme. These typically include limits on resources and compliance.

The main constraints that should be considered in developing a solution for future delivery of the All Wales PET Programme include the following parameters:

- Timescales for completion of the work.
- Availability of key human resource to deliver the programme of work due to existing work commitments.
- Availability of the highly skilled workforce to safely and effectively run a PET service at each site.
- Undefined financial models.

### 1.6.5 Dependencies

Dependencies include items that must be in place to enable the project or project phases to run successfully. Typically these include links to other projects and funding requirements that are likely to be managed elsewhere.

The success of the future service model relies on the following main dependencies:

- The strategic direction for PET services outlined in the Imaging Statement of Intent for NHS Wales.
- 'Buy in' from all Health Boards and stakeholders.
- Availability of capital funding.

### 1.6.6 Conclusion

Stakeholders have identified the benefits, risks, constraints and dependencies in relation to the agreed scope of the All Wales PET Programme. These together with the key spending objectives are used to develop and assess a shortlist of options. This option development process is covered in the Economic Case.

## 2 Economic Case

### 2.1 Options Framework

#### 2.1.1 Introduction

The purpose of the Economic Case is to identify and appraise the options for the delivery of project and to recommend the option that is most likely to offer best value for money.

The first stage of this explores the preferred way forward by undertaking the following actions:

- Agree critical success factors (CSFs).
- Identify and evaluate the long list of options.
- Recommend the preferred way forward in the form of a shortlist of options.

#### 2.1.2 Critical Success Factors

Critical success factors (CSFs) are the essential attributes for successfully delivering the project and are used along with spending objectives to evaluate the options. The CSFs for the project are crucial, not merely desirable, and not set at a level that could exclude important options at an early stage of identification an appraisal.

Table 22: Critical success factors

Critical Success Factor		How well the option
CSF1	Strategic fit and business needs	Meets the agreed spending objectives, related business needs and service requirements, and Provides holistic fit and synergy with other strategies, programmes and projects.
CSF2	Potential value for money	Optimises public value (social, economic and environmental), in terms of the potential costs, benefits and risks.
CSF3	Supplier capacity and capability	Matches the ability of potential suppliers to deliver the required services, and Is likely to be attractive to the supply side.
CSF4	Potential affordability	Can be funded from available sources of finance, and Aligns with sourcing constraints.
CSF5	Potential achievability	Is likely to be delivered given the organisation's ability to respond to the changes required, and Matches the level of available skills required for successful delivery.

#### 2.1.3 Key elements of the options framework

The options framework, outlined in the Welsh Government Better Business Cases guidance, provides a systematic approach to identifying and filtering a broad range of options.

An overview of the key dimensions within the options framework is provided in Table 23 below.

Table 23: Key elements of the Options framework

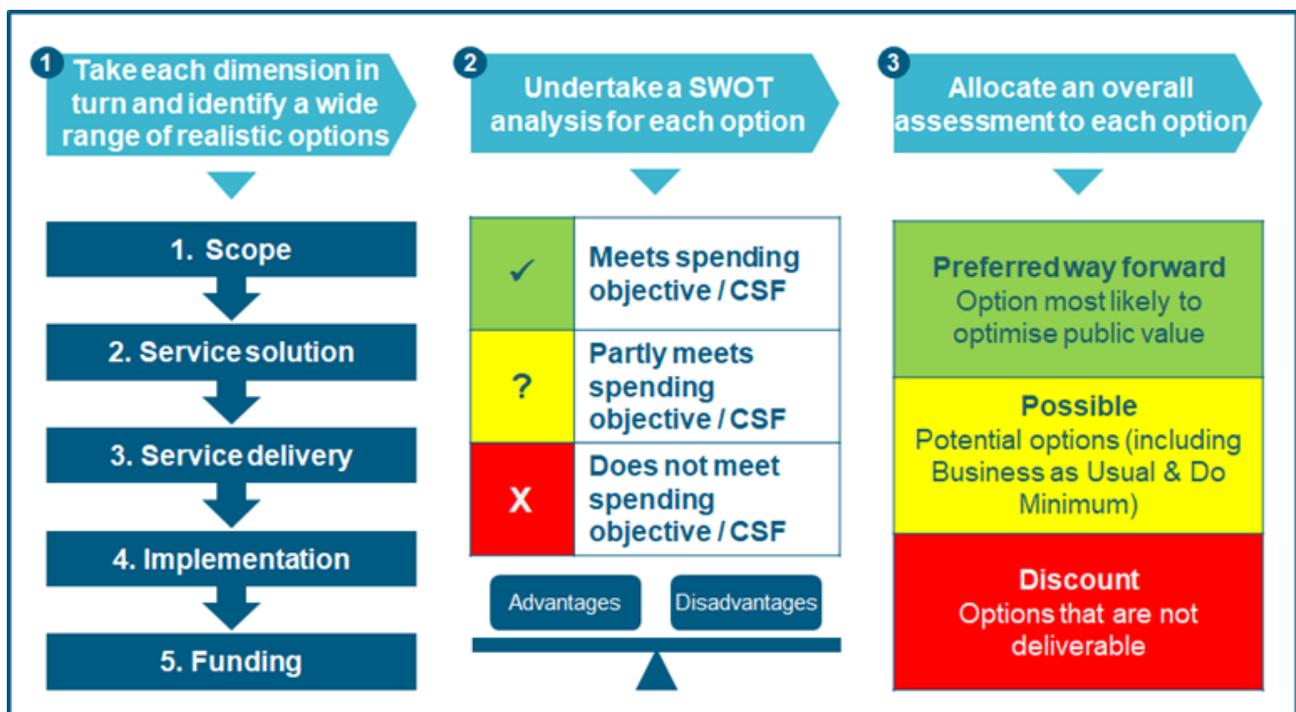
Dimension	Description
Scope	What to include in the future service model
Service solution	How to deliver the future service model
Service delivery	Who will deliver the future service model
Implementation	Timescales and phasing for delivering the future service model
Funding	Financing the future service model

The process for identifying and assessing options takes each of the key dimensions in turn and undertakes the following steps:

- Identify a wide range of realistic potential options within that dimension
- Undertake an analysis for each option to:
  - Assess how well the option meets the project’s spending objectives and critical success factors; and
  - Identify the option’s main strengths, weaknesses, opportunities and threats.
- Use the outputs of the analysis to determine whether the option will be carried forward as the preferred way forward, carried forward as a possible solution, or discounted at this stage.

A diagram illustrating this process is shown in Figure 11 below.

Figure 11: Process to identify and assess the long list of options



## 2.1.4 Identifying and assessing the long list

A long list of options for each of the five dimensions was developed by the Programme Board and evaluated to determine how well each meets the spending objectives and critical success factors at a series of workshops. The detailed analysis is provided in Appendix 1 and an overview in the sections below.

## 2.1.5 Scope

The options related to the project 'scope' are concerned with establishing the service coverage and key service requirements to be included within the programme over a ten-year period. The potential scope analysis outlined in section 5 provided a basis for developing these options. The evaluation results are provided in the table below.

Table 24: Long list - Scope

Dimension	Option	Description	Conclusion
Do nothing	1A	3 scanners 3 x PET-CT scanners located in Cardiff, North Wales and Swansea	Carry forward (Baseline)
Intermediate options	1B	3 scanners + 1 cyclotron + Centres of Excellence 3 x PET-CT scanners located in Cardiff, North Wales and Swansea 1 x Cyclotron co-located with Cardiff PET-CT Centres of Excellence facilities	Carry forward (Do minimum)
	1C	4 scanners + 1 cyclotron + Centres of Excellence 3 x PET-CT scanners located in Cardiff, North Wales and Swansea 1 x Cyclotron co-located with Cardiff PET-CT Centres of Excellence facilities 1 x additional scanner (PET-CT or PET-MR) in location to meet population needs	Carry forward (Preferred way forward)
	1D	5 scanners + 1 cyclotron + Centres of Excellence 3 x PET-CT scanners located in Cardiff, North Wales and Swansea 1 x Cyclotron co-located with Cardiff PET-CT Centres of Excellence facilities 2 x additional scanners (PET-CT or PET-MR) in location to meet population needs	Carry forward (More Ambitious)
Do maximum	1E	5 scanners + 1 cyclotron + Centres of Excellence + additional cyclotron 3 x PET-CT scanners located in Cardiff, North Wales and Swansea 1 x Cyclotron co-located with Cardiff PET-CT Centres of Excellence facilities 2 x additional scanners (PET-CT or PET-MR) in location to meet population needs Additional cyclotrons	Discount

## 2.1.6 Solution

The options related to 'solution' are concerned with establishing how the preferred scope for the programme can best be delivered. A range of options has been considered and the results of the evaluation of these options are provided in the table below.

Table 25: Long list - Solution

Dimension	Option	Description	Conclusion	
Do nothing	2A	Do nothing	Outsource unmet demand	Carry forward (Baseline)
Intermediate options	2B	Replace Cardiff + extend mobile capacity	Replace PET-CT scanner and cyclotron in Cardiff Extend operating hours of Swansea and North Wales mobile sites	Carry forward (Do minimum)
	2C	Replace Cardiff + 2 new fixed units (Swansea, N Wales)	Replace PET-CT scanner and cyclotron in Cardiff Create 2 x facilities for fixed PET-CT scanners (Swansea and North Wales)	Discount
	2D	Replace Cardiff + 3 new fixed units (Swansea, N Wales, TBD)	Replace PET-CT scanner and cyclotron in Cardiff Create 2 x facilities for fixed PET-CT scanners (Swansea and North Wales) 1 x additional scanner (location, type and timescales to be determined based on demand)	Carry forward (Preferred way forward)
Do maximum	2E	Replace Cardiff + 4 new fixed units (Swansea, N Wales, 2 x TBD)	Replace PET-CT scanner and cyclotron in Cardiff Create 2 x facilities for fixed PET-CT facilities (Swansea and North Wales) 2 x additional scanners (location, type and timescales to be determined based on demand)	Carry forward (More ambitious)

## 2.1.7 Delivery

The options related to the programme 'delivery' are concerned with establishing the ways in which the preferred scope and solution can be delivered, specifically around who will deliver services in the future. The results of the evaluation of these options are provided in the table below.

Table 26: Long list - Delivery

Dimension	Option	Description	Conclusion	
Do nothing	3A	Continue with existing arrangements	PETIC operates Cardiff facility External provider operates mobile facilities External radiopharmaceuticals contracts	Carry forward (Baseline / Do Minimum)
Intermediate options	3B	Bring service delivery in house for new facilities and retain PETIC partnership in Cardiff	PETIC operates Cardiff facility NHS Wales operates new fixed facilities External radiopharmaceuticals contracts	Carry forward (Preferred Way Forward)

Dimension	Option	Description	Conclusion
Do maximum	3C	Entire service delivered by NHS Wales	Discount

### 2.1.8 Implementation

The options related to the programme ‘implementation’ are concerned with establishing the phasing for delivering the preferred scope, solution, and delivery options.

This analysis in section 5 of the Strategic Case provides a clear indication at the tipping points at which capacity will be exceeded. Indicative assumptions can therefore be made about timescales for delivering the potential scope and these are outlined in the table below.

It would be prudent to put in place the PET scanners and associated facilities ahead of reaching the tipping points at each site, so as to avoid risks associated with potential service failure and avoid reaching a critical state in scanning provision. In addition, given the additional benefits to patient experience, realisation of wider Programme benefits, and in line with the strong case for change made within this Strategic Case, there is a strong argument to bring forward implementation to before the projected tipping points.

Table 27: Timescales for delivering the potential scope

Scanner requirements	Capacity exceeded	Timescale
Provide access to 1 x PET-CT scanner to meet forecast South East Wales demand	2021	2021
Provide access to 1 x PET-CT scanner to meet forecast North Wales demand	2025-2026	2023-2024
Provide access to 1 x PET-CT scanner to meet forecast South West Wales demand	2024-2025	2023-2024
Provide access to 4th PET-CT or PET-MR scanner (Location and type to be determined according to future demand requirements)	2026	2026
Provide access to 5th PET-CT or PET-MR scanner (Location and type to be determined according to future demand requirements)	2029	2028

The results of the evaluation of these options are provided in the table below.

Table 28: Long list - Implementation

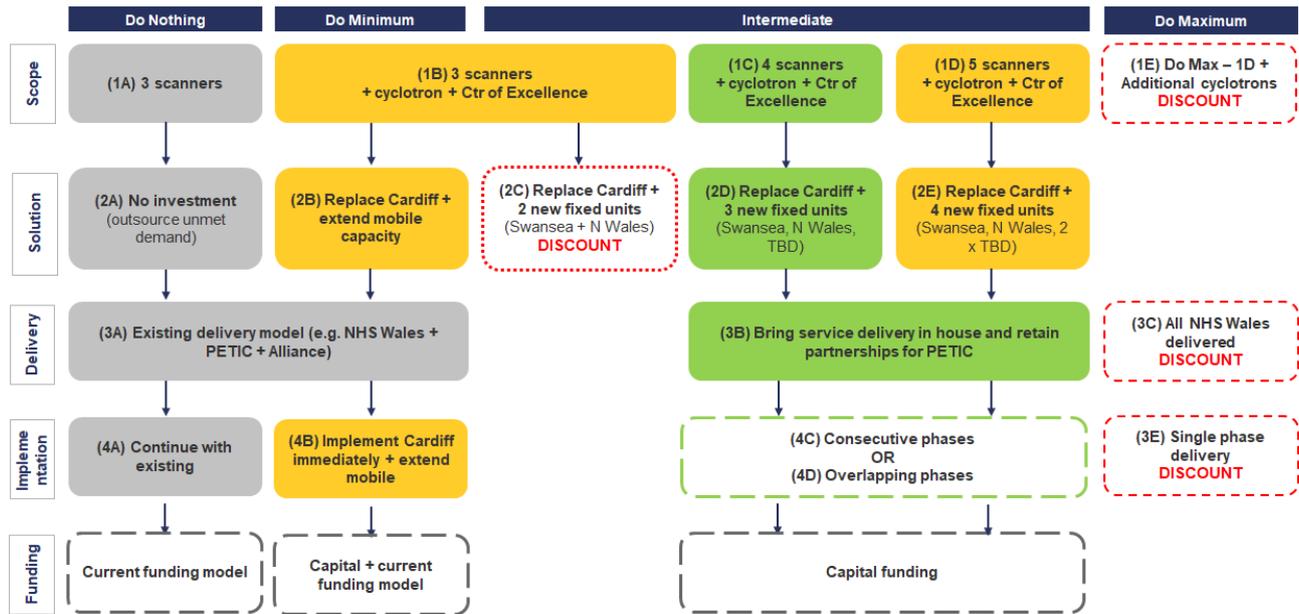
Dimension	Option	Description	Conclusion
Do nothing	1A	Continue with current arrangements	Carry forward (Baseline)
Intermediate options	1B	Deliver Cardiff capital solution in tandem with extending mobile scanning capacity	Carry forward (Do minimum)
	1C	Phased approach	Cardiff 2021/22 North Wales 2023/24 Swansea 2023/24 4 <sup>th</sup> scanner 2026/27

Dimension	Option	Description	Conclusion	
Do maximum	1D	Single phase approach	Full programme delivered simultaneously	Discount

### 2.1.9 Options Framework Summary

The figure below demonstrates a summary of the longlist using the options framework.

Figure 12: Options framework



### 2.1.10 Short Listed Options

The options framework can be used to filter the options considered at the long-list stage to generate the potential short-list for the project, as illustrated below.

Table 29: Shortlist of options

Options	Option 1 Business as Usual	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
Scope	<b>3 Scanners (Core scope)</b> • Access to 3 PET-CT scanners in Cardiff, Swansea, North Wales	<b>3 Scanners (Core + Desirable scope)</b> • Access to 3 PET-CT scanners in Cardiff, Swansea, North Wales • Cyclotron co-located Cardiff • Centres of Excellence facilities (with new scanners)	<b>4 scanners (+Desirable)</b> • Access to 3 PET-CT scanners in Cardiff, Swansea, North Wales • Cyclotron co-located Cardiff • Centres of Excellence facilities • 1 additional PET-CT or PET-MR scanner (aligned to clinical model/demand)	<b>5 scanners (+Optional)</b> • Access to 3 PET-CT scanners in Cardiff, Swansea, North Wales • Cyclotron co-located Cardiff • Centres of Excellence facilities • 2 additional PET-CT or PET-MR scanner (aligned to clinical model/demand)
Solution	No investment (Outsource unmet demand to mobile scanners)	Replace Cardiff equipment + extend mobile capacity in Swansea and North Wales	Replace Cardiff equipment + 3 new fixed units (Swansea, North Wales, 1 location to be determined)	Replace Cardiff equipment + 4 new fixed units (Swansea, North Wales, 2 locations to be determined)
Delivery	Existing delivery model (e.g. NHS Wales + PETIC + Alliance)	Existing delivery model (e.g. NHS Wales + PETIC + Alliance)	Bring service delivery in house and retain partnerships for PETIC	Bring service delivery in house and retain partnerships for PETIC
Implementation	Continue with existing arrangements	Deliver Cardiff replacement + extend mobile provision	<b>Phased approach</b> • Cardiff 2021/22 • North Wales 2023/24 • Swansea 2023/24 • 4 <sup>th</sup> scanner 2025/26	<b>Phased approach</b> • Cardiff 2021/22 • North Wales 2023/24 • Swansea 2023/24 • 4 <sup>th</sup> scanner 2025/26 • 5 <sup>th</sup> scanner 2028/29
Funding	Current funding model	Capital and revenue	Capital funding	Capital funding

As a result of this the following shortlist of options is carried forward to explore in greater detail within the economic appraisal:

- Option 1 – Business as Usual: Do nothing.
- Option 2 – Do Minimum: Retain 1 fixed and extend capacity of 2 mobile scanners.
- Option 3 – Preferred Way Forward: Provide 4 fixed scanners (10-year programme).
- Option 4 – More Ambitious: Provide 5 fixed scanners (10-year programme).

## 2.2 Economic Appraisal

### 2.2.1 Introduction

The purpose of the economic appraisal is to evaluate the costs, benefits and risks of the shortlisted options in order to identify the option that is most likely to offer best public value for money. In line with current HM Treasury Green Book and Welsh Better Business Case programme business case guidance, this involves:

- Estimating indicative whole life capital and revenue costs for each option.
- Undertaking an assessment of benefits and risks for each option, outlining how these will be quantified in monetary-equivalent values at OBC stage.
- Using DHSC's Comprehensive Investment Appraisal (CIA) Model to prepare discounted cash flows and estimate the Net Present Social Value (NPSV) and Benefit Cost Ratio (BCR) for each option.
- Presenting the results, including sensitivity analysis, to determine the preferred way forward for the overall programme.

### 2.2.2 The Short List of Options

As outlined in the previous section, a short list of options has been identified. A comparison of the key features of each of the shortlisted options is provided in the table below.

Table 30: Comparison of shortlisted options

	Option 1 Business as Usual (BAU)	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
<b>Description</b>	Do nothing	Retain 1 fixed and extend capacity of 2 mobile scanners	Provide 4 fixed scanners (10-year programme)	Provide 5 fixed scanners (10-year programme)
<b>Project 1 Cardiff 2021/22</b>		Replace PET-CT Upgrade of cyclotron	Replace PET-CT Upgrade of cyclotron	Replace PET-CT Upgrade of cyclotron
<b>Project 2 North Wales 2023/24</b>		No capital investment Extend capacity of mobile unit	New PET-CT New build (260m <sup>2</sup> )	New PET-CT New build (260m <sup>2</sup> )
<b>Project 3 Swansea 2023/24</b>		No capital investment Extend capacity of mobile unit	New PET-CT Refurbish an existing building (176m <sup>2</sup> ) + new build extension (40m <sup>2</sup> )	New PET-CT Refurbish an existing building (176m <sup>2</sup> ) + new build extension (40m <sup>2</sup> )
<b>Project 4 4th scanner 2025/26</b>			New PET-CT New build (260m <sup>2</sup> )	New PET-CT New build (260m <sup>2</sup> )
<b>Project 5 5th scanner 2028/29</b>				New PET-CT New build (260m <sup>2</sup> )

### 2.2.3 Estimating Initial Capital Costs

Indicative capital costs have been estimated by SES for the purposes of the PBC based on the following assumptions:

- Floor area required to create a facility to house a PET-CT including supporting areas, such as waiting areas and uptake rooms.
- Construction costs based on:
  - Refurbishment costs £2k per m2 + on costs; and
  - New build costs £4k per m2 + on costs.
- Allowance for lead lining.
- On costs at 35%.
- Fees at 16%.
- Non works as estimated.
- Equipment costs:
  - PET-CT scanner £2.9m (including ancillary equipment and Radiotherapy adaptations); and
  - Cyclotron refresh £1.75m (including ion source replacement and hot cells).
- Planning contingency 10%.
- VAT at 20% on all costs except fees.

The resulting capital costs estimates for the programme are summarised in the table below. Copies of the PBC Capital Cost Forms are provided in Appendix 2.

Table 31: Capital costs - Programme (£'000)

	Option 1 Business as Usual (BAU)	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
Construction	0	45	4,593	6,341
Fees	0	0	735	1,015
Non works	0	15	80	120
Equipment costs	0	4,673	13,553	16,513
Planning contingency	0	473	1,896	2,399
<b>Subtotal</b>	<b>0</b>	<b>5,206</b>	<b>20,857</b>	<b>26,387</b>
VAT	0	1,041	4,024	5,075
<b>Total capital costs incl. VAT</b>	<b>0</b>	<b>6,248</b>	<b>24,881</b>	<b>31,462</b>

Indicative capital costs for each of the individual projects is shown in the table below.

Table 32: Capital costs – By Project (£'000)

	Option 1 Business as Usual (BAU)	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
Project 1 - Replace Cardiff equipment	0	6,248	6,248	6,248
Project 2 - Fixed scanner North Wales	0	0	6,573	6,576
Project 3 - Fixed scanner Swansea	0	0	5,486	5,488
Project 4 - 4th fixed scanner	0	0	6,573	6,576
Project 5 - 5th fixed scanner	0	0	0	6,576
<b>Total capital costs incl. VAT</b>	<b>0</b>	<b>6,248</b>	<b>24,881</b>	<b>31,462</b>

Indicative cash flow profiles for each of the options are shown in the table below.

Table 33: Capital costs – By Project (£'000)

Date	Option 1 Business as Usual (BAU)	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
2021/22		4,472	4,675	4,688
2022/23		1,775	2,026	2,040
2023/24		0	11,693	11,693
2024/25		0	152	152
2025/26		0	6,335	6,322
2026/27		0	0	94
2027/28		0	0	152
2028/29		0	0	6,322
<b>Total capital costs incl. VAT</b>	<b>0</b>	<b>6,248</b>	<b>24,881</b>	<b>31,462</b>

For completeness and ease of reference to capital cost forms, these figures are shown here including VAT and inflation adjustment. However, it should be noted that for the purposes of the economic appraisal all costs exclude VAT and are restated at base year prices in accordance with HM Treasury Green Book guidance.

More detailed design work will be required at Project Business Case stage and costs will be refined accordingly.

## 2.2.4 Estimating Lifecycle Capital Costs

Indicative lifecycle costs have been estimated over a 30-year appraisal period based on the following assumptions:

- Equipment replacement every 10 years.
- Building lifecycle costs based on typical average annual costs per m2 as follows:
  - New build spaces at £29 per m2; and
  - Refurbished spaces at £35 per m2.
- Allowances applied as follows:
  - 10% management and fees; and
  - 10% contingency.
- Costs applied where appropriate to option as follows:
  - Swansea 176m2 of refurbished space and 40m2 of new build space from 2023/24;
  - North Wales 260m2 of new build space from 2023/24;
  - 4<sup>th</sup> scanner 260m2 of new build space from 2025/26; and
  - 5<sup>th</sup> scanner 260m2 of new build space from 2028/29.

The resulting indicative lifecycle costs over the 30-year appraisal period are summarised in the table below. Detailed calculations are provided in the Economic and Financial Calculations in Appendix 3.

Table 34: Lifecycle during 30-year appraisal period (£'000)

	Option 1 Business as Usual (BAU)	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
Lifecycle for refurbished areas	0	0	173	173
Lifecycle for new build areas	0	0	442	624
Equipment replacement	0	14,019	31,779	37,699
Allowances	0	2,804	6,479	7,699
<b>Total lifecycle costs (30-year period)</b>	<b>0</b>	<b>16,823</b>	<b>38,873</b>	<b>46,195</b>
<b>Equivalent annual cost</b>	<b>0</b>	<b>543</b>	<b>1,254</b>	<b>1,490</b>

Lifecycle costs will be refined at Project Business Case stage based on detailed design.

## 2.2.5 Estimating Transitional Costs

Transitional costs will be incurred in relation to delivery of programme, including activities such as programme management and dual running costs during any disruptive works.

Indicative costs have been calculated based on the following assumptions:

- Programme team costs including:
  - 1 WTE x Band 8b and 1 WTE Band 4.
  - Mid-point of pay scale including on-costs.
  - Incurred from 2021/22 until final project delivered (2025/26 for Option 3 and 2028/29 Option 4).
- Dual running costs:
  - 3 months of dual running costs during replacement of Cardiff scanner.
  - No other dual running costs required as the use of mobile scanners can continue during the construction of the new fixed scanner units.

The resulting indicative transitional costs are summarised in the table below.

Table 35: Transitional costs (£'000)

	Option 1 Business as Usual (BAU)	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
Programme team	0	0	502	804
Dual running costs	0	543	543	543
<b>Total transitional costs</b>	<b>0</b>	<b>543</b>	<b>1,045</b>	<b>1,347</b>

## 2.2.6 Estimating Recurring Revenue Costs

Baseline costs have been identified which demonstrate that it currently costs WHSSC £4.5m p.a. to deliver PET-CT services in Wales, based on 2020/21 budget. This equates to £872 per scan based on 2021 predicted demand.

An analysis of this is provided below.

Table 36: Baseline revenue costs

	Total costs	Basis
Betsi Cadwaladr University Health Board	1,105	2020/21 Budget
Swansea Bay University Health Board and PETIC (Cardiff)	2,937	2020/21 Budget
New indications Wales	500	2020/21 Budget
<b>Total cost to WHSSC (£'000)</b>	<b>4,542</b>	
<b>Average number of scans</b>	<b>5,207</b>	Predicted 2021 demand
<b>Average cost per scan</b>	<b>£872.29</b>	

Recurring revenue costs are anticipated to increase over the next 10 years in line with the demand modelling outlined in the Strategic Case section 5.5. Depending on the option, it may be possible to partly mitigate the increased costs by reducing the average cost per scan.

The current pricing model includes the following range of charges:

- The cost from PETIC is between £850 - £925 per scan.
- The mobile scanner at Wrexham costs between £806 - £896 per scan.
- The mobile scanner at Swansea costs around £950 per scan.
- The Christie tariff for 2020/21 is £846 per scan.
- The cost from external providers can increase to up to £1,500 per scan.
- PSMA scans cost between £1600 - £1825 per scan.

Initial work undertaken suggests that a fixed digital scanner operated by NHS Wales would provide opportunities to significantly reduce the cost per scan. Indicative costs have been calculated based on the following assumptions:

- Pay costs are based on the Workforce Group's agreed target staffing model. A preliminary workforce costing suggests that at mid-point of pay scale including on costs, this is likely to cost between £892k and £1,060k. For the purposes of the PBC, the maximum end of the range has been used.
- Non pay costs are based on the following assumptions:
- Equipment maintenance at 10% of capital costs.
- Radiopharmaceutical costs are based on estimated external provider prices which for the most common F-FDG scans typically range between £2580 - £3705 per day (equating to between 12-17 patient doses) plus £300 per delivery. F-PSMA radiopharmaceuticals are estimated to cost £950 per patient dose and have been applied to 6% of overall activity, in line with recent activity mix.
- Consumables and transport costs are based on the average cost per scan determined from total estimated costs outlined in the North Wales SOC revenue analysis.
- Building running costs are based on an overall average cost of £100 per m2 which includes Utilities, Soft FM and Hard FM.

Based on these assumptions it is estimated that it will cost NHS Wales £2.9m p.a. to operate each fixed digital scanner at full capacity. This is equivalent to £577 per scan, based on an average of 5,000 scans. An analysis of this is provided in the table below.

Table 37: Indicative revenue costs to operate digital scanner (£'000)

Element	Total annual costs (£'000)	Equivalent cost per scan
Workforce to operate digital scanner (7-12 patients per session)	1,060	£212.01
<b>Pay costs</b>	<b>1,060</b>	<b>£212.01</b>
Equipment maintenance	296	£59.20
Radiopharmaceuticals	1,308	£261.64
Consumables	47	£9.30
Delivery and transport	147	£29.45
Building running costs	26	£5.20
<b>Non pay costs</b>	<b>1,824</b>	<b>£364.80</b>
<b>Total costs</b>	<b>2,884</b>	<b>£576.81</b>

Indicative recurring revenue costs for each option in line with 10-year demand model have therefore been estimated based on the following assumptions:

- Digital scanner capacity is 5,288 scans.
- PETIC charges continue at £925 for first 2,150 scans, then £850 for 2150+ and are applied to South East Wales demand up to 5,288 scans.
- Operating costs for the new fixed scanners at North Wales and South West Wales, and the subsequent 4<sup>th</sup> and 5<sup>th</sup> scanners, where relevant to an option, are based on indicative operating costs outlined in Table 37 above and are applied as follows:
  - Variable costs (Radiopharmaceuticals, Consumables, Transport) applied based on the average cost per scan to predicted demand up to 5,288 scans.
  - Fixed costs (Equipment Maintenance, Building Running Costs) are applied in full from the year of opening.
  - Pay costs are also applied in full from the year of opening for the purposes of these calculations, although it should be noted than in reality pay costs are likely to be phased during the initial years of each scanner in line with activity. Further work will be undertaken at Project business case stage to develop detailed workforce plans and associated costs.
  - Any unmet demand assumed to be outsourced at average £935 per scan (to reflect range of fees including type and provider).

Detailed calculations are available in the PET-CT Revenue Workings in Appendix 4 and an extract provided below.

Table 38: Indicative 10-year recurring revenue costs (£'000)

Total costs £'000	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	2031/32	10-year total
Option 1: BAU - Outsource all activity	4,869	5,843	7,011	8,412	10,096	12,115	14,537	17,445	20,935	25,122	30,145	156,529
Option 2: Do Minimum	4,806	5,736	6,850	8,187	9,268	11,287	13,709	16,617	20,107	24,294	29,317	150,179
Option 3: 4 scanners	4,806	5,736	6,850	8,125	8,546	8,714	11,251	12,185	14,327	18,279	23,303	122,122
Option 4: 5 scanners	4,806	5,736	6,850	8,125	8,546	8,714	11,251	12,185	14,688	16,305	21,329	118,536
<b>Average cost per scan £</b>	<b>2021/22</b>	<b>2022/23</b>	<b>2023/24</b>	<b>2024/25</b>	<b>2025/26</b>	<b>2026/27</b>	<b>2027/28</b>	<b>2028/29</b>	<b>2029/30</b>	<b>2030/31</b>	<b>2031/32</b>	<b>10-year total</b>
Option 1: BAU - Outsource all activity	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00
Option 2: Do Minimum	£923.05	£917.89	£913.59	£910.00	£858.32	£871.10	£881.75	£890.62	£898.02	£904.18	£909.32	£897.07
Option 3: 4 scanners	£923.05	£917.89	£913.59	£903.07	£791.46	£672.53	£723.63	£653.09	£639.88	£680.32	£722.77	£729.47
Option 4: 5 scanners	£923.05	£917.89	£913.59	£903.07	£791.46	£672.53	£723.63	£653.09	£656.03	£606.86	£661.55	£708.06

This analysis demonstrates how the average price per scan is expected to change in relation to each of the options:

- Option 1 (BAU) – Average price increases to £935 per scan as all activity is outsourced.
- Option 2 (Do Minimum) – Average price increases to £898 as only the Cardiff scanner is replaced, for which PETIC pricing is retained, and there is significant reliance on outsourcing.
- Option 3 (4 fixed scanners) – Average price reduces to £729 due to the benefits of 3 new fixed scanners although there is some reliance on outsourcing from 2029/30 based on current demand predictions.
- Option 4 (5 scanners) – Average price reduces to £708 as there is no reliance on outsourcing during the 10-year period.

These costs have been incorporated into the economic appraisal for each option for the first 10 years. Costs are assumed to remain static from Year 11 onwards. This results in recurring revenue costs over a 30-year period as outlined in the table below.

Table 39: Recurring revenue costs (£'000)

Element	Option 1 Business as Usual (BAU)	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
Total revenue costs (30-year appraisal period)	759,436	759,374	588,176	545,115
Equivalent annual cost	25,315	25,312	19,606	18,171

### 2.2.7 Benefits

The delivery of the programme will deliver a range of benefits including:

- Improved quality and reduction in patient harm.
- Workforce resilience.
- Improved efficiency and economy.
- Improved access reducing patient travel time.
- Cost effective service supported by income generation.
- Provide capacity that meets population needs in line with international best practice.
- Increased opportunities for Research and Development.
- Increased opportunities for innovation.

Work will be required at Project Business Case to explore these benefits in detail and quantify them, where possible in monetary equivalent terms. Indicative methodologies and assumptions for doing so are provided in the table below.

Table 40: High level benefits assumptions

Benefit	Benefit type	Indicative methodology / assumptions for quantifying
<b>Improved quality and reduction in patient harm</b>		
B01 Avoid high-cost late-stage interventions	Cash releasing benefit	<p>As the demand modelling is refined, identify the number of patients for which improved staffing would reduce the need for high cost interventions.</p> <p>Allocate potential cost saving based on current evidence base. For instance the Evidence Review outlined in Specialised Services Commissioning Policy CP50a suggests PET-CT is c.£1500 cheaper than a neck dissection.</p> <p>As an indication, if even 10% of overall predicted demand was associated with reducing late stage cost interventions, based on an indicative £1500 per patient, this would equate to £4.8m annual financial benefit by 2031/32.</p>
B02 Improved diagnostic accuracy	Qualitative	It is anticipated that this benefit will be difficult to measure with any degree of certainty.
B03 Reduced waiting times	Quantitative (Unmonetised)	Determine baseline referral to reporting time and identify how many scans will achieve 10 day referral to report target.
B04 Improved patient experience	Qualitative	It is anticipated that it is difficult to demonstrate a direct correlation between the investment and patient experience.
<b>Workforce resilience</b>		
B05 Improved recruitment and retention	Qualitative	It is anticipated that it is difficult to demonstrate a direct correlation between the investment and recruitment and retention rates.
B06 Improved access to training and education	Quantitative (Unmonetised)	Based on learning needs analysis and evaluation data, identify baseline position and agree target improvement.
B07 Improved staff satisfaction	Qualitative	It is anticipated that it is difficult to demonstrate a direct correlation between the investment and staff satisfaction.
<b>Improved efficiency and economy</b>		
B08 Increased capacity resulting in ability to meet demand	Cash releasing	<p>Estimate average cost per scan based on refined costs at Project stage.</p> <p>Based on indicative costs outlined in section 2.6, it is anticipated that this will result in a reduction to overall average from £873 to between £708 - £729 depending on the option.</p>
B09 Reduced downtime	Non-cash releasing	<p>At the time of developing the PBC, there was limited data showing a significant number of cancelled sessions that were impacting on utilisation, however this is likely to be as a result of additional efforts by local service leads.</p> <p>This should be revisited at Project Business Case stage to determine whether number of cancellations has changed or whether any estimation can be made of time spent by local teams to manage utilisation.</p>
B10 Reduced reliance on mobile scanners	Cash releasing	<p>Estimate average cost per scan based on refined costs at Project stage.</p> <p>Based on indicative costs outlined in section 2.6, it is anticipated that the average cost per scan for NHS Wales managed digital scanners will equate to £577 which is significantly below the average of £935 per scan associated with mobile scanners currently.</p>

Benefit	Benefit type	Indicative methodology / assumptions for quantifying
<b>Improved access reducing patient travel</b>		
B11 Reduced patient travel time – value to patients	Societal (monetised)	Patient travel time analysis to be undertaken at Project business case stage. DfT TAG values of time can be used to estimate the economic value of any reduction in travel time.
B12 Reduced patient travel time – value to patients	Societal (monetised)	Converting the travel time analysis into mileage will enable a calculation to be made using the HMT Green Book toolkit to estimate reduction in CO2e and corresponding economic value.
<b>Cost effective service supported by income generation</b>		
B13 Income generation opportunities	Cash releasing	Work should be undertaken at Project business case stage to estimate the value of additional income from RD&I activity. It is estimated that up to 10% of a scanner's capacity could be used for this purpose and the demand modelling includes an estimate of around 7%.  As an indication, if 7% of activity generated income of £1500 per scan, that would result in a financial benefit of £3.3m by 2031/32.
<b>Provide capacity that meets population needs in line with best practice</b>		
B14 Better equity of access	Quantitative (Unmonetised)	At Project business case stage, determine the range of indications available at each centre and associated waiting times.
<b>Increase opportunities for Research and Development</b>		
B15 Increased proportion of staff research active	Quantitative (Unmonetised)	At Project business case stage, determine number of research posts at each site and potential impact in terms of publications, etc.
B16 Increased proportion of patients on clinical trials	Quantitative (Unmonetised)	At Project business case stage, determine number of patients able to participate at each site.
B17 Greater number of trials led by and participated in by PET site	Quantitative (Unmonetised)	At Project business case stage, determine number of potential trials at each site.
<b>Increased opportunities for innovation</b>		
B18 Improved access to a greater range of diagnostics to support greater range of therapeutics	Qualitative	It is anticipated that it is difficult to measure as dependent on a number of factors.

## 2.2.8 Risks

For the purposes of preparing an indicative cost benefit analysis for the PBC, a planning contingency of 10% has been incorporated into the capital costs.

At Project business case stage more detailed risk analysis will be undertaken and, where possible, risks will be quantified in monetary-equivalent values. This will include an analysis of:

- Optimism bias.
- Expected risk value.

## 2.2.9 Economic Appraisal Results

DHSC's Comprehensive Investment Appraisal (CIA) model has been populated with these indicative assumptions to support the appraisal of overall value for money and cost-benefit analysis of the shortlisted options.

The assumptions above have been incorporated into a discounted cash flow for each of the options. In line with HMT Green Book requirements:

- Costs, benefits and risks are calculated over a 31-year appraisal period including Year 0 (baseline year) + 30 years estimated useful life.
- Year 0 is 2021/22.
- Costs and benefits use real base year prices – all costs are expressed at 2020/21 prices in line with the baseline costs.
- The following costs are excluded from the economic appraisal:
  - Exchequer 'transfer' payments, such as VAT.
  - General inflation.
  - Sunk costs.
  - Non-cash items such as depreciation and impairments.
- A discount rate of 3.5% is applied.

A summary of the economic appraisal is shown in the table below.

Table 41: Economic appraisal overview (£'000)

	Option 1 Business as Usual (BAU)	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
<b>Undiscounted inputs</b>				
Initial capital costs	0	5,206	20,857	26,387
Lifecycle capital costs	0	16,823	38,873	46,195
<b>Total capital costs</b>	<b>0</b>	<b>22,029</b>	<b>59,729</b>	<b>72,583</b>
Transitional revenue costs	0	543	1,045	1,347
Recurring revenue costs	759,436	759,374	588,176	545,115
<b>Total revenue costs</b>	<b>759,436</b>	<b>759,917</b>	<b>589,221</b>	<b>546,462</b>
<b>Undiscounted Net Present Cost</b>	<b>759,436</b>	<b>781,946</b>	<b>648,950</b>	<b>619,045</b>
<b>Discounted outputs</b>				
Initial capital costs	0	5,156	19,453	23,813
Lifecycle capital costs	0	8,791	21,005	24,506
<b>Total capital costs</b>	<b>0</b>	<b>13,948</b>	<b>40,458</b>	<b>48,319</b>
Transitional revenue costs	0	543	1,012	1,258
Recurring revenue costs	428,611	428,548	333,182	310,723
<b>Total revenue costs</b>	<b>428,611</b>	<b>429,091</b>	<b>334,194</b>	<b>311,981</b>
<b>Discounted Net Present Cost</b>	<b>428,611</b>	<b>443,039</b>	<b>374,653</b>	<b>360,300</b>
<b>Ranking</b>	<b>3</b>	<b>4</b>	<b>2</b>	<b>1</b>

This analysis demonstrates that Option 4 (More Ambitious) results in the lowest Net Present Cost (NPC), closely followed by Option 3 (Preferred Way Forward).

The economic summary in the CIA model calculates the incremental costs and benefits (which in this case refers to reduction in revenue costs) in relation to the baseline option, Option 1 (BAU).

Table 42: Economic appraisal results (£'000)

	Option 1 Business as Usual (BAU)	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
Incremental costs - total	0	(14,491)	(41,471)	(49,577)
Incremental benefits - total	0	62	95,429	117,888
Incremental Net Present Social Value	0	(14,428)	53,958	68,311
Benefit-cost ratio	0.00	0.00	2.30	2.38
Rank	4	3	2	1

This analysis suggests that, on the face of it, Option 4 (More Ambitious) provides the best value for money since it results in the following:

- Lowest Net Present Cost (£360.3m over 30 years).
- Lowest incremental Net Present Social Value (i.e. Net Present Cost is £68.3m lower than the baseline option).
- Highest Benefit Cost Ratio of 2.38.

However, this is closely followed by Option 3 (Preferred Way Forward) with the following results:

- Second lowest Net Present Cost (£374.7m over 30 years).
- Second lowest incremental Net Present Social Value (i.e. Net Present Cost is £54.0m lower than the baseline option).
- Second highest Benefit Cost Ratio of 2.30.

In addition to offering the second best value for money this option also provides greater flexibility since the need for the 5th scanner can be reviewed at a later date, reducing capital investment requirements and minimising risk. The impact of this is explored in the section on sensitivity analysis below.

### 2.2.10 Sensitivity Analysis

The ranking of the economic appraisal is highly dependent on the financial benefits associated resulting from the revenue costs. These have been calculated based on the current demand modelling which assumes 20% year on year demand growth.

The analysis below demonstrates that if actual demand growth is less than 17.5% year on year, Option 3 (Preferred Way Forward) consistently results in the highest Benefit Cost Ratio (BCR).

Table 43: Summary of Sensitivity analysis

	Option 1 Business as Usual (BAU)	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
BCR - Results of economic appraisal	0.0	0.0	2.3	2.4
BCR - Scenario 1: Growth at 17.5%	0.0	0.0	2.3	2.3
BCR - Scenario 2: Growth at 15%	0.0	0.0	2.1	1.5
BCR - Scenario 3: Growth at 12.5%	0.0	0.0	1.4	0.9
BCR - Scenario 4: Growth at 10.0%	0.0	0.0	0.8	0.4

This demonstrates that the ranking of options is heavily dependent on demand modelling assumptions and, on this basis, Option 3 (Preferred Way Forward) results in best value for money given the additional flexibility.

## 2.2.11 Conclusion

A summary of the overall options appraisal results is provided in the table below.

Table 44: Options overview

Element	Option 1 Business as Usual (BAU)	Option 2 Do Minimum	Option 3 Preferred Way Forward	Option 4 More Ambitious
<b>Description</b>	Do nothing	Retain 1 fixed and extend capacity of 2 mobile scanners	Provide 4 fixed scanners (10-year programme)	Provide 5 fixed scanners (10-year programme)
<b>Incremental NPSV</b>	-	£(4.4)m	£54.0m	£68.3m
<b>Benefit Cost Ratio</b>	-	0.00	2.30	2.38
<b>Average cost per scan (10 year period)</b>	£935	£898	£729	£708
<b>Sensitivity and risks</b>	Consistently ranks as worst value for money even with significant changes in assumptions	Consistently ranks as second worst value for money even with significant changes in assumptions	Ranks as best value for money if demand growth is lower than 17.5% year on year	If demand growth is lower than predicted 5 <sup>th</sup> scanner will be significantly underutilised

Based on the overall results, it is recommended that Option 3 (Preferred Way Forward) is carried forward as the preferred way forward for delivering the programme and the potential need for a 5th scanner assessed at a later date.

## 2.2.12 Preferred way forward

The preferred way forward is to implement a programme which will deliver 4 fixed digital scanners in NHS Wales. This will require capital investment of £24.9m to deliver the following projects:

Table 45: Preferred way forward programme

Project	Implementation	Investment requirements
Project 1 - Cardiff	2021/22	<ul style="list-style-type: none"> <li>Replace PET-CT</li> <li>Upgrade of cyclotron</li> </ul>

Project	Implementation	Investment requirements
Project 2 - North Wales	2023/24	<ul style="list-style-type: none"> <li>• New PET-CT</li> <li>• New build (260m2)</li> </ul>
Project 3 - Swansea	2023/24	<ul style="list-style-type: none"> <li>• New PET-CT</li> <li>• Refurbish an existing building (176m2) + new build extension (40m2)</li> </ul>
Project 4 - 4 <sup>th</sup> scanner	2025/26	<ul style="list-style-type: none"> <li>• New PET-CT</li> <li>• New build (260m2)</li> </ul>

As a result of this investment the preferred way forward is expected to deliver the following:

- Capacity to meet predicted demand to 2028/29.
- Opportunities to reduce the cost per scan to an average of £729 per scan in the first 10 years, based on indicative operating costs of NHS Wales fixed digital scanners estimated at £577 per scan and continuing with current PETIC charging arrangements.
- Opportunities to reduce overall system costs due to avoiding late stage interventions. This could be significant since the evidence base suggests for certain diseases and patient pathways, such as the treatment of neck cancers, PET-CT scans are potentially £1,500 more cost effective. Further work will be required at Project business case stage to determine more accurate activity levels in relation to patient pathways. As an indication, if this sort of benefit was applied to 10% of activity, this would equate to a financial benefit of around £4.8m by 2031/32.
- Opportunities to generate income from RD&I activity. It is estimated that 7% of predicted demand relates to RD&I activity. Again, further work will be required at Project business case stage to identify accurate numbers but, as an indication, if research scans were charged at £1500, this would equate to an annual financial benefit of around £3.3m by 2031/32.
- Delivery of non-financial benefits including:
  - Improved quality and reduction in patient harm including reduced waiting times, better diagnostic accuracy and improved patient outcomes and experience.
  - Workforce resilience including improved recruitment and retention, greater access to training and education, and improved staff satisfaction.
  - Improved access reducing patient travel time which benefits patient and reduces greenhouse gases.
  - Provide capacity that meets population needs in line with international best practice.
  - Increased opportunities for Research and Development.
  - Increased opportunities for innovation.

In addition to this, there is flexibility to introduce a 5th scanner at a later date based on updated demand and capacity analysis at that time, reducing committed capital expenditure and minimising risk.

Plans to implement the preferred way forward and the commercial, financial and management implications are outlined in the subsequent chapters of this business case.

## 3 Commercial Case

### 3.1 Introduction

#### 3.1.1 Purpose

The purpose of this section is to set out an initial high level Procurement Strategy to establish appropriate procurement and contractual arrangements in order to implement and deliver the Programme's Projects and key activities.

The Programme will look to acquire four fixed, digital (AI enabled) PET-CT (Positron Emission Tomography combined with Computerised Tomography) scanners and install these key items of equipment at four locations across Wales. This procurement includes ancillary equipment, radiotherapy adaptations, in addition to an ion source and hot cell replacement for the cyclotron at the Cardiff site.

#### 3.1.2 Considerations

The Programme Manager has developed this commercial case with support and advice from specialist colleagues at NHS Wales Shared Services Partnership - Specialist Estates Services [NWSSP-SES] and Procurement Services [NWSSP-PS].

It should be emphasised that whilst the Programme is being hosted by WHSSC, capital funding will be given to the respective organisations, all of which have Estates & Facilities and Procurement teams that will have capability to carry out procurement activities. Dependent upon availability of a suitably experienced individual during the time period, there would be some benefit in an individual taking the procurement lead for this Programme.

Another key consideration is that the capital funding for the PETIC Cardiff site will be given to Cardiff University, and therefore this site will be subject to the University procurement processes and procedures. This will require a close working relationship with Cardiff and Vale University Health Board for effective implementation.

There are multiple procurement routes that can be followed, however all of the major items of equipment are available on a compliant preapproved framework. NHS Wales has direct access to this framework and at the time of writing it is thought that Cardiff University can, through its own procurement department, access this same agreement.

In line with clinical demand and workforce availability, the implementation of the Programme will need to be carried out in a phased manner. Dependent upon the timings of the phases and or the available funds, it may be possible to aggregate NHS Wales purchasing requirements so as to generate additional value.

Given the scale and impact on current Welsh NHS services that the All Wales PET Programme will deliver, it is imperative to ensure appropriate governance is in place for procurement. As such we propose that a multidisciplinary team will make up membership of a Procurement Workstream that will support the Programme.

## 3.2 Key Objectives of the Procurement

The key objectives of the procurement and its scope have been considered to ensure an optimum approach.

The key objectives are:

- a solution that delivers safe and effective clinical outcomes for patients;
- a solution that is capable of future development to meet expanding clinical needs, such as radiotherapy planning;
- a solution that is capable of answering research, development and innovation needs;
- a solution that offers value for money over its lifetime;
- a solution that is "*best in class*" (where technically, clinically and financially feasible);
- a solution that is fully interoperable across all elements;
- a solution that provides the requisite business management as well as clinical functions;
- a solution that, as far as possible, enables efficient, high quality diagnostic regimens to be introduced;
- a solution that offers full audit facilities for process development and research;
- a solution capable of meeting the needs of All Wales PET Service Clinical Model.

It is important to highlight that the objectives derive from the requirements of All Wales PET Programme.

## 3.3 Scope of Procurement

The Equipment/items covered under the procurement is:

- Four PET-CT Scanners (AI enabled; one scanner at each site)
- Ancillary equipment and phantoms (Robotic radiotracer dispenser)
- Radiotherapy adaptations (laser bridge, flat table top)

The Equipment must be interoperable, meet all relevant standards (as a minimum) and be demonstrably proven to operate as a complete technical and clinical solution.

The total estimated capital value of the Equipment for the Preferred Way Forward is circa £13.5 million. This will be profiled over the period of five years. This is supported by build works costs of circa £4.6 million, with fees and non-works costs circa £815,000. A quantified risk and contingency has been allocated at circa £1.9 million. Net VAT has been calculated at circa £4 million, with the total Programme cost being circa £24.9 million, inclusive of quantified risk and contingency.

Programme Management is based at the host organisation WHSSC and costs for this post are currently sourced via the NHS Wales Collaborative and have been agreed until 31st March 2022.

The revenue for staffing and maintenance/ongoing support is not included in these figures and are addresses in the Economic and Financial Cases.

Project Management support is expected to be funded by Health Boards and the Programme Management funding is to be confirmed.

The full extent of the capital and revenue costs will not be known until Full Business Cases are complete for each site. As such, implementation and roll out is not considered in any detail within this document.

The prospective timelines for the four projects within this Programme can be seen in Table 46.

Table 46: High level dates of the Projects and business cases

Business Case (BC)	Proposed date of Welsh Gov. BC approval	Proposed “go live” date	
<b>Project 1</b>			
BJC	July 2021	PET Scanner	March 2022
		Ion Source replacement	March 2022
		Hot Cell replacement	March 2023
<b>Project 2</b>			
SOC1	July 2021	January 2024	
OBC/FBC	March 2022		
<b>Project 3</b>			
OBC2	November 2021	November 2023	
FBC2	July 2022		
<b>Project 4</b>			
Appraisal Process	April 2023	June 2026	
OBC3	January 2024		
FBC3	December 2024		

### 3.4 Proposed Contractual Structure

The decision of supplier will sit with the procuring organisation following evaluation, which will enter into a contract with the organisation directly. However it should be noted that a collaborative approach may add additional value should this be deemed deliverable given the extended timeline of the phases.

The Procurement Workstream membership will consist of the specialists within NWSSP-SES, NWSSP-PS, organisations Procurement and Estates representatives, Programme Manager and Project Teams at relevant Health Boards, Trusts and Cardiff University.

The question as to whether the Equipment requirement should be procured as (i) single contract or (ii) a series of separate contracts, has been considered. As the procurement will utilise a compliant framework agreement to secure the requirements, then there will likely be separate contracts between suppliers and the organisation that will purchase the equipment.

It is possible that the Procurement Workstream will propose running one procurement for the NHS equipment, depending upon the timings. For instance if phasing of projects is less than two years apart, there may be option to fix the costs and place orders at the same time, deploying when needed at a future date.

It is anticipated that each organisation that subsequently hosts a digital PET scanner will enter into a contract with the supplier. This contract will be subject to the hosting organisations local governance, procurement and due diligence processes.

An initial assessment of the key risks, issues and options determined that procuring through separate contracts for the requirements would:

- be the most likely to achieve the key objectives
- allow the Programme to phase implementation, in line with clinical demand and infrastructure constraints
- allow Cardiff University to follow its procurement and contracting processes
- provide each NHS organisation with the least risk approach in terms of achieving a solution that delivers Equipment interoperability
- allow each NHS organisation to manage its procurement process more easily
- be less complex
- place risk in the most appropriate place

However, it should be noted that procuring through separate contracts may cause interoperability issues, result in a diminished value for money opportunity, a potential loss of consistency of approach across Wales and additional contract management burden. Therefore, these items will require additional consideration at the Procurement Workstream.

### 3.5 Evaluation

On conclusion of the procurement phase and final evaluation of the responses, the Procurement Workstream will make a recommendation based on the most economically advantageous tender(s). This recommendation will be recorded in a final evaluation report, which will set out the basis for the award decision, for the formal approval of the PET Strategic Programme Board and internal governance of the receiving organisation.

Any award will be subject to a mandatory 10-day Standstill period. Final award will also be subject to approval by the National Imaging Strategic Programme Board and Collaborative Executive Group, Full Business Case Approval and Notification being provided from the Welsh Government Cabinet Secretary for Sport, Health and Wellbeing.

Suppliers will be allowed an opportunity for a full debrief following the formal decision being ratified and approved.

The full evaluation methodology will be set out in the procurement strategy which will be developed post PBC approval and be consistent and in accordance with the requirements of the Framework Agreement being utilised.

### 3.6 Procurement Resources

The Procurement Workstream will consist of an experienced and suitably skilled multi-disciplinary team. They will be able to advise each PET scanning site procurement team and membership of this Workstream should include appropriate representation from each site procurement team.

Each local site procurement team could consist of the following membership:

- Organisation or Health Board responsible person
- Head of PET scanning Services (if applicable)
- PET Scanning Services Manager
- Organisation or Health Board Estates representation
- Organisation or Health Board Procurement representation
- End User Clinical lead
- Organisation or Health Board Finance lead
- NWSSP – Senior Advisor
- NWSSP – Procurement Lead
- PET site Project Manager.

A fully resourced, suitably experienced and structured Procurement Workstream and Project Team to oversee the procurement process would be a pre-requisite to achieving a successful outcome.

### 3.6.1 Procurement of Specialist Advisors

Each Organisation or Health Board will have in-house resources and expertise and experience in procuring this or similar equipment. Indeed, in-house legal support will be pertinent as a good reference point.

Additional support will be provided by colleagues from NWSSP-SES and PS.

## 3.7 Key Procurement Risks and Challenges

Set out in Table 47 below, is a non-exhaustive list of key risks and challenges which can compromise the outcome of the tender process in the absence of adequate preparation and governance arrangements

Table 47: Key Risks and Challenges

Key Risk & Challenges	Actions to Mitigate / Manage
Interfaces and requirements between the PET scanner Procurement and the Programme agreement for the scanners do not align	Sharing of key document and alignment of personnel.
Nuclear Medicine Consolidation Programme at North Wales site delayed – impact on All Wales PET Programme delivery	The Health Board would still be required to undertake appropriate procurement of equipment/solutions. Sharing of key documents between Programmes Boards.
Timeline between concluding procurement and the likely timeline for deployment into Health Boards	As above.
Issues stemming from insufficient numbers of staff and a lack of internal resources.	Each Health Board staffing and skill profile must be identified, understood, resourced and deployed effectively prior to procurement.
Adequate and appropriate engagement from senior management and operational staff	Ensure governance arrangements are in place to secure senior management and Health Boards key operational

Key Risk & Challenges	Actions to Mitigate / Manage
	staff engagement with, and commitment to, each project throughout to ensure that Programme needs are truly reflected in the final outcome.
Associated facilities are not up to service specification	Ensure breakpoints to review purchase are included in contract and ensure financial contingency is in place

### 3.8 Prospective Timeline

Table 48 below sets out the prospective timeline for the procurement at each site. The timescales are compliant with the relevant procurement procedures/regulations at the time of writing this Programme Business Case.

Soon after this Programme Business Case is endorsed by Welsh Government, the Procurement Workstream will hold a workshop that will include membership as noted above from Shared Services and local organisation. This will act as the catalyst to evaluating all aspects of procurement, as noted throughout this document.

*Table 48: Prospective Timeline*

Activity	Timeframe
Health Board approval of Outline Business Case	2 months
Welsh Government approval of Outline Business Case	2 months
Pre-tender market engagement	20 days
Time for Outline Tender returns/clarification	40 days
Time for final tender returns	25 days
Evaluate final tenders	20 days
Full Business Case drafting and submission	2 months
Welsh Government approval of Full Business Case	2 months
Contract Award	Minimum 10 days+

# 4 Financial Case

## 4.1 Financial Appraisal

### 4.1.1 Introduction

The purpose of the Financial Case is to consider the financial impact of the delivering preferred way forward and demonstrate affordability of the programme.

The preferred way forward identified in the Economic Case is to implement a programme that will deliver four fixed digital scanners in Wales and involves investing in the following projects:

- Project 1: To replace the PET-CT scanner and upgrade the cyclotron at the existing PETIC site in Cardiff during 2021/22.
- Project 2: To create a new fixed PET-CT scanner in North Wales by constructing a new build facility and procuring a PET-CT scanner by 2023/24.
- Project 3: To create a new fixed PET-CT scanner in South West Wales by refurbishing and extending an existing building and procuring a PET-CT scanner by 2023/24.
- Project 4: To create a fourth fixed PET-CT scanner in a location which will be determined in relation to demand needs at the time by constructing a new build facility and procuring a PET-CT scanner by 2025/26.

### 4.1.2 Capital Requirements

Capital funding of £24,881k is sought from Welsh Government to deliver the All Wales PET-CT programme.

This is based on indicative costs which have been estimated by SES based on the following high level assumptions:

- The floor area required to create a facility to house a PET-CT including supporting areas, such as waiting areas and uptake rooms has been calculated.
- Construction costs have been allocated to the floor areas as follows:
  - Refurbishment costs £2k per m<sup>2</sup> + on costs; and
  - New build costs £4k per m<sup>2</sup> + on costs.
- An allowance for lead lining has been included.
- On costs have been included at 35%.
- Fees have been included at 16%.
- An estimate for non-works has been estimated.
- Equipment costs are based on typical market costs:
  - PET-CT scanner £2.9m (including ancillary equipment and Radiotherapy adaptations); and
  - Cyclotron refresh £1.75m (including ion source replacement and hot cells).
- Planning contingency has been included at 10%.
- VAT has been applied at 20% to all costs except fees.

The PBC capital cost forms are provided in Appendix 10. The table below provides an overview of total capital costs for the delivering the overall programme.

Table 49: Capital costs - Programme

	Net Costs £'000	VAT £'000	Total Costs £'000
Construction	4,593	919	5,511
Fees	735	0	735
Non works	80	16	96
Equipment costs	13,553	2,711	16,264
Planning contingency	1,896	379	2,275
<b>Total capital costs</b>	<b>20,857</b>	<b>4,024</b>	<b>24,881</b>

Indicative capital costs for each of the individual projects are shown in the table below.

Table 50: Capital costs - By Project

	Net Costs £'000	VAT £'000	Total Costs £'000
Project 1 - Replace Cardiff equipment	5,206	1,041	6,248
Project 2 - Fixed scanner North Wales	5,525	1,048	6,573
Project 3 - Fixed scanner Swansea	4,600	886	5,486
Project 4 - 4th fixed scanner	5,525	1,048	6,573
<b>Total capital costs</b>	<b>20,857</b>	<b>4,024</b>	<b>24,881</b>

An indicative cash flow for capital costs is shown in the table below.

Table 51: Capital costs - Cash flow

	Net Costs £'000	VAT £'000	Total Costs £'000
2021/22	3,919	756	4,675
2022/23	1,719	307	2,026
2023/24	9,780	1,913	11,693
2024/25	145	7	152
2025/26	5,293	1,042	6,335
<b>Total capital costs</b>	<b>20,857</b>	<b>4,024</b>	<b>24,881</b>

More detailed design work will be required at Project Business Case stage and costs will be refined accordingly.

### 4.1.3 Transitional Costs

Non-recurring revenue costs of £1,045k are expected to be incurred in relation to delivery of the programme, including activities such as programme management and dual running costs during any disruptive works.

This has been estimated based on the following assumptions:

- Programme team costs including:
  - 1 WTE x Band 8b and 1 WTE Band 4.
  - Mid-point of pay scale including on-costs.
  - Incurred from 2021/22 until final project delivered in 2025/26.
- Dual running costs:
  - 3 months of dual running costs during replacement of Cardiff scanner.
  - No other dual running costs required as the use of mobile scanners can continue during the construction of the new fixed scanner units.

The resulting indicative transitional costs are summarised in the table below.

Table 52: Transitional costs – Cash flow

	Programme team £'000	Dual running £'000	Total costs £'000
2021/22	100	545	645
2022/23	100		100
2023/24	100		100
2024/25	100		100
2025/26	100		100
<b>Total capital costs</b>	<b>500</b>	<b>545</b>	<b>1,045</b>

#### 4.1.4 Estimating Recurring Revenue Costs

Baseline costs have been identified which demonstrate that it currently costs WHSSC £4.5m p.a. to deliver PET-CT services in Wales, based on 2020/21 budget. This equates to £872 per scan based on 2021 predicted demand. An analysis of this is provided below.

Table 53: Baseline revenue costs

	Total costs	Basis
Betsi Cadwaladr University Health Board	1,105	2020/21 Budget
Swansea Bay University Health Board and PETIC (Cardiff)	2,937	2020/21 Budget
New indications Wales	500	2020/21 Budget
<b>Total cost to WHSSC (£'000)</b>	<b>4,542</b>	
Average number of scans	5,207	Predicted 2021 demand
<b>Average cost per scan</b>	<b>£872.29</b>	

Demand is anticipated to increase by 20% year on year over the next 10 years as outlined in the demand modelling outlined in the Strategic Case section 5.5.

Given the existing capacity, this is likely to result in a significant cost pressure if no investment is made, particularly since the current cost model includes the following range of potential costs:

- The cost from PETIC is between £850 - £925 per scan.

- The mobile scanner at Wrexham costs between £806 - £896 per scan.
- The mobile scanner at Swansea costs around £950 per scan.
- The Christie tariff for 2020/21 is £846 per scan.
- The cost from external providers can increase to up to £1,500 per scan.
- PSMA scans cost between £1600 - £1825 per scan.

Investing in fixed digital scanners which are operated by NHS Wales provides opportunities to significantly reduce the average cost per scan and partly mitigate the cost pressure created by the growing demand.

Indicative costs for each new NHS Wales fixed scanner have been calculated based on the following assumptions:

- Pay costs are based on the Workforce Group's agreed target staffing model. A preliminary workforce costing suggests that at mid-point of pay scale including on costs, this is likely to cost between £892k and £1,060k. For the purposes of the PBC, the maximum end of the range has been used.
- Non pay costs are based on the following assumptions:
- Equipment maintenance at 10% of capital costs.
- Radiopharmaceutical costs are based on estimated external provider prices which for the most common F-FDG scans typically range between £2580 - £3705 per batch (equating to between 12-17 patient doses) plus £300 per delivery. F-PSMA radiopharmaceuticals are estimated to cost around twice as much and have been applied to 6% of overall activity, in line with recent activity mix.
- Consumables and transport costs are based on the average cost per scan determined from total estimated costs outlined in the North Wales SOC revenue analysis.
- Building running costs are based on an overall average cost of £100 per m2 which includes Utilities, Soft FM and Hard FM.

Based on these assumptions it is estimated that it will cost NHS Wales £2.9m p.a. to operate each fixed digital scanner at full capacity. This is equivalent to £577 per scan, based on an average of 5,000 scans. An analysis of this is provided in the table below.

Table 54: Indicative revenue costs to operate digital scanner (£'000)

Cost element	Total annual costs (£'000)	Equivalent cost per scan
Workforce to operate digital scanner (7-12 patients per session)	1,060	£212.01
<b>Pay costs</b>	<b>1,060</b>	<b>£212.01</b>
Equipment maintenance	296	£59.20
Radiopharmaceuticals	1,308	£261.64
Consumables	47	£9.30
Delivery and transport	147	£29.45
Building running costs	26	£5.20
<b>Non pay costs</b>	<b>1,824</b>	<b>£364.80</b>
<b>Total costs</b>	<b>2,884</b>	<b>£576.81</b>

Indicative recurring revenue costs for in line with the 10-year demand model have therefore been estimated based on the following assumptions:

- Digital scanner capacity is 5,288 scans.
- PETIC charges continue at £925 for first 2,150 scans, then £850 for 2150+ and are applied to South East Wales demand up to 5,288 scans.
- Operating costs for the new fixed scanners at North Wales and South West Wales, and the subsequent fourth scanners based on indicative operating costs above and are applied as follows:
- Variable costs (Radiopharmaceuticals, Consumables, Transport) applied based on the average cost per scan to predicted demand up to 5,288 scans.
- Fixed costs (Equipment Maintenance, Building Running Costs) are applied in full from the year of opening.
- Pay costs are also applied in full from the year of opening for the purposes of these calculations, although it should be noted than in reality pay costs are likely to be phased during the initial years of each scanner in line with activity. Further work will be undertaken at Project business case stage to develop detailed workforce plans and associated costs.
- Any unmet demand assumed to be outsourced at average £935 per scan (to reflect range of fees including type and provider).

Detailed calculations are available in the PET-CT Revenue Workings in Appendix 2 and an extract provided below.

*Table 55: Indicative 10-year recurring revenue costs (£'000)*

<b>Business as Usual option (No investment; outsource unmet demand)</b>												
	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	2031/32	10-year total
Total activity (Number of scans)	5,207	6,249	7,498	8,997	10,798	12,957	15,548	18,658	22,390	26,868	32,241	167,411
Total recurring revenue costs (£'000)	4,869	5,843	7,011	8,412	10,096	12,115	14,537	17,445	20,935	25,122	30,145	156,529
Total cost per scan	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00	£935.00
<b>Variance to baseline costs 2020/21</b>	<b>327</b>	<b>1,301</b>	<b>2,469</b>	<b>3,870</b>	<b>5,554</b>	<b>7,573</b>	<b>9,995</b>	<b>12,903</b>	<b>16,393</b>	<b>20,580</b>	<b>25,603</b>	<b>106,567</b>
<b>Preferred way forward option (Provide 4 fixed scanners)</b>												
	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	2031/32	10-year total
South East Wales (PETIC)	2,629	3,155	3,786	4,543	5,288	5,288	5,288	5,288	5,288	5,288	5,288	51,129
South West Wales (Fixed digital scanner)	1,434	1,721	2,065	2,478	2,974	3,569	4,282	5,139	5,288	5,288	5,288	39,526
North Wales (Fixed digital scanner)	1,144	1,373	1,647	1,976	2,372	2,846	3,415	4,098	4,918	5,288	5,288	34,365
4th scanner (Fixed digital scanner)	0	0	0	0	0	1,254	2,563	4,133	5,288	5,288	5,288	23,814
Capacity shortfall - Outsourced	0	0	0	0	164	0	0	0	1,608	5,716	11,089	18,577
<b>Total activity (Number of scans)</b>	<b>5,207</b>	<b>6,249</b>	<b>7,498</b>	<b>8,997</b>	<b>10,798</b>	<b>12,957</b>	<b>15,548</b>	<b>18,658</b>	<b>22,390</b>	<b>26,868</b>	<b>32,241</b>	<b>167,411</b>
South East Wales (PETIC)	2,396	2,843	3,379	4,023	4,023	4,023	4,023	4,023	4,023	4,023	4,023	40,801
South West Wales (Fixed digital scanner)	1,341	1,609	1,931	2,126	2,275	2,454	2,668	2,926	2,971	2,971	2,971	26,243
North Wales (Fixed digital scanner)	1,070	1,284	1,540	1,976	2,095	2,237	2,408	2,613	2,859	2,971	2,971	24,022
4th scanner (Fixed digital scanner)	0	0	0	0	0	0	2,152	2,624	2,971	2,971	2,971	13,687
Capacity shortfall - Outsourced	0	0	0	0	153	0	0	0	1,503	5,344	10,368	17,369
<b>Total recurring revenue costs (£'000)</b>	<b>4,806</b>	<b>5,736</b>	<b>6,850</b>	<b>8,125</b>	<b>8,546</b>	<b>8,714</b>	<b>11,251</b>	<b>12,185</b>	<b>14,327</b>	<b>18,279</b>	<b>23,303</b>	<b>122,122</b>
South East Wales (PETIC)	£911.34	£901.11	£892.59	£885.49	£760.74	£760.74	£760.74	£760.74	£760.74	£760.74	£760.74	£797.99
South West Wales (Fixed digital scanner)	£935.00	£935.00	£935.00	£858.13	£765.11	£687.64	£623.16	£569.33	£561.75	£561.75	£561.75	£663.93
North Wales (Fixed digital scanner)	£935.00	£935.00	£935.00	£999.82	£883.05	£786.01	£705.10	£637.65	£581.42	£561.75	£561.75	£699.03
4th scanner (Fixed digital scanner)						£0.00	£839.63	£634.79	£561.75	£561.75	£561.75	£574.76
Capacity shortfall - Outsourced					£935.00				£935.00	£935.00	£935.00	£935.00
Total cost per scan	£923.05	£917.89	£913.59	£903.07	£791.46	£672.53	£723.63	£653.09	£639.88	£680.32	£722.77	£729.47
<b>Variance to baseline costs 2020/21</b>	<b>264</b>	<b>1,194</b>	<b>2,308</b>	<b>3,583</b>	<b>4,004</b>	<b>4,172</b>	<b>6,709</b>	<b>7,643</b>	<b>9,785</b>	<b>13,737</b>	<b>18,761</b>	<b>72,160</b>
<b>Variance to BAU option</b>	<b>(62)</b>	<b>(107)</b>	<b>(161)</b>	<b>(287)</b>	<b>(1,550)</b>	<b>(3,401)</b>	<b>(3,286)</b>	<b>(5,260)</b>	<b>(6,608)</b>	<b>(6,843)</b>	<b>(6,843)</b>	<b>(34,407)</b>

This analysis demonstrates that over a 10-period, continuing to meet growing demand by relying on external providers is likely to cost an additional £25,603k p.a. by 2031/32 with average cost per scan increasing to £935.

Investing in the four PET-CT scanners will reduce the cost pressure by £6,843k p.a. by providing sufficient capacity for NHS Wales and PETIC to meet demand to 2028/29 which reduces the average cost per scan to £729.

In addition, this investment will deliver other benefits which will be explored at Project business case stage including:

- Opportunities to reduce overall system costs due to avoiding late stage interventions. This could be significant since the evidence base suggests for certain diseases and patient pathways, such as the treatment of neck cancers, PET-CT scans are potentially £1,500 more cost effective. Further work will be required at Project business case stage to determine more accurate activity levels in relation to patient pathways. As an indication, if this sort of benefit was applied to 10% of activity, this would equate to a financial benefit of around £4.8m by 2031/32.
- Opportunities to generate income from RD&I activity. It is estimated that 7% of predicted demand relates to RD&I activity. Again, further work will be required at Project business case stage to identify accurate numbers but, as an indication, if research scans were charged at £1500, this would equate to an annual financial benefit of around £3.3m by 2031/32.
- Delivery of non-financial benefits including:
  - Improved quality and reduction in patient harm including reduced waiting times, better diagnostic accuracy and improved patient outcomes and experience.
  - Workforce resilience including improved recruitment and retention, greater access to training and education, and improved staff satisfaction.
  - Improved access reducing patient travel time which benefits patient and reduces greenhouse gases.
  - Provide capacity that meets population needs in line with international best practice.
  - Increased opportunities for Research and Development.
  - Increased opportunities for innovation.

#### 4.1.5 Balance Sheet Treatment and Impairment

The impact on organisations' individual Balance Sheets will be considered at Project business case stage.

This will include estimating non-cash funding requirements which will be sought from Welsh Government including:

- Impairment on completion of the resulting assets.
- Capital charges that represent an increase in organisations' baseline depreciation.

An overview of potential balance sheet impact and associated annual capital charges, excluding the impact of impairment, is provided in the table below, based on straight-line depreciation of 60 years for buildings and 10 years for equipment.

Table 56: Capital costs – By Project

	Balance Sheet Impact £'000	Annual depreciation £'000
Project 1 - Replace Cardiff equipment	6,248	494
Project 2 - Fixed scanner North Wales	6,573	356
Project 3 - Fixed scanner Swansea	5,486	338
Project 4 - 4th fixed scanner	6,573	356
<b>Total capital costs</b>	<b>24,881</b>	<b>1,544</b>

## 4.2 Conclusion and Overall Affordability

Delivery of the preferred way forward, which involves implementing a programme that will deliver four fixed digital scanners in Wales requires capital investment of £24.881m for which funding is sought from Welsh Government.

As well as delivering a wide range of non-financial benefits in relation to service improvements and patient experience and outcomes, this will enable three of the scanners to reduce the average cost per scan to £572, compared with an average cost from external providers of £935. This will result in an overall average cost per scan for all four scanners over a 10-year period to £729.

Indicative modelling suggests that revenue costs could increase by £25.6m by 2030/31 based on predicted demand growth. This investment will contribute to mitigating the ongoing cost pressure associated with growing demand including:

- Reduction in average cost per scan resulting in £6.6m annual financial benefit by 2030/31.
- Opportunities to deliver system-wide financial benefits due to increased PET-CT scanning reducing the need for high-cost late stage interventions. There is insufficient detail available on specific demand by patient pathway to calculate this at this stage.
- Opportunities for income generation from RD&I activities which, based on 7% of predicted demand, is estimated at around £3.3m by 2030/31.

# 5 Management Case

## 5.1 Introduction

This Management Case provides a summary of the arrangements that will be put in place to ensure the successful delivery of the All Wales PET Programme and its associated projects, and to ensure the programme realises the optimum benefits of the investment.

The case for change for the All Wales PET Programme has been clearly articulated within the Strategic Case. To achieve an effective implementation and full Benefits realisation, the Programme must manage, co-ordinate and oversee the delivery of all activities and key deliverables over the next ten years.

The All Wales PET Programme has a robust governance structure, well defined processes and has identified tranches and subprojects for the delivery of the Programme.

The All Wales PET Programme requires funding for Programme Management and Administration support in order to facilitate the oversight, governance and delivery of the programme. Projects requiring local implementation (for example at Health Board level) will need to ensure Project Management support from the respective organisation for the duration of the Project.

This PBC Management Case sets out the management arrangements that will successfully deliver the All Wales PET Programme to time, cost and quality. The Management Case outlines the following arrangements:

- Programme Scope;
- Projects within the Programme;
- Programme and Project Management Arrangements;
- External Advisors;
- Use of Special Advisors;
- Programme and Project Scrutiny and Assurance;
- Procurement and Contracts Management;
- Programme and Project Plan;
- Benefits Realisation;
- Risk Management.

### 5.1.1 Post Project Evaluation

This Management Case provides assurance on the capacity and capability of the management arrangements to deliver the Programme.

## 5.2 Programme Scope

The rationale and narrative that supports and defines the Programme scope is set out in detail within the Strategic Case (Section 5).

The purpose of the All Wales PET Programme is to plan, design, build and implement an All Wales PET strategy and associated business cases for services up to 2031.

The scope of this Programme is limited to procurement of the following list of equipment:

- Four digital PET-CT Scanners (Artificial Intelligence enabled; one scanner at each site)

- Ancillary equipment and phantoms (robotic radiotracer dispenser)
- Radiotherapy adaptations (laser bridge, flat table top)#

The equipment is to be located at Cardiff (replacement scanner), Swansea (new scanner) and North Wales (new scanner). The fourth scanner (new) placed at a location to be defined at a later date will be based upon clinical demand and population density.

Associated build works for the PET site facilities are also within scope.

Furthermore, refresh of equipment connected with the cyclotron at Cardiff is within scope of this Programme, thus requiring procurement of:

- Ion source replacement within the cyclotron
- Hot cell replacement and associated GMP build.

Programme implementation will be phased so that sufficient time is given to scrutinise supporting business cases for Projects. This will ensure supporting infrastructure requirements are solved at appropriate timings, in order to optimise delivery and ultimately PET service provision.

Supporting infrastructure has been identified as an essential consideration to the success of the PET Programme delivery, including workforce and research and development. As such, these elements have been considered as within scope and are addressed in the Programme structure.

Radiopharmaceutical provision is an additional infrastructure factor for the All Wales PET Programme and this has been addressed in the Programme structure. However, during development of the Programme, it was evident that requirements for radiopharmaceutical provision for Wales may stretch beyond the scope of the All Wales PET Programme. Therefore, it is possible that additional investment via a Project or Programme is identified for radiopharmaceutical provision, and the workstream structure of the Programme reflects this.

### 5.3 Projects within the programme

A Programme can be defined as a temporary and flexible organisation created to coordinate and oversee the delivery of a set of related Projects and activities in order to deliver outcomes and benefits related to Spending Objectives.

A “tranche” can be defined as a group of projects, transition activities and governance, structured around distinct step-change in capability and benefit delivery<sup>5</sup>.

A “Project” can be defined as a temporary organisation that exists for a shorter duration, which will deliver one or more outputs in accordance with the business case. In this case, four Projects form the All Wales PET Programme.

A “workstream” is often used to describe the logical grouping of activities together to enable effective management. Workstreams concentrate dependencies and may run through a number of tranches.

<sup>5</sup> Sowden R et al., 2011, **Managing Successful Programmes**, 2011 Edition, Published by TSO Norwich

The All Wales PET Programme will consist of four tranches and four Projects. These are arranged to address installation of PET scanners and update a cyclotron. The output of each tranche will see a step-change in capability of the All Wales PET service (see Table 57).

Detailed information relating to the management arrangements for each of the Projects will be contained within the respective business cases. The business case plan can be noted in Table 58.

The host local organisation (Cardiff University, NHS Health Board, or NHS Trust) for Projects 1, 2, 3 and 4, will be responsible for taking forward the PET scanner installation at the relative site.

The supporting infrastructure is critical to the success of each tranche. As such, the Programme consists of four enabling workstreams which will be established to support the delivery of the programme and projects. The workstreams are thematic and manage deliverables across the programme and should ensure effective integration between the various projects (see Table 59 for a detailed breakdown of responsibilities and outputs of these workstreams).

As noted in the Strategic Case, there may be developments related to radiopharmaceutical provision in Wales that could need further investment. However, any requirement is not yet clear. Therefore, this Programme will expect the radiopharmaceutical workstream to include this aspect within its Terms of Reference and aims, with any additional Project development communicated clearly through the Programme Governance structure.

AWPET will maintain its advisory role and function, informing the SPB on potential changes to referral pathways and indications for commissioning.

WHSSC, as commissioners of the PET service in Wales and host of the PET Programme, will remain responsible for assessing the live and ongoing clinical demand for PET scans across Wales. This data is currently captured by data analysts and PET service planners at WHSSC and will be reported regularly to the SPB.

The location of the fourth scanner has not been identified at the time of writing this PBC. The clinical demand model noted in the Strategic Case (section 5.5) states that the likely population needs would benefit from the fourth scanner being positioned in south east Wales. The Programme has been designed so this can be reviewed with “live” demand and needs data at the appropriate time.

A robust appraisal process will be undertaken to identify to optimum location of the fourth scanner. Detailed plans are yet to be made; however the appraisal process will likely include two steps:

- expressions of interest to host a PET-CT scanner, and
- review of potential site(s) ability to answer population demand, have sufficient workforce, patient access, clinical alignment, estates and facilities considerations and costs.

Table 57: Structure of the All Wales PET Programme tranches, Projects and business cases

Description	Business Case	Deliverable	PET site Organisation	Accountable Officer
<b>Tranche 1</b>				
<b>Project 1</b>				
Replacement scanner at PETIC and cyclotron refresh (replacement of ion source and hot cells)	BJC (to be submitted alongside PBC May 2021)	To procure replacement digital scanner, replacement equipment associated with cyclotron and facilities on site and upgrade the cyclotron	Cardiff University responsible for business case delivery, with close engagement with C&VUHB	Chris Marshall (Project SRO)
<b>Tranche 2</b>				
<b>Project 2</b>				
New fixed PET scanner at North Wales site (part of a wider Nuclear Medicine Consolidation Programme)	SOC1*, OBC / FBC combined (TBC by WG)	To deliver access and utilities to the site, build and procure a digital PET scanner and associated facilities	Site to be confirmed. Betsi Cad Health Board responsible for business case delivery	David Jones (Project SRO)
<b>Project 3</b>				
New fixed PET scanner at Swansea site	OBC2, FBC2	To deliver access and utilities to the site, build and procure digital scanner and associated facilities	Swansea Bay Health Board responsible for business case delivery	Neil Hartman (Project SRO)
<b>Tranche 3</b>				
<b>Project 4</b>				
New fixed PET scanner (PET-CT or PET-MR)	OBC3, FBC3	To deliver access and utilities to the site, build and procure digital scanner and associated facilities	Location is to be determined based on population needs. Host Organisation to be identified	To be confirmed during site selection
<b>Tranche 4</b>				
Programme Closure, PPE & Lessons Learned				Sian Lewis (Programme SRO)

\* SOC was submitted to WG in October 2020

Table 58: High level dates of the All Wales PET Programme tranches, Projects and business cases

Business Case (BC)	Proposed date of Welsh Gov. BC approval	Proposed "go live" date	
<b>Tranche 1</b>			
<b>Project 1</b>			
BJC	July 2021	PET Scanner	March 2022
		Ion Source replacement	March 2022
		Hot Cell replacement	March 2023

Business Case (BC)	Proposed date of Welsh Gov. BC approval	Proposed “go live” date
<b>Tranche 2</b>		
<b>Project 2</b>		
SOC1	July 2021	January 2024
OBC/FBC	March 2022	
<b>Project 3</b>		
OBC2	November 2021	November 2023
FBC2	July 2022	
<b>Tranche 3</b>		
<b>Project 4</b>		
Appraisal Process	April 2023	
OBC3	January 2024	June 2026
FBC3	December 2024	
<b>Tranche 4</b>		
January 2027		

Table 59: Scope of the All Wales PET Programme Enabling Workstreams

Workstream	Responsibilities	Key Outputs
Radiopharmaceutical Provision	<p>Responsible to the SRO for leading the planning and delivery of radiopharmaceutical provision, in partnership NHS organisations and third sector partners, with a view to ensuring long-standing, cost-effective and assured supply of MA licensed radiopharmaceuticals across Wales.</p> <p>Responsible for informing the wider Programme on radiopharmaceutical supply under Specials or IMP licenses across Wales, for clinical use or research activity, to enable Centres of Excellence.</p> <p>Responsible for informing the wider Programme on horizon scanning.</p>	<p>Effective linkage with other key national programmes or projects.</p> <p>Have input into (where appropriate) developing robust and cost effective contracts with suppliers for radiopharmaceutical provision for non-PETIC sites.</p> <p>Carry out an in-depth horizon scanning exercise.</p> <p>Carry out a full assessment of needs, benefits, costs and risks associated with PETIC attaining MA license for FDG products and/or scope for an additional cyclotron in Wales. Write business case(s) for options (if appropriate).</p>
Centres of Excellence	<p>Responsible for developing and leading the planning and delivery of an integrated, collaborative and pan-Wales Research, Development and Innovation Group, focussed on PET scanning and radiopharmaceutical developments.</p> <p>This Workstream Group should have membership from all PET scanning sites, Cancer Network, Dementia Network (+others), Bangor University, LSHW, Health and Care Research Wales, and relevant academic institutions.</p>	<p>Build a network of key personnel and organisations both within and outside Wales.</p> <p>Develop a scope whereby an “all Wales research approach” is defined – ranging from basic, through to applied clinical trials.</p> <p>Create a virtual research hub where best practice is shared openly.</p> <p>Produce joint bids and advertise national capacity &amp; capability.</p>

Workstream	Responsibilities	Key Outputs
Workforce Provision	<p>Responsible for advising the Programme on the strategic and operational planning and delivery of the future workforce, including ensuring that forecasted workforce gaps are accounted for in training needs.</p> <p>To include the management of key strategic and operational issues relating to skills-mix and commissioning of training places. This Workstream Group should have membership from HEIW, IWEW and NIAW to ensure deliverability is at the centre of all considerations. The Group should also have membership from all professional groups across the NHS.</p>	<p>Carry out constructive challenge for workforce planning at each site during business case planning phases.</p> <p>Ensure that training needs are appropriately fed into training providers, in a timely fashion. Ensure that relevant bodies are appropriately linked to facilitate Health Boards in attaining the relevant staffing levels for a PET scanning service.</p> <p>Link with the RISP Programme to assess how working behaviour can change for remote reporting.</p>
Procurement	<p>Responsible for making recommendations about providers that each organisation may use. The Procurement Workstream membership will consist of the specialists within NWSSP-SES, NWSSP-PS, PET site organisation Procurement and Estates representatives, Programme Manager and Project Teams at relevant Health Boards, Trusts and Cardiff University.</p>	<p>The Procurement Workstream will make a recommendation on the most economically advantageous tender. This recommendation will be recorded in a final evaluation report, which will set out the basis for the award decision, for the formal approval of the PET Strategic Programme Board.</p>

Please note that at the time of writing this PBC, some leads for Workstreams are to be confirmed.

## 5.4 Programme and project Management Arrangements

### 5.4.1 Programme Roles and Responsibilities (The People)

The All Wales PET Programme is a strategic Programme that is hosted by WHSSC and sits within the “Strategic Resource Planning” category of the National Imaging Programme Strategic Board (NIPSB). The NIPSB is hosted and supported by the NHS Wales Collaborative and the NHS Wales Collaborative Executive Group (CEG).

At the time of writing, the NHS Wales Collaborative fund a Programme Manager that is hosted by WHSSC on a fixed-term basis. This role forms the core of the All Wales PET Programme Management arrangements and is funded until at least March 2022.

At the time of writing this document, the NHS Wales Collaborative and NIPSB are within Scope of the Rapid Review of Precision Medicine Programmes and the Consolidation of Precision Medicine Programmes Implementation Plan Phase 1, which is seeking to centralise hosting of Programmes and consolidate Programme budgets. It was agreed at a meeting of the NHS Wales Collaborative Executive Group (CEG; 16.03.2021), that the All Wales PET Programme will remain hosted by WHSSC. As such, this Management Case makes clear the governance arrangements.

The existing PET Strategic Programme Board (SPB) has the capacity and capability to facilitate the effective delivery of the Programme. Local Projects will rely on local organisational capacity and provision of project management, with facilitation from the SPB and Programme Manager.

If this Programme is endorsed by Welsh Government, the existing membership of the SPB will be expanded to include some additional roles noted in Table 60. Members of the SPB will provide

resource and specific commitment to support the Programme Lead and Programme Manager to deliver the Programme deliverables.

The key individual roles and responsibilities required to support the delivery of the All Wales PET Programme are set out in Table 60 below, and at the time of writing some of the membership is yet to be confirmed.

*Table 60: All Wales PET Strategic Programme Board (SPB)*

Role	Name	Responsibility
Senior Responsible Owner (SRO)	Sian Lewis (Andrew Champion Deputy)	Accountable for the success of the Programme and is responsible for enabling the organisation to exploit the new environment resulting from the Programme, meeting the new business needs and delivering new levels of performance, benefit, service delivery and value. The SRO owns the vision for the Programme and provides clear leadership and direction and secures the investment required to set up and run the Programme. The SRO is called upon at times of escalation.
Programme Lead	Andrew Champion	Responsible for providing the interface between Programme ownership and delivery, and is accountable for defining the Programme objectives and ensuring they are met within the agreed time, cost and quality constraints. Act as the link point for stakeholders at a strategic level.
Programme Manager	Sarah McAllister	Responsible for leading and managing the programme through to the delivery of new capabilities, realisation of benefits and programme closure. Responsible for providing the interface between Programme and delivery of Projects.
Clinical Lead	Martin Rolles	Responsible for providing clinical leadership to the programme, ensuring effective clinical engagement and securing clinical consensus within and outside of the organisation for the improvements identified within the programme.
PETIC site	Project SRO (Chris Marshall) and Project Manager (TBC)	Project SRO: Responsible for the development of business case(s) required to provide an effective PET scanning service at the site. Responsible for providing leadership to the delivery of Project 1. Project Manager: Responsible for managing the Project through to the delivery of outputs. Responsible for providing the Programme Board with updates on Project progress.
North Wales site	Project SRO (Adrian Hartman) and Project Director (David Fletcher)	Project SRO: Responsible for the development of business case(s) required to provide an effective PET scanning service at the site. Responsible for providing leadership to the delivery of Project 2. Project Manager: Responsible for managing the Project through to the delivery of outputs. Responsible for providing the Programme Board with updates on Project progress.
Swansea site	Project SRO (Neil Hartman) and Project Manager (TBC)	Project SRO: Responsible for the development of business case(s) required to provide an effective PET scanning service at the site. Responsible for providing leadership to the delivery of Project 3. Project Director: Responsible for managing the Project through to the delivery of outputs. Responsible for providing the Programme Board with updates on Project progress.
Fourth scanner site	Project Manager and Project SRO	Project SRO: Responsible for the development of business case(s) required to provide an effective PET scanning service at

Role	Name	Responsibility
	(TBC when site selection process is complete)	the new site. Responsible for providing leadership to the delivery of Project 4. Project Manager: Responsible for managing the Project through to the delivery of outputs. Responsible for providing the Programme Board with updates on Project progress.
Finance Lead	Mark Osland & Stuart Davies	The Finance Lead(s) is/are responsible for all financial aspects of the Programme. This includes the strategic financial planning for the Programme, financial reporting, and financial risk management.
Planning / Transformation Leads	Representation from all Health Boards and Trusts	Responsible for acting as an effective interface between the SPB and the Health Boards, ensuring that Site Leads and Health Boards are supported and informed.
Radiopharmaceutical workstream Lead	Neil Hartman	Responsible for acting as an effective interface between the SPB and the workstream, ensuring that Site Leads are supported and informed.
Centres of Excellence workstream Lead	TBC	Responsible for acting as an effective interface between the SPB and the workstream, ensuring that Site Leads are supported and informed.
Workforce workstream Lead	TBC	Responsible for acting as an effective interface between the SPB and the workstream, ensuring that Site Leads are supported and informed.
Procurement workstream Lead	TBC	Responsible for acting as an effective interface between the SPB and the workstream, ensuring that Site Leads are supported and informed.
Professional Leads	Where professional roles are not represented through existing pan-Wales membership to be sought	Professional leads that require representation: Clinical Radiologists, Clinical Oncologist, Clinical Scientists/Medical Physics Experts, and Radiographers.
PET Service Planning Manager	Luke Archard (WHSSC)	Responsible for reporting live PET scanning demand figures to the Board, assisting and advising on interim arrangements during implementation and other planning.
NHS Health Collaborative	Imaging Portfolio Lead (post being appointed)	Responsible for acting as an effective interface between the SPB and the NHS Health Collaborative.
Admin and Programme Support	TBC with funding decision	Responsible for providing high quality administrative and project management support to the Project across all phases.
Communication Lead	TBC	Responsible for providing high quality advice on Communications for the Programme.

### 5.4.2 Programme Management: Roles and Responsibilities

The Programme Management and Administration roles and responsibilities for the All Wales Programme are set out in Table 61 below.

The costs of the Programme Management and Programme Support have been included within the Finance Case. A Programme Manager will be responsible for the delivery of the Programme. It is

proposed that some Project Management support will be required at each PET site to manage the delivery and implementation at each site and it is expected that each Health Board/Trust/Cardiff University will make use of existing Project Management resource for implementation.

*Table 61: Project Management and Administration Specific Roles and Responsibilities*

Role	Responsibility
Programme Manager (based at WHSSC)	<p>The Programme Manager will support the Programme Lead to deliver the overall Programme objectives and associated change. The role requires effective co-ordination of the Programme’s Projects and management of their interdependencies including oversight and management of risks and issues that arise. The role is crucial for creating and maintaining focus, enthusiasm and momentum within the Programme and to support the workstream delivery.</p> <p>The Programme Manager has overall responsibility for the delivery of the Programme and all sub projects and workstreams. To ensure that they are delivered to time, cost and quality.</p> <p>Tasks also include day to day responsibility for the programme and subprojects and workstreams, to meet the parameters described within the programme business case.</p> <p>The provision of appropriate reports on status to the Programme Lead.</p> <p>The management of risks and issues and escalation of appropriate matters for executive direction/approval. Monitoring, co-ordinating and controlling the work of the Programme Working Groups.</p>
Project Manager (based at local implementation site)	<p>The Project Manager will have the overall responsibility for supporting the Project SRO with the successful initiation, planning, execution, monitoring, controlling and eventually closure of their project. They provide a structured approach to support the conveyance of the key deliverables and provide an escalation route for both Programme and work level risks.</p>
Programme Support (based at WHSSC)	<p>The Project Administration duties include all aspects of facilitating a programme: scheduling meeting times and locations, taking meeting minutes and capturing action points.</p>

### 5.4.3 Programme and Project Management (The Methodology)

The Programme will be managed in accordance with ‘Managing Successful Programmes methodologies, suitably adapted for local circumstances in order to meet the needs of this Programme. The constituent projects will be delivered utilising PRINCE2 (‘PProjects IN in a Controlled Environment’) methodology.

The Programme management arrangements will therefore be driven by outcomes, and Project management arrangements driven by outputs, or in PRINCE2 terminology, “Products”.

This governance framework will ensure that appropriate oversight is present at all stages.

The All Wales PET Programme is predicated on the following principles:

- Decisions on the strategic direction and future needs of health care are only made after careful consideration;
- The views and interests of patients, staff and all stakeholders are fully considered;
- Appropriate behaviour with respect to the codes of corporate governance and policy are maintained;
- Guidance and good management practice is followed;
- Open and regular reporting of Projects progress and performance.

To ensure the quality of the outputs are maintained, objectives are met, and benefits are realised, the Programme Plan will be managed and undertaken on the basis of:

- Proven methodologies and standards;
- Effective monitoring procedures;
- Review and acceptance procedures;
- Effective change / issues / problem management;
- Appropriate documentation and record keeping.

In addition, the Strategic Programme Board and local PET site organisation(s) (where appropriate), will obtain specialist and professional advice as required during the life cycle of the Programme.

#### 5.4.4 Programme Governance and Management Arrangements to deliver programme and projects

Key to the success of the Programme are the programme governance and management inputs required for the co-ordination of sub projects and their outputs. This will include reporting progress against plans, approvals and escalations of risks and issues. The governance and management processes have been designed to allow for approvals to occur at the most appropriate level.

Of particular importance is the uniting of the constituent Projects within the All Wales PET Programme and governance arrangements, in line with WHSSC Corporate Governance arrangements and that of Welsh Government's sponsorship, scrutiny and approvals process. In particular, this will allow for rapid approval and the effective escalation of risks and issues to a level where senior sponsors can intervene as necessary to support the delivery of this important project.

The Governance Arrangements are organised over five levels, namely:

- Level 1 – NHS Wales Collaborative Executive Group;
- Level 2 – National Imaging Programme Strategic Board;
- Level 2 – The All Wales PET Strategic Programme Board;
- Level 3 – Project Boards;
- Level 4 – Project Teams.

The Programme structure as set out below ensures clear accountability and also deploys mechanisms to facilitate decision making, escalation, communication and alignment.

Tranches and their projects can only commence once the SPB give approval to do so. The Programme Plan has been arranged so that end-of-tranche reviews are used as critical control points in the programme delivery cycle, where ongoing viability of the programme is evaluated and lessons learned are assessed.

Each Project will have a Project Board that will hold expert and local membership.

Workstream Groups will primarily consist of the membership from the task and finish groups that were used in the development of this Programme Business Case and will be reviewed and extended to ensure that appropriate stakeholders are included to successfully facilitate delivery.

Projects will be governed by the structures and processes that exist within the relevant PET site organisation (Cardiff University, Health Board or Trust). However, the Project Manager and Project SRO must regularly attend and update the SPB on progress for the duration of the Project.

The Programme Manager will sit on all Project Boards and Workstream groups for continuity.

All Project Business Cases will be formally signed off by the appropriate Project Board which may include the local Health Board governance structures, before being endorsed by the Strategic Programme Board (SPB). Once endorsed by the SPB, the Project Business Case(s) can be submitted to Welsh Government. This is to ensure that Project outputs are directly aligned to the Programme outcomes and benefits realisation plan.

All Projects will report to the SPB bi-monthly and issues should be escalated as appropriate.

The SPB will provide quarterly reports to the NIPSB and NHS Collaborative Executive Group, escalating issues as appropriate.

The Programme Plan includes all the management controls required to ensure the All Wales PET Programme and contracted firms meet their fiduciary obligations with respect to the development of the Business Cases, the implementation of the Programme, and the management of the Programme within a framework of acceptable risk.

Figure 13: Governance structure of the All Wales PET Programme

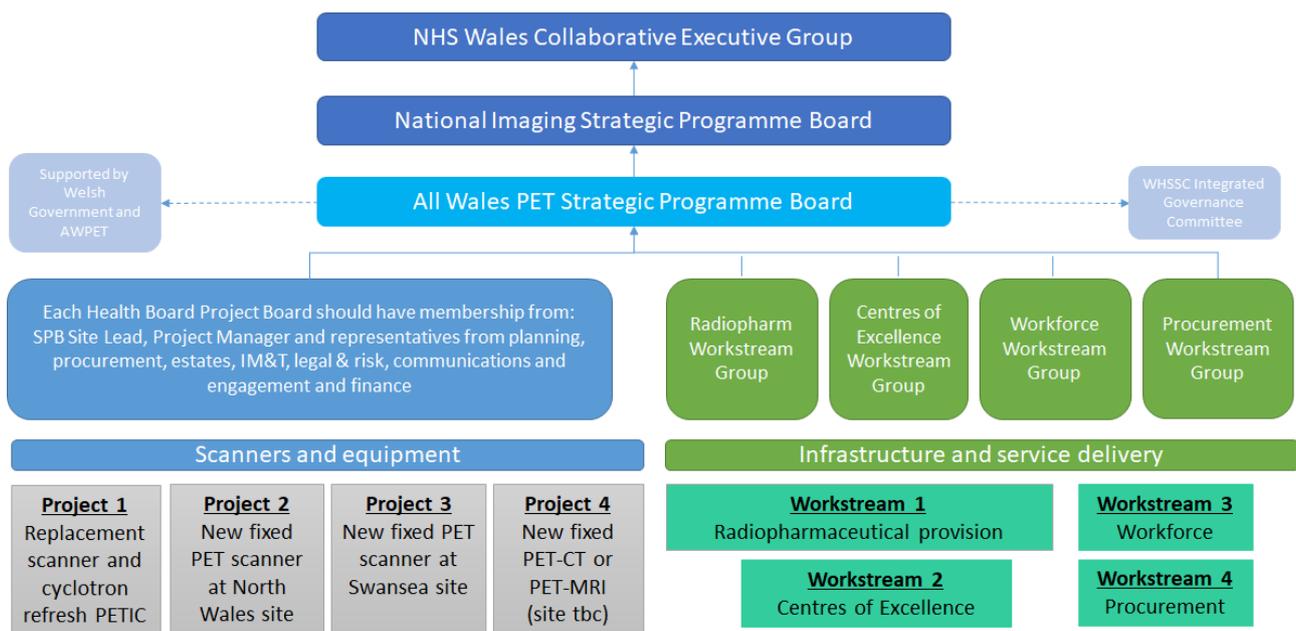


Table 62: Project Board Specific Role and Responsibilities

Project Boards		Lead
<p><b>Project 1, 2, 3 and 4</b> Installation of new PET scanner and equipment</p>	<p>Responsible for leading the planning and development of the relevant business cases at the preferred site location for PET services at the relevant PET site organisation and subsequent implementation.</p> <p>Each Project Board should have membership from: Project SRO, Project Manager and representatives from planning, procurement, estates, IM&amp;T, legal &amp; risk, communications and engagement and finance.</p>	<p>Project SRO</p>

## 5.5 Internal and External Advisors

### 5.5.1 Programme Roles and Responsibilities (The People)

The All Wales Programme is supported by a range of external advisors, these are listed in Table 63 below. The Programme Manager is responsible for coordinating the activity of the external advisors:

Table 63: External Advisors

Role	Name / Status	Responsibility
Head of Sourcing: Commissioning, Capital & IMT NWSSP-PS	Samantha Pennington (Deputy Head of Sourcing)	Responsible for providing professional leadership in matters relating to procurement. A pivotal role in advising on the delivery of an effective procurement process and subsequent contract development. Whilst Projects will be led by Health Boards, this role will be able to bring in resources as needed from NHS Wales Shared Services Partnership – Procurement Services (NWSSP- PS) as dictated by the needs of the Programme.
National Imaging Equipment Advisor NWSSP- SES	Andrew Ward (Senior Diagnostic Imaging Advisor)	Advisory role - supporting the SPB and Project Boards with technical, specialist equipment and Commercial advice. Responsible for advising on the delivery of optimum commercial deals and strategic partnerships with partners. Whilst Projects will be led by Health Boards, this role will be able to bring in resources as needed from NHS Wales Shared Services Partnership - Specialist Estates Team, as dictated by the needs of the Programme.
Radiation Protection	Matthew Talboys	Advisory role – supporting the SPB and Project Boards with technical and specialist advice, as required. Chair of the WSAC Medical Physics & Clinical Engineering Sub-Committee: Radiation Protection Standing Specialist Advisory Group.
External Clinical and Technical Assurance	Wai-Lup Wong (Chair of the National PET-CT Clinical Governance Board)	Responsible for providing independent and expert advice to assure the quality of project outputs and to advise on complex and challenging issues.

### 5.5.2 Use of Specialist Advisors (Non-NHS)

The All Wales PET Programme will utilise appropriate specialists / subject matter experts (SMEs) whom are listed in the table below and managed by the Programme Lead:

Table 64: External Advisors (non-NHS)

Company	Name / Status	Responsibility
Archus Limited	Anouska Huggins	Archus Ltd. have been appointed to support this PBC. This role includes benefits identification and quantification and economic analysis and preparation of the Financial Case.

## 5.6 External Programme Review and Assurance

To ensure that robust Programme Governance is achieved, clear governance arrangements are established and a range of reviews and audits will take place. These fall into the following categories:

- Internal governance arrangements;
- Gateway Reviews (Gates 0 - 5);
- Internal Audit.

### 5.6.1 Internal Governance Arrangements

Programme Governance arrangements are described in Section 4 of the Management Case.

As the Programme is hosted by WHSSC, it will be governed within the existing WHSSC arrangements, but with clear avenues for escalation to NIPSB which are described in Section 4 of the Management Case. For clarity, change management and risk management are further described in the following sections of the Management Case.

### 5.6.2 Gateway Reviews

The OGC Gateway Process examines Programmes and Projects at key decision points in their lifecycle. It looks ahead to provide assurance that they can progress successfully to the next stage. OGC Gateway Reviews deliver a 'peer review', in which independent practitioners from outside the programme/project use their experience and expertise to examine the progress and likelihood of successful delivery of the programme or project.

Programme Reviews are carried out under OGC Gateway™ Review 0: Strategic Assessment. A Programme will generally undergo three or more OGC Gateway Reviews 0: an early Review; one or more Reviews at key decision points during the course of the programme, and a final Review at the conclusion of the programme.

Project Reviews are carried out under OGC Gateway Reviews 1 - 5; typically a project will undergo all five of these Reviews during its lifecycle – three before commitment to invest, and two looking at service implementation and confirmation of the operational benefits.

It has been agreed with the Welsh Government Assurance Hub that Programme Gateway Reviews 0 will be carried out. The initial Gateway Review of the All Wales PET Programme will be a Programme Assessment Review, so that the Business Justification Case for the Cardiff site can be considered at the same time. This will take place in June 2021.

Gateway reviews relating to subordinate projects will be agreed with the Welsh Government Assurance Hub and reflected in respective business cases following endorsement of this PBC.

The likely profile of Gateway Reviews in the Programme is shown in the Table 65 below. The likely profile of Gateway Reviews for the Projects are shown in the Table 66 below.

*Table 65: Programme Review Gateways*

Type of Gateway (Gate)	Proposed Date
Programme Assessment Review	June 2021
Gate 0: Strategic Review	January 2023
Gate 0: Strategic Review	January 2025

*Table 66: Project Review Gateways*

Type of Gateway (Gate)	Proposed Dates			
	Project 1 - (Cardiff)	Project 2 - (North Wales)	Project 3 - (South West)	Project 4 - (4 <sup>th</sup> scanner)
1. Business Justification				June 2022
2. Delivery Strategy				
3. Investment Decision		June 2022	June 2022	December 2024
4. Readiness for Service	April 2022			
5. Operations Review and Benefits Realisation	January 2023			April 2027

The proposed Project Review Gateways are aligned with key decision points that are applicable to each Projects individual local circumstance. For instance, there is urgency surrounding the need for update equipment at the Cardiff site which already has a fixed analogue scanner, therefore it would be appropriate to check on readiness for service here. In contrast however, the fourth scanner may benefit from more in-depth assurance as it will entail business justification based on live clinical demand data and a new site will need to be identified.

### 5.6.3 Internal Audit and Assurance

WHSSC is hosted by Cwm Taf Morgannwg University Health Board. There are established, existing governance processes in place at WHSSC. NWSSP (Audit and Assurance Services) carry out annual internal audits at WHSSC and internal audit reports are submitted to the Cwm Taf Morgannwg Audit Committee (Part 2) on a planned basis.

The benefit of effective internal audit is recognised within the NHS Wales Infrastructure Investment Guidance issued by Welsh Government. This expects Welsh NHS organisations to utilise internal audit to benefit from independent and objective opinions to Executives, Accounting Officers and respective Boards. This should be supplemented by regular and appropriate reporting to respective audit committees.

The team at NWSSP (Audit and Assurance Services) have reviewed implementation plans and assessed the best approach for audit of the Programme. Colleagues at Audit and Assurance Services have suggested a one-off initial audit at programme level to assess the overall risk, governance arrangements and engagement (a suggested brief can be found in Appendix 2).

At the time of writing this PBC, we are awaiting approval from the Audit Chair to add the PET Programme Audit to the 2021/22 Internal Audit Plan, following which it will be submitted to the audit committee for approval.

The NWSSP Audit and Assurance Services may progress further reviews of the programme via the internal audit plan or project audits via the respective UHB audit plans (or provisions within respective BJC's), should key issues arise and subject to risk assessment.

### 5.6.4 Other areas of Assurance

The need for other areas of assurance was discussed by the Strategic Programme Board in March 2021 and it was agreed that no additional assurances are required for this Programme.

## 5.7 Procurement and Contract Management

The All Wales PET Programme will use Capital funding via the All Wales Capital Programme.

All of the major items of equipment are available on a compliant preapproved framework. NHS Wales organisations have direct access to this framework.

The multidisciplinary team within the Procurement Workstream of this Programme will make recommendations on the most economically advantageous tender and which providers that each organisation may use. The decision of which provider will sit with the procuring organisation, and they will enter into a contract with the organisation alone.

It is possible that the Procurement Workstream will propose running one procurement for the NHS equipment, depending upon the timings. For instance, if phasing of projects is less than two years apart, there may be an option to fix the costs and place orders at the same time, deploying when needed at a future date.

Carrying out a procurement exercise at a national level will most likely make the process at local level much faster.

The Procurement Workstream membership will consist of the specialists within NWSSP-SES, NWSSP-PS, organisations Procurement and Estates representatives, Programme Manager and Project Teams at relevant Health Boards, Trusts and Cardiff University.

It is anticipated that each organisation that subsequently hosts a PET scanner will enter into a contract with the supplier. This contract will be subject to the hosting organisations local governance and review processes.

## 5.8 Change Control

### 5.8.1 Change Control and Configuration Management

The Change Control Procedure will be managed by the Programme Manager. The Change Control Procedure will comprise of:

- Change Management Document - which gives guidance of version control in regards to documents and the change control procedure;
- Change Management Log - captures all version-controlled documents/products and change requests;
- Change Form - is a formal process, which staff are required to follow to request change to a version-controlled document / products.

The Project Teams and external contractors are expected to comply fully with the Change Control Procedure.

### 5.8.2 Change Management Framework

This framework will underpin the change process. The framework will shape the way that the process is managed, reflecting the following change management philosophy and principals:

- Recognise the need to maximise the Benefits of the change for patients, who should be at the heart of the changes made;
- Phase the Programme implementation so that lessons learned can be appropriately ascertained and avoid risks related to a 'big bang' approach;
- Test and prove the changes through careful piloting of any aspects of the new models and processes that can be implemented before new PET scanning facilities are commissioned;
- Work in partnership with staff and other stakeholders both within and outside of the All Wales PET Programme to engage all those involved in the delivery of care in the change process;
- Work effectively with stakeholders of interdependent Programmes and Projects, to ensure that the impact of any items outside of the control of this Programme are considered in a timely fashion, and
- Focus on staff skills and development required so staff are both capable and empowered to deliver healthcare effectively and to a high-quality standard in the new facility through new models of care.

Once the PBC has been endorsed, these principles will be revisited and confirmed. The change management framework and change management principles will be communicated to all stakeholders and staff as part of the launch of the change management process.

### 5.8.3 The Project Change Management Approach

The Programme Manager will design a change management approach that will encompass the framework and principles outlined above.

The implementation of a change management process will progress well in advance of relevant FBC approval for implementation sub projects.

Where proposed changes to the service impact on the workforce, the NHS Wales, Organisational Change Policy will apply. This national document makes clear the onus upon the service to consult with staff affected and their individual employment rights.

### 5.8.4 The Change Control Plan

Once the PBC has been endorsed a Change Management Plan will be developed and three actions will occur:

- The Core Plan will be reviewed by the SPB to identify other relevant areas that need to be included;
- Detailed plans will be set up for each of the tasks in the Core Plan; and
- An overall timetable will be developed and the high-level milestones communicated as part of the launch of the Change Management Plan.

Table 67 below outlines the core plan and the main tasks identified to date.

Table 67: Core Change Management Plan

Area	Planned tasks
Planning phase	Appoint key Programme roles and Change Managers, confirming responsibilities and leadership Confirm stakeholders and interested parties both within and outside the Programme Develop core plan in more detail, identifying high level milestones for the Change Management Plan, mapped to the overall Programme Plan Confirm involvement of HR, managers and other individuals/groups in the process
Communications and stakeholder engagement	Confirm communications lead and protocols (route and timing of approval of communications) Develop communications routes, including face to face briefings bulletins, intranet pages Formulate and agree key communications messages against high level milestones Set up stakeholder map and engagement plan Launch change Programme Ongoing communications work
Training and development	Work with HEIW, NIAW and national workforce groups for each professional role Work with staff through workshops and other training to clarify the workings of the new PET scanning Service Models and how these will impact in practice Identify national training and development required to fulfil roles and competencies Link training and development into communications plan and Workforce Workstream
Piloting	Identify and confirm areas where piloting of new models and practice will be implemented Confirm schedule of pilot work, mapped against high level project and change management milestones Agree feedback arrangements from pilots and how this links into training/development, communications and overall change management plan Execute pilots, feedback and report progress
Full Implementation	Identify scheduling/phasing of full implementation Using results of piloting and training work, develop detailed implementation and transition plan, mapped to project phasing Discussion and agreement with key staff Execute implementation and transition plans

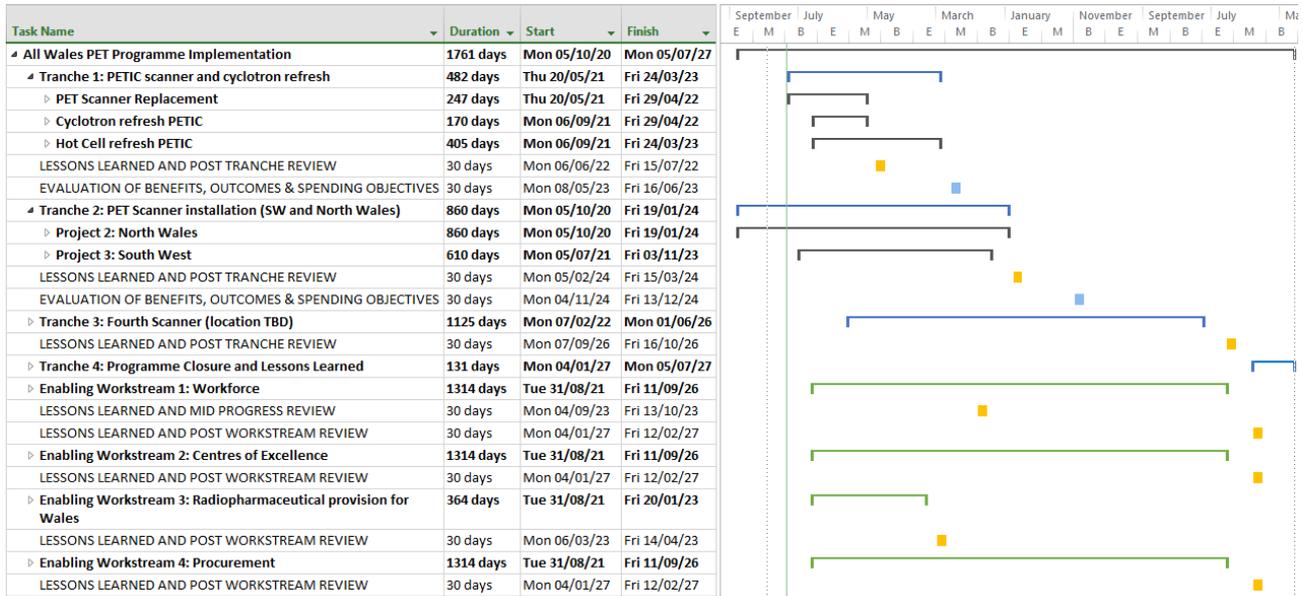
## 5.9 Programme Plan

The Programme plan with details of milestones, durations of tranches and work streams is shown in Figure 14 below.

At the time of writing this Management Case many of the component Project plans are not substantially developed. This is a result of the level of infrastructure design maturity and the fact that no procurement activities have yet taken place. Please see Appendix 1 for a more detailed plan.

All programme time estimates have been based on advice from NHS Wales Shared Services Partnership and following benchmarking with other similar health schemes.

Figure 14: High level Programme Plan



Key: Dark Blue lines denote a tranche, dark grey lines denote a Project, green lines indicate a workstream. Yellow bars denote mid-progress and end-progress evaluation, light blue bars indicate evaluation of benefits, outcomes and Spending Objectives.

## 5.10 Benefits Realisation

### 5.10.1 Benefits Realisation Strategy

The All Wales PET Programme team has worked closely with Welsh Government and other partners to ensure that management of the All Wales PET Programme benefits is robust. This work has included the identification and quantification of Programme benefits, where possible. This has allowed for the quantified benefits to influence the Economic Case where the selection of the preferred way forward was made. The quantification of benefits relating to the All Wales PET Programme reflect some wider societal benefits. These are included only where they can be directly attributable to the provisioning of the PET scanners.

The Blueprint for the Programme (Appendix 3) has been considered in developing the Benefits. Programme Benefits will be applied 100% in the PBC and then proportioned out across the subordinate business cases for Projects 1-4.

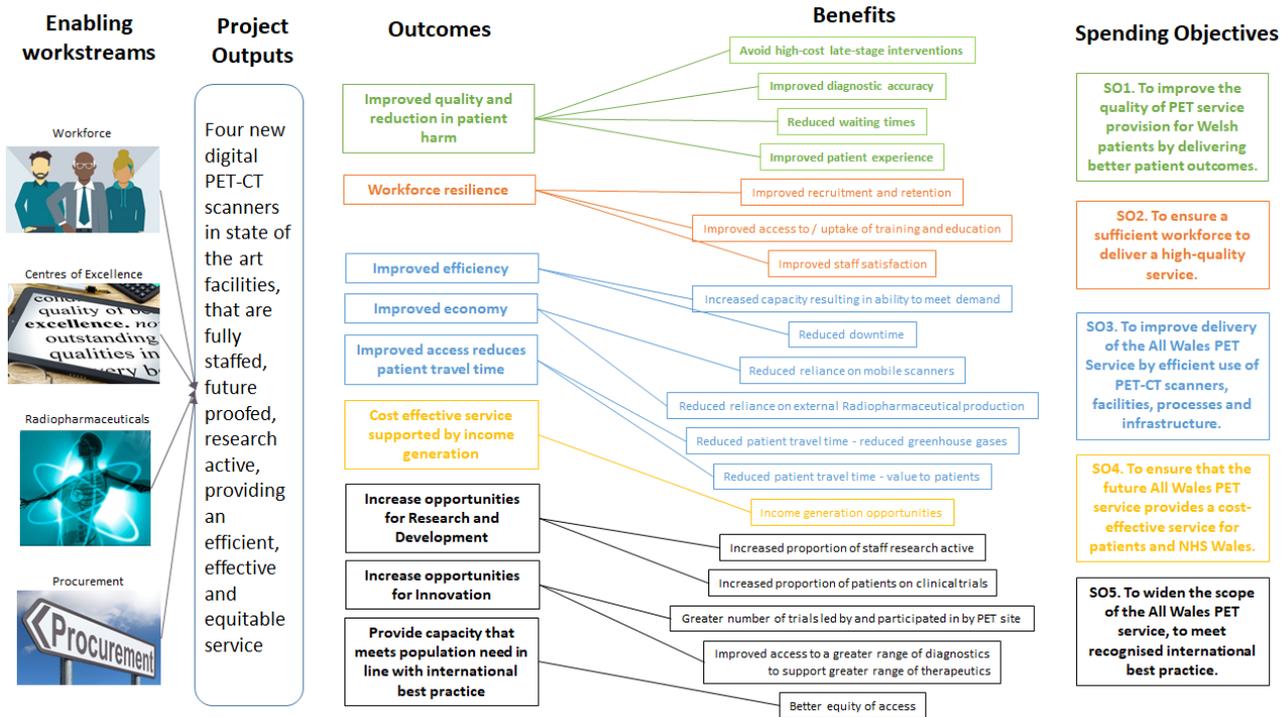
The Programme also contains non-quantifiable benefits and the Programme intends to maximise the delivery of all benefits, especially those that relate to improvement in the quality of patient outcomes.

All the Benefits identified in the Strategic Case and appraised in the Economic Case sections of the PBC are accounted for in the Benefits Register (Appendix 4). This Register notes timescales and ownership of benefits, in addition to how benefits will be measured.

### 5.10.2 Benefits Assurance and Mapping

One of the most important features in Benefits realisation is to ensure that the perceived benefits identified as part of the proposed investment will deliver the Spending Objectives. This can be visualised in Figure 15.

Figure 15: Benefits Map



As previously described in the Strategic Case the benefits associated with the programme have been identified and analysed, grouped by benefit criteria, and also matched to a beneficiary as illustrated in Figure 16 below.

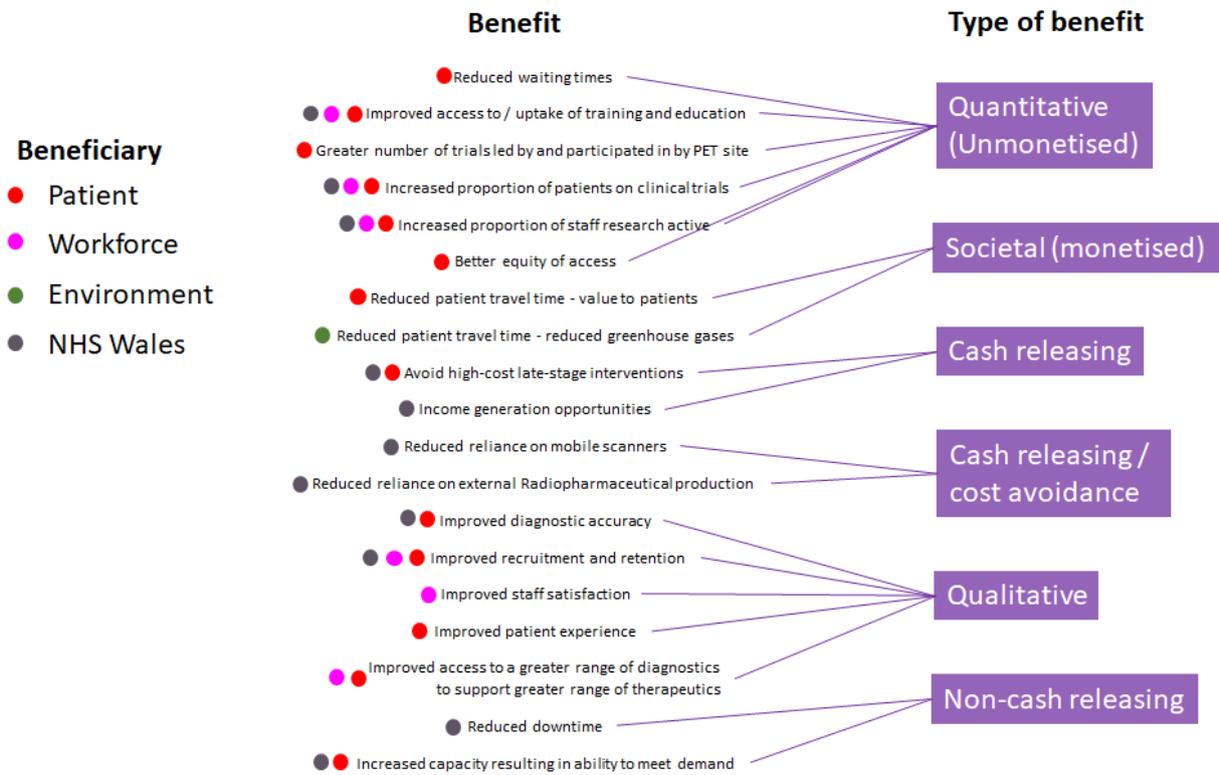
The outcome of the benefits mapping exercise demonstrated that there is a strong correlation between the five spending objectives and the benefits groups for the wider Programme. All Benefit Groups have been matched to a beneficiary, whether this be a patient, workforce, NHS Wales or the Economy.

### 5.10.3 Benefits Realisation Plan

Programme Benefits Realisation is intrinsically linked to Business Change delivery and as such, it requires a nationally agreed approach across all NHS Wales organisations. This must be supported by both local Project implementation teams.

A Benefits Realisation Plan will be prepared for the All Wales PET Programme. The plan will be designed to enable benefits that are expected to be derived from the Programme, to be planned for, managed, tracked and realised.

Figure 16: Benefit Criteria and Beneficiary



As part of the information required for the PBC, Benefits have been incorporated into a Benefits Realisation Register (Appendix 4) which details:

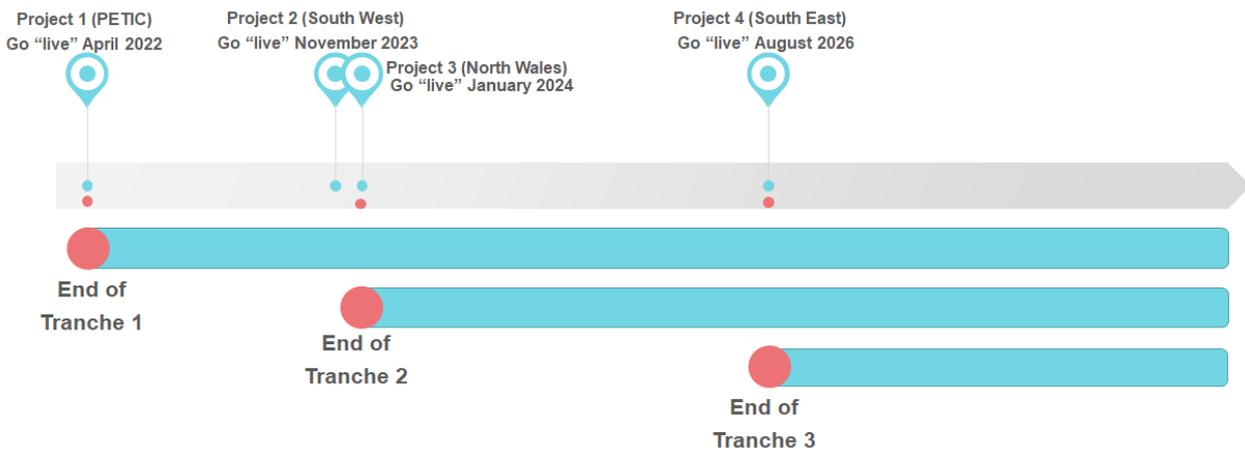
- Beneficiaries;
- Category of benefit;
- Baseline measure;
- Trajectory to target; and
- Benefit owners.

Each Project and their associated business cases will provide more detailed plans for Benefits Realisation.

Benefits will be baselined shortly after this PBC is endorsed and the Programme Manager will work with Project SROs and Project Managers to do this. As Benefits Owners, the Project SROs at each site will hold the responsibility for measuring the Benefits.

Completion of each Project will deliver a new (updated in Cardiff) PET scanning site. This will build and create core capability in each tranche, that will ultimately achieve the new operational state (or Outcome) when the scanners are “live”. Therefore, the All Wales PET Programme should begin to realise Benefits following completion of each tranche. This realisation phasing can be visualised as per Figure 17 below.

Figure 17: Benefits Realisation Timeline



## 5.11 Risk Management Plan

### 5.11.1 Risk Management Overview

The All Wales PET Programme will utilise its governance structure and arrangements to ensure the effective management of risk. The governance structures allow for risks to be escalated from Project boards and Workstream groups, through to the Strategic Programme Board and/or the Health Board/Trust, as appropriate.

Each Project will hold its own risk register and this will be updated dynamically but also formally reviewed on a monthly basis by Project Boards.

A bimonthly risk report for the Projects will be submitted by the Project SRO and Project Manager to the All Wales PET Programme SRO and local Health Board appropriate body. This risk register will highlight new risks, the movement in existing risks and issues and where appropriate, it will recommend the closure of resolved risks or issues.

A comprehensive Programme risk register and accompanying paper will be produced by the Programme Manager for all Strategic Programme Board meetings. This paper will highlight new risks across the Programme including the Projects and workstreams, the movement in existing risks and issues and recommends the closure of resolved risks or issues.

The All Wales PET Strategic Programme Board, upon receiving a Project risk register (via the Programme Manager), will consider if the mitigating actions are sufficient and if the identified risks are receiving the right level of treatment.

The Strategic Programme Board will consider the escalation of Programme Risks onto the NIPSB Risk Register, as appropriate. The remainder of this section sets out the detailed management of risks and issues.

### 5.11.2 Issue and Risk Management Philosophy

Managing risk is a holistic approach, seeing effective risk management as a positive way of achieving the Programme's wider aims, rather than simply a mechanistic 'tick box' exercise, to comply with guidance. The Programme regards risk as the mirror opposite of benefits. Inadequate risk management would therefore reduce the potential benefits to be gained from the Programme.

Effective Risk Management supports the achievement of wider aims, such as:

- Effective Change Management;
- Enhanced use of resources;
- Better Programme and Project Management.

The programme will utilise WHSSC's Risk Management Framework to systemically identify, actively manage and minimise the impact of risk. This is done by:

- Identifying possible risks before they materialise and putting mechanisms in place to minimise the likelihood of them materialising with adverse effects on the project;
- Putting in place robust processes to monitor risks and report on the impact of planned mitigating actions;
- Implement the right level of control to address the adverse consequences of the risks if they materialise; and
- Having strong decision-making processes supported by a clear and effective framework of risk analysis and evaluation.

Once risks are identified, the response for each risk will be one or more of the following types of action:

- **Prevention** - where countermeasures are put in place that either stop the threat or problem from occurring, or prevent it from having an impact on the business or Programme;
- **Reduction** - where the actions either reduce the likelihood of the risk developing or limit the impact on the business or Programme to acceptable levels;
- **Transfer** - where the impact of the risk is transferred to the organisation best able to manage the risk, typically a third party (e.g. via a penalty clause or insurance policy);
- **Contingency** - where actions are planned and organised to come into force as and when the risk occurs; and
- **Acceptance** - where the Programme Management Board decides to go ahead and accept the possibility that the risk might occur, believing that either the risk will not occur or the potential countermeasures are too expensive. A risk may also be accepted on the basis that the risk and any impacts are acceptable.

The All Wales PET Programme will adopt a proactive approach to the identification, assessment and management of risks throughout the whole Programme. The effective management of risk and the prevention of issues arising will support the timely delivery of the Programme, by preventing delays, avoiding costs and ensuring quality is upheld.

The management of Programme risk will be in accord with the principals of WHSSC's Risk Management Policy where the All Wales PET Programme holds a Risk Register which is regularly monitored and updated.

### 5.11.3 Recording and assessment of risk

The All Wales Programme has a Risk Register that is a dynamic document which will be updated with all new identified risks being assessed. All risks will have an individual identifier, an assigned owner and be scored using the standard 5 by 5 matrices to ascertain the risk rating colour.

It is worth reiterating that as set out in the Commercial Case a number of the risks associated with the procurement will be either wholly transferred or shared with the supplier.

Figure 18: Risk Scoring Matrix

Impact	Likelihood				
	1 = Rare	2 = Unlikely	3 = Possible	4 = Likely	5 = Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

### 5.11.4 Review and Escalation of Risk

WHSSC has a simple Risk Management Framework that focuses on effective identification, reporting and management of risks. There are only three roles in the risk management process that are summarised in Table 68 below.

Table 68: Risk Management Roles

Role	Responsibility	Reporting / accountability
Risk Management Lead	Manages the process for identifying and addressing risk, maintaining the risk register on a day to day basis	SRO
Risk Management Sub Group	Brings together key risk owners to co-ordinate the identification and assessment of risks plus the management of key risks	PET Strategic Programme Board
Risk Owner	Individual or group responsible for developing and implementing risk mitigation measures for individual risks they are responsible for	As defined in the relevant Risk Register

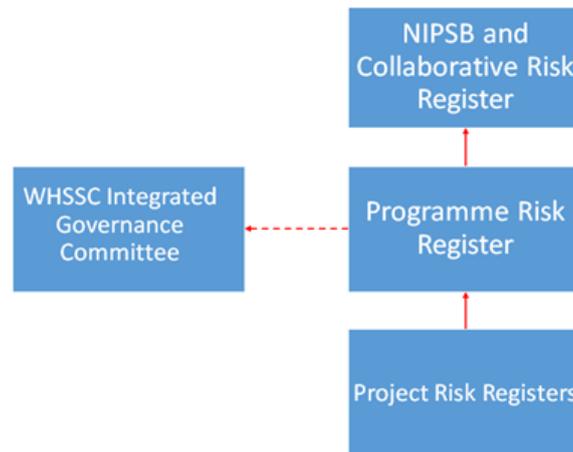
As mentioned above, Project risk registers will be reviewed monthly by the relevant organisation Project Team and by the PET Programme Board on a bi-monthly basis. Those risks that are marked as “Red” or “Amber” on a Project risk Register will be noted in the wider Programme Risk Register.

The Programme Risk Register will be reviewed once per quarter by the WHSSC Integrated Governance Committee for assurance purposes.

Programme risks noted as “Red” following countermeasure mitigation scoring will be escalated through the existing governance structure to the NIPSB at the monthly meeting.

Issues are Risks that have materialised. Similar to risk, the Strategic Programme Board will hold an Issues Register and follow the same escalation path. All issues should have an owner and an aligned action plan and will be reviewed during all Programme Project Board meetings. Issues that are outside the scope or authority of the Strategic Programme Board will be referred to the relevant Board or Group.

Figure 19: Risk Escalation Route



## 5.12 Arrangements for Post Programme Evaluation

The requirement to carry out a post programme evaluation is essential to determine if a Programme has (i) been successful; (ii) has it met the Spending Objectives and; (iii) realised its expected Benefits. Additionally, it ensures that lessons learned can be factored into future Projects and Programmes.

The All Wales PET Programme is committed to ensuring that a thorough Post-Programme Evaluation (PPE) is undertaken after the Programme has concluded, to ensure that positive lessons can be learnt. This is noted in tranche 4 of the Programme Plan.

The All Wales PET Programme is also committed to ensuring that lessons are learned at all key stages during implementation, so these can be fed into the wider Programme.

As such, there will be two Evaluation sessions held after each Tranche:

- **Lessons Learned and Post Tranche Review** – to be held two to three months post tranche completion.
- **Evaluation of Benefits, Outcomes and Spending Objectives** – to be held six to twelve months post tranche completion.

Immediately following implementation, all Projects will be reviewed against the usual measures for Projects: time, cost and performance, in addition to management and procurement processes. This will form the foundation of the “lessons learnt” sessions. The “lessons learnt” sessions will also provide benefits such as:

- An opportunity to improve the design, organisation, implementation and strategic management of projects and workstreams;
- An opportunity to ascertain whether the programme is running smoothly so that corrective action can be taken if necessary;
- Promote organisational learning to improve current and future performance;
- Avoid repeating costly mistakes;
- Improve decision-making and resource allocation;

- Improve accountability by demonstrating to internal and external parties that resources have been used efficiently and effectively, and
- Demonstrate acceptable outcomes and/or management action thus making it easier to obtain extra resources to develop healthcare services.

In addition to “lessons learned”, these post-tranche sessions will also provide an opportunity for the Programme to begin to assess and implement the Benefits Realisation Plan.

After a reasonable bedding-in period of six to twelve months, all Projects within a tranche will be subject to a more wide-ranging evaluation of costs and performance, as well as being reviewed against the Spending Objectives and the Benefits Realisation Plan.

It should be noted that as all Projects and Workstreams will report into the Strategic Programme Board on a bimonthly basis. In addition, the Board will remain open to comment and opportunities to determine lessons learned throughout the Programme life-cycle, and not just at the post-tranche formal reflection sessions.

The SRO will be responsible for ensuring that arrangements have all been put in place and that the requirements for PPE are fully delivered.

An Evaluation Steering Group (ESG) will be set-up and the Programme Manager will coordinate and oversee the Evaluation.

The costs of the final Post-Project Evaluation will be identified once the ESG and Evaluation Team are fully-established. These costs are therefore not currently included in the costs set out in this PBC.

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# Appendices

Appendix 1 – Service Operating Model

Appendix 2 – Population Growth Projections

Appendix 3 – Collated Clinical Questionnaire narrative

Appendix 4 – PET demand forecast 10 year with variable inflation

Appendix 5 – Clinical Indication Analysis

Appendix 6 - Clinical Demand Model narrative

Appendix 7 – Workforce Board Output

Appendix 8 – Life Sciences Hub Wales – Horizon Scanning of Artificial Intelligence

Appendix 9 – Options Framework

Appendix 10 – PBC Forms

Appendix 11 – Economic and Financial Calculations

Appendix 12 – Full Programme Delivery Plan

Appendix 13 – Suggested Audit Brief from NWSSP Audit and Assurance Services

Appendix 14 – Programme Blueprint

Appendix 15 – Programme Benefits Tracker

