

Appendix B

Outline / Full Business Case: Update May 2022

Integrated Radiotherapy Solution

Strategic Case

STRATEGIC CASE

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1 INTRODUCTION AND BACKGROUND

Introduction

- 1.1 The purpose of this business case is to present proposals for the procurement of an Integrated Radiotherapy Solution (IRS) that will ensure Velindre University NHS Trust (VUNHST) can continue to deliver safe, efficient and effective Radiotherapy Services to the population of Southeast Wales.
- 1.2 Having previously scrutinised and endorsed a Programme Business Case (PBC), VUNHST and Welsh Government have approved the commencement of an IRS procurement and the associated development of a combined Outline Business Case and Full Business Case (OBC/FBC). This approach recognises the non-traditional nature of this business case, in particular:
- There is an increasingly urgent need to start to replace aging Radiotherapy Equipment in the current Velindre Cancer Centre (Phase 1) as part of normal equipment replacement.
 - Delivery of the IRS Project within required timescales is critical to delivery of the overall Transforming Cancer Services in Southeast Wales (TCS) programme timelines; and
 - Dependencies and overlaps with the new Velindre Cancer Centre (nVCC) and Radiotherapy Satellite Centre (RSC) Projects.
- 1.3 This introductory section provides an overview of:
- The context of the proposed investment
 - The governance arrangements for the Project; and
 - The structure and content of the business case.

Context of proposed investment

- 1.4 The Trust, and its partners, are committed to providing safe, efficient and effective care to all our patients. To achieve this from a Radiotherapy perspective, it is essential that major medical equipment is renewed as part of a regular replacement cycle. This reduces the likelihood of equipment failure, obsolescence and ensures the most up to date treatments are available to our patients to support improved outcomes and quality of life.
- 1.5 This procurement project is critical to delivery of the Trust's long-term strategy, specifically the Transforming Cancer Services in South Wales (TCS) programme. This is an ambitious programme, which aims to deliver transformed Tertiary non-surgical Cancer Services for the population of Southeast Wales.

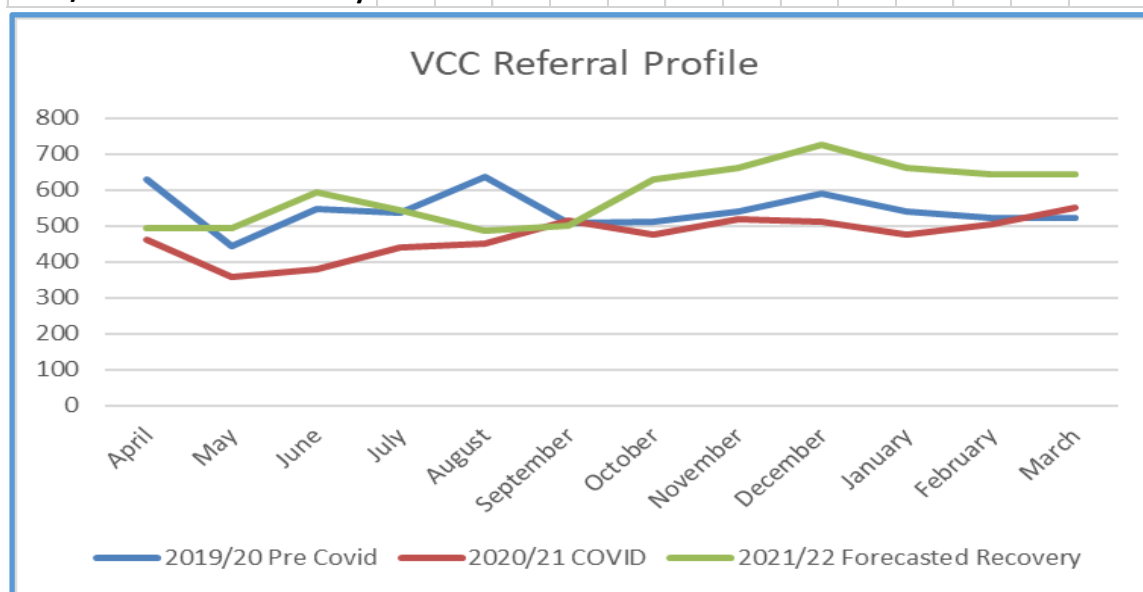
- 1.6 Central to this strategy is the need to provide new radiotherapy clinical equipment and digital solutions that will support the new Velindre Cancer Centre (nVCC), the Radiotherapy Satellite Centre (RSC) and, importantly, the existing Velindre Cancer Centre (VCC). This will facilitate the transformation opportunities that modern clinical equipment and digital solutions can deliver. It will also support service resilience, at a time of significant service demands, on an aged radiotherapy treatment machine fleet, which will be described in more detail later in this section.
- 1.7 Originally, it was planned that most of the major medical equipment, including radiotherapy equipment, would be replaced when the nVCC was opened. The rationale for this was that implementation costs would be reduced with the existing equipment 'stretched' beyond its recommended lifespan.
- 1.8 This original approach negated the need to relocate major medical equipment, which would affect service capacity, as downtime would be required during the lengthy recommissioning period.
- 1.9 Unfortunately, delays to the nVCC Project resulted in an increasing operational service delivery risk due to aging radiotherapy equipment at the VCC. This increasing risk, combined with the long lead times for equipment procurement, meant that alternative approaches needed to be considered. A review identified that the 'decoupling' of the IRS requirements from the nVCC Project and Radiotherapy Satellite Centre projects was required to effectively manage the new environment.
- 1.10 In order to effect this change, a Digital and Equipment Procurement Decoupling PBC was submitted to Welsh Government. After consideration and scrutiny, this PBC was endorsed by Welsh Government on 5th June 2019. Subsequently, VUNHST received a funding letter to facilitate the initial procurement phase of the IRS Project to a value of £1.11 million over three financial years starting in September 2019.
- 1.11 The Trust subsequently established the IRS Project Team that was independent of, but still related to, both the nVCC and RSC Project Teams.
- 1.12 It is also important to highlight that any decision to proceed with the contract will not commit the Trust or Welsh Government to any equipment and services beyond that which would be required to replace the existing treatment machine fleet at the VCC. The procurement is designed to achieve this aim whilst also facilitating the nVCC and RSC Projects through commercial and contractual design.

- 1.13 To support this independent, but facilitative approach, a Project agreement has been reached with the Welsh Government to develop a combined OBC/FBC which seeks approval to procure an IRS independent of approval of the nVCC and RSC OBCs. This procurement will include the following items:
- Radiotherapy Treatment Machines / Equipment
 - Radiotherapy Informatics Solution (including Oncology Information System (OIS) and Treatment Planning System (TPS))
 - Dosimetry, Quality Assurance Systems
 - Clinical & Patient Safety Systems
 - Ancillary equipment, IT and infrastructure.
 - Project Management, Ongoing Support and Development Services
 - Research & Development (including the option of a research machine in a bunker at the nVCC)
- 1.14 The business case confirms the need for VUNHST to deliver a modern radiotherapy solution that is resilient and has greater capability and capacity to enable the Trust to continue to treat increasing numbers of referrals from secondary care, which increasingly require more complex radiotherapy treatments.
- 1.15 The post COVID-19 surge of patients who have not accessed healthcare during the pandemic is still a distinct possibility. Some of these patients may present with later “staging” and require more complex treatments which will put additional pressure on VCC resource.

1.16 The table below shows the referral profile for 2019/20, 2020/21 (COVID) and 2021/22 Actual and Forecast recovery including the impact of the following:

- In 2020/21 referrals dropped by 13% due to the impact of Covid
- Recovery in 2021/22 includes full recovery from 2020/21 plus 8% growth in referrals based on growth experienced as at October 2021.

	April	May	June	July	August	September	October	November	December	January	February	March	Annual
2019/20 Pre Covid	628	442	547	536	635	506	511	539	591	539	522	523	6519
2020/21 COVID	461	357	379	441	452	515	477	520	510	476	503	552	5643
2021/22 Forecasted Recovery	493	494	594	545	486	500	629	663	727	663	642	643	7079



1.17 This includes the following assumptions:

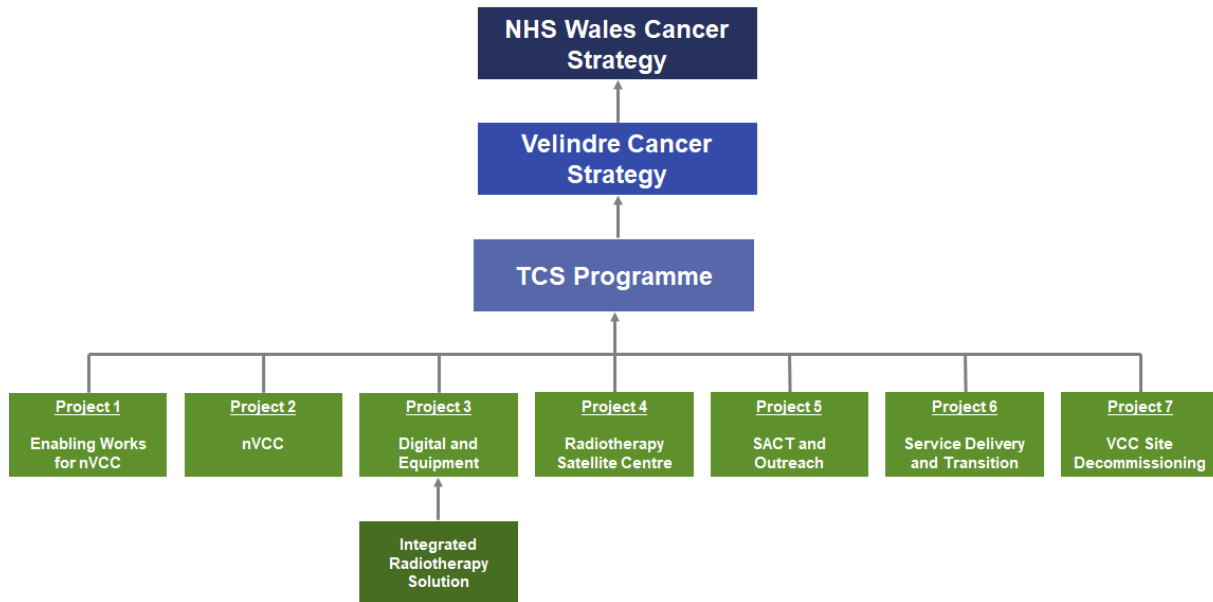
- As covered above the COVID impact in 2020/21 was a reduction of 13% (876 Referrals), recovery started in October 2020 with Radiotherapy impacted due to lack of surgical bed capacity in UHB's. This continued through to September 2021 where an increase to Pre Covid levels occurred in September 2021
- The predicted 'Surge' or suppressed demand forecasted by the DU did not materialise at VCC due to extended diagnostic and treatment delays within UHB's, as well as suspension and reactivation of screening. We now have 12 – 14 weeks visibility of referrals from 'Point of Suspicion referrals and are now refining this to the 'Decision to Treat' stage.
- The patient pathway timing from 'Point of Suspicion' referrals within the UHB's has increased from 127 days to 200 days, this varies by tumour site as well as by UHB 's now giving priority to Medium – High Risk patients in some instances presenting with later stage
- We have patient referrals on a frequent basis from our 3 predominant University Health Boards which act as an early warning of potential surge

- We are experiencing higher than forecast referrals for Breast (5%) and Colorectal (18%) we also suspect a significant number of Urology referrals are currently retained within UHB's
- 1.18 The IRS solution is also needed as a core element of the radiotherapy equipment replacement cycle at VCC, which had previously slowed due to the original planned delivery of the nVCC (now delayed). As predicted previously, the reliability of some of the Trust's Linear Accelerators has deteriorated with time. This has led to operational reliability issues and increased maintenance costs.
- 1.19 The procurement provides capacity to meet current demand and future growth forecasts. Forecasts that also underpin the need for the planned Radiotherapy Satellite Centre, and to facilitate the delivery and timeline of the nVCC and RSC Projects.
- 1.20 This OBC/FBC explores a range of options to identify a solution that both supports the urgent need to mitigate service delivery risks and enable current services, whilst supporting the key dependencies of the TCS Programme; specifically, the nVCC and the RSC projects.
- 1.21 At the time of finalising this business case the nVCC Project, is in the process of concluding competitive dialogue and moving towards final tender. Once the tendered costs are known from the Successful Participant the Full Business Case will be finalised and submitted to the Trust Board, Welsh Government and the Trust's Commissioners.
- 1.22 This document, as agreed by Welsh Government colleagues, comprises the second phase of a two-phase submission process which incorporates the following phases set out overleaf:
- **Phase 1:** An initial draft of the business case (submitted in November 2020) was developed in advance of the procurement process being completed. It set out the OBC requirements for the Strategic and Management Cases. It also set down the core components of the Commercial Case that are supplemented with the final contractual arrangements at FBC Stage. In addition, it outlined the options and set out the templates for the Economic and Financial Cases, although at that stage the templates within these chapters excluded costs and no conclusions were reached as the procurement was ongoing.
 - **Phase 2:** This final version incorporates the results of the procurement process to complete the Economic, Commercial and Finance Cases, and refine, following feedback from WG scrutiny at Phase 1, the Strategic and Management Cases. This aligns with FBC requirements for all cases.

Project governance arrangements

- 1.23 As described earlier, the IRS project sits within the wider TCS programme which is designed to facilitate key aspects of the Velindre Cancer Strategy and NHS Wales Cancer Strategy.

Figure 1-1 Programme overview



- 1.24 The approval process for this business case is outlined in the table below.

Table 1-1 Business case approvals process

Approval Step	Purpose	Submission Target Date
Phase 1 Draft to Welsh Government	For review	November 2020
Phase 2 Final to Trust Board	For approval	May 2022
Phase 2 Final to Welsh Government	For approval	May 2022

- 1.25 The Project structure, and detailed governance arrangements, are further outlined in the Management Case.

Structure and content of OBC/FBC

- 1.26 This business case has been prepared in accordance with HMT Green Book and Welsh Government Better Business Case guidance, adapted to reflect the combined OBC/FBC format and two-phase submission approach that has been agreed with Welsh Government colleagues. The table below outlines how the phased approach has been applied to the Five Case model.

Table 1-2 - Phased approach and key components of the OBC/FBC

Chapter	Phase 1	Phase 2
Strategic Case	Sets out the strategic context and the case for change, together with the supporting investment objectives for the scheme.	Refined and updated.
Economic Case	Explores the potential long list of options and identifies the preferred way forward and shortlist of options. Provides a template for completing the economic appraisal and outlines the main benefits of shortlisted options.	Appraises the economic costs, benefits and risks for the short-listed options based on the results of the procurement process. Demonstrates the preferred option best meets the needs of the service and optimises value for money.
Commercial Case	Describes the procurement strategy adopted and outlines the content and structure of proposed contract and associated contractual arrangements.	Provides the results of the procurement process and final proposed contractual arrangements.
Financial Case	Provides a template for completing the financial appraisal.	Sets out the financial implications of the preferred option based on the results of the procurement process. Confirms funding arrangements and affordability and explains any Balance Sheet impact.
Management Case	Demonstrates that the scheme is achievable and can be delivered successfully to cost, time and quality.	Refined and updated.

2 ORGANISATIONAL OVERVIEW

Introduction

- 2.1 The purpose of this section is to provide an overview of Velindre University NHS Trust (VUNHST) and Velindre Cancer Centre and its role in delivering non-surgical specialist cancer services to the population of Southeast Wales.

Velindre University NHS Trust

- 2.2 The Trust has evolved significantly since its establishment in 1994 and is operationally responsible for the management of the following two divisions:
- Velindre Cancer Centre; and
 - Welsh Blood Service.
- 2.3 The Trust is also responsible for hosting the following organisations on behalf of the Welsh Government (WG) and NHS Wales:
- NHS Wales Shared Services Partnership (NWSSP); and
 - Health Technology Wales (HTW)

Velindre Cancer Centre

- 2.4 Velindre Cancer Centre is located in Whitchurch on the North-West edge of Cardiff and is one of the ten largest regional clinical oncology centres in the United Kingdom (UK Radiotherapy Equipment Survey, 2008) and the largest of the three centres in Wales. The centre is in a building which is over 60 years old and does not have the facilities, space or modern infrastructure required to meet future service standards and predicted demand.
- 2.5 Velindre Cancer Centre is responsible for the delivery of non-surgical treatment, including Radiotherapy and SACT, recovery, follow-up and specialist palliative care. Following their specialist cancer treatment, Velindre Cancer Centre continues to support patients during their recovery and through follow up appointments. A significant proportion of Outpatient and SACT activity is already delivered in Health Board settings by Velindre Cancer Centre staff. However, all Radiotherapy activity is currently delivered at the Velindre Cancer Centre.
- 2.6 Specialist teams provide care using a well-established multi-disciplinary team (MDT) model of service for oncology and palliative care, working closely with local partners and ensuring services are offered in appropriate locations in line with best practice standards of care. The range of services delivered by Velindre Cancer Centre includes:

- Radiotherapy
- Systemic Anti-Cancer Therapies (SACTs);
- Inpatients
- Ambulatory care
- Outpatient services
- Pharmacy
- Specialist radiology/imaging
- Nuclear Medicine
- Specialist Palliative care
- Acute Oncology Service (AOS)
- Living with the impact of cancer
- Education and Learning; and
- Research, Development and Innovation

2.7 The following patient services are delivered in outreach settings across Southeast Wales from the Velindre Cancer Centre in Health Board settings:

- SACT delivery
- Outpatient appointments
- Inpatient reviews; for patients receiving care and treatment in HB locations
- Health Board MDTs; and
- Research and Education

2.8 However, all Radiotherapy activity is currently delivered at the Velindre Cancer Centre.

Overview of Cancer Services in Southeast Wales

2.9 The planning and delivery of cancer services in Southeast Wales is the responsibility of the four Health Boards (HBs) as part of their statutory responsibility to meet the health needs of the populations they serve. The HBs are supported by the Welsh Health Specialist Services Committee (WHSSC) which commissions specialist cancer services on their behalf.

2.10 The four HBs in Southeast Wales are:

- Aneurin Bevan University Health Board
- Cardiff and Vale University Health Board
- Cwm Taf Morgannwg University Health Board; and
- Powys Teaching Health Board

Figure 2-1 Map of Local Health Boards across South East Wales



- 2.11 The HBs also work in partnership with the All-Wales Cancer Network, NHS Trusts, Community Health Councils, Voluntary and Charitable Organisations and Public Health Wales.
- 2.12 The four Health Boards, in conjunction with VUNHST and other stakeholders e.g., Wales Cancer Network (WCN), have formed the Southeast Wales Collaborative Cancer Leadership Group (CCLG). The purpose of the *Southeast Wales CCLG* is to provide effective system leadership for Cancer Services across Southeast Wales and to deliver improvements in outcome and service experience for the catchment population. It aims to achieve this through the building and nurturing of a sustainable, collaborative cancer community across the region to align change across the whole cancer system.
- 2.13 The CCLG oversees all Collaborative Cancer Programmes of work within the region, ensuring clear leadership and coordination with a focus on benefits delivery for patients, putting into practice the national policies, standards and procedures for the benefit of patients. The CCLG functions at a regional level in support of the work of the Cancer Implementation Group (CIG), a national group leading the implementation of the Single Cancer Pathway, and other Strategic Groups, on an All-Wales level.

- 2.14 The CCLG also looks beyond health to ensure its ways of working embed the Well-being and Future Generations (Wales) Act 2015 and contribute to the seven Well-being goals, the five ways of working and the embedding of the sustainability principle.

The Cancer Pathway

- 2.15 The delivery of cancer services across Wales generally conforms to a well-defined pathway of care which includes the following five key stages:

Table 2-1: The Cancer Pathway

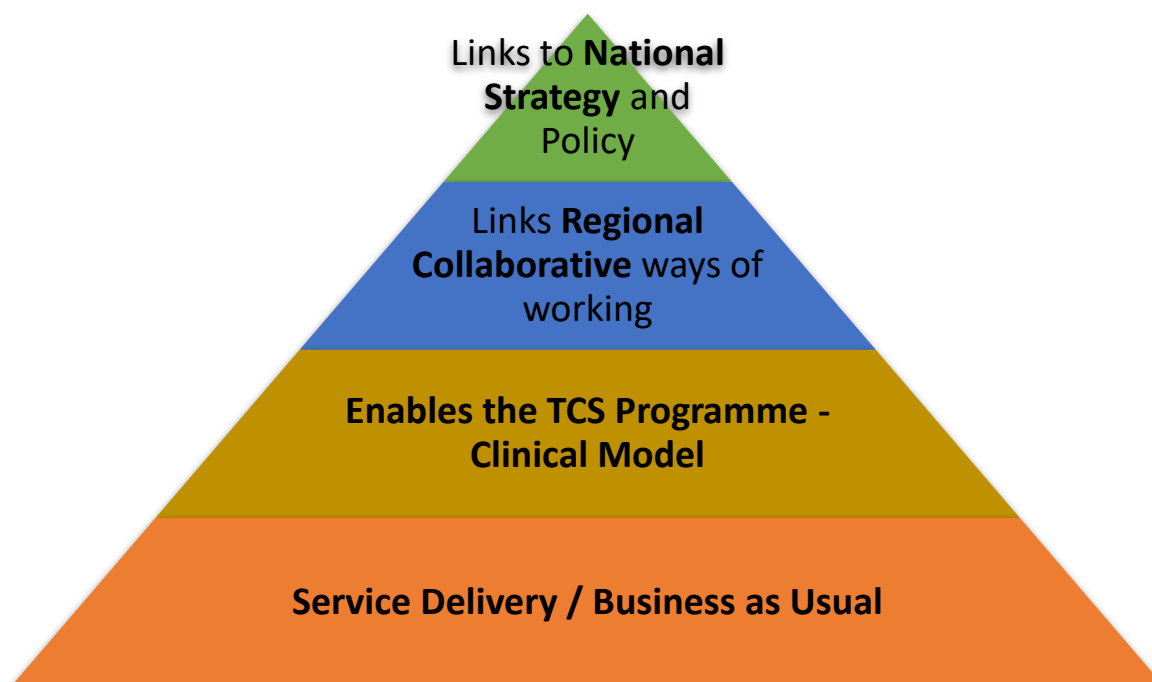
<p>Cancer Prevention: Enhancing public awareness and education to make informed decisions about lifestyle choices that promote a healthy, cancer free population.</p>
<p>Cancer Diagnosis: Cancer can be identified through a National Screening Programme or where cancer symptoms are identified by the patient/health care professional. If cancer is suspected the patient is assessed by a multi-disciplinary team in the Health Board (often supported by Velindre Cancer Centre staff) and cancer may be diagnosed.</p>
<p>Treatment: The treatment options for every patient are discussed and considered by multi-disciplinary teams (MDTs). The treatment options include surgery, non-surgical treatment e.g., Radiotherapy or Systemic Anti-Cancer Therapy (SACT), a combination of these treatments and supportive care. Care often straddles organisational boundaries.</p>
<p>Recovery/Follow Up: Regular follow up appointments are important to monitor recovery, manage and reduce the aftereffects of treatment and to ensure any signs of cancer relapse/recurrence are identified at their earliest stage.</p>
<p>End of Life Care: Sadly, not all patients survive cancer – openness about the need to plan end of life care is essential. A focus on living and dying well, early identification of needs and access to fast, effective palliation are important to reduce distress for both the patient and their family.</p>

3 STRATEGIC CONTEXT

Introduction

- 3.1 This section of the business case outlines the strategic context for the proposals to procure an Integrated Radiotherapy Solution (IRS) by explaining how the project is strategically placed to support delivery of local and national goals.
- 3.2 Specifically, it considers the fundamental drivers behind these proposals including:
- Links to National Strategy and Policy
 - Links to Regional Collaborative ways of working
 - Enabling the Transforming Cancer Services in Southeast Wales (TCS) Programme by identifying the need for investment to support the future Clinical Model; and
 - Service Delivery / Business as Usual needs: The need to maintain business as usual activities and to regularly and routinely replace major medical equipment

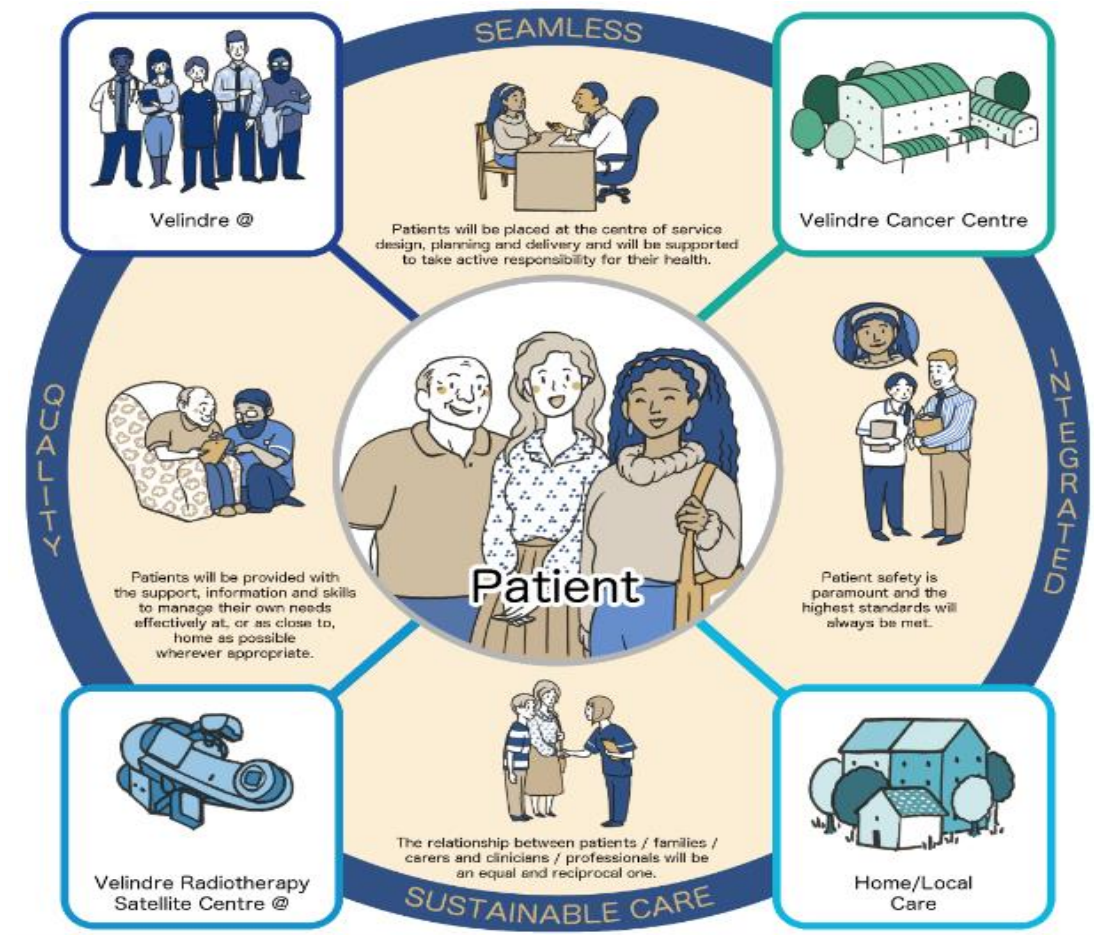
Figure 3-1 Fundamental Drivers



Alignment with TCS Programme

- 3.3 It is important to understand where this business case sits in the context of the overall Transforming Cancer Services (TCS) Programme and in the context of the requirement to continue to deliver safe, resilient and effective services from the VCC. In the case of the former, the TCS Programme is an ambitious Programme which aims to deliver transformed Tertiary non-surgical Cancer Services for the population of Southeast Wales.
- 3.4 The Strategic Case for the TCS Programme, its links to the Welsh Government Cancer Strategy and Velindre's own Cancer Strategy, are made in the TCS PBC. It is not the intention of this business case to restate these, rather to show alignment with this wider Programme's aims and objectives.
- 3.5 The TCS Programme developed a detailed clinical model through over 70 workshops/events/meetings involving more than 1,000 people – professionals, patients and public from a range of organisations including HBs, Third Sector and CHC. The clinical model is shown overleaf.

Figure 3-2 Clinical model



- 3.6 The Clinical Model within the TCS PBC, and as outlined in the diagram above, describes how services will be delivered in the future and is predicated on the following principles:

- The service model seeks to promote a new set of relationships which work in partnership to improve the way we collectively design and deliver services around patients' needs and to achieve these improvements in a truly sustainable way.
- The patient will be central to our plans with an integrated network of services organised around them. The organising principle seeks to 'pull' high quality care towards the patient that is accessible in their preferred location and will support them achieving their personal goals during treatment and subsequently living with the impact of cancer.
- Patient safety is paramount, and the highest standards will always be met.
- The relationship between patients / families / carers and clinicians / professionals will be an equal and reciprocal one.
- Patients will be provided with the support, information and skills to manage their own needs effectively at, or as close to, home as possible wherever appropriate.
- Optimising information technology, quality improvement systems, patient involvement, education and embracing innovative approaches to healthcare will all be essential to achieve high levels of service quality in a sustainable way.

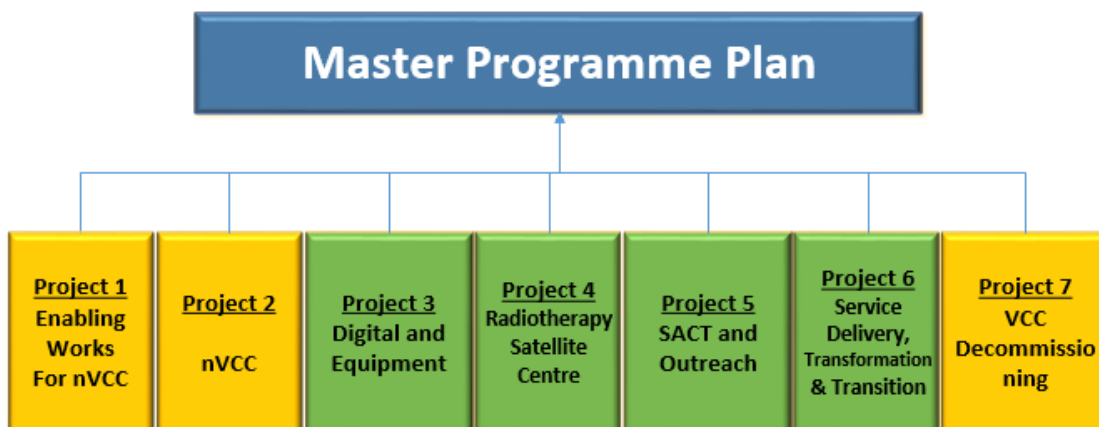
3.7 To deliver the principles of the new clinical model, care will be delivered differently and at different locations. This will require a number of infrastructure and technology projects as well as service change projects to be established.

3.8 These locations and their functions are described briefly below:

- **Health Boards:** A range of cancer care occurs within the Local Health Boards (LHBs), with a proportion of patients having all their care delivered by the Local Health Board (LHB) teams. For other patients who need non-surgical treatment, their care needs to be seamlessly planned with the non-surgical aspects of the pathway, as patient care can often transition from one team to another. The Velindre Outreach facilities and collaborative working will support this approach.
- **Velindre Outreach Centres:** These facilities will provide SACT, outpatient services, education and information provision and ambulatory care procedures within LHBs.
- **Velindre Radiotherapy Satellite Centre:** The Radiotherapy Satellite Centre (RSC) will provide radiotherapy treatment for approximately 20% of our patients (provided by 2 new treatment machines). This means better access for patients, reduced travel for patients and less use of transport services. This will mean that fewer patients need to travel to VCC for their radiotherapy.
- **New Velindre Cancer Centre:** The new Velindre Cancer Centre will provide specialist and complex cancer treatment including SACT, radiotherapy (including brachytherapy and unsealed sources) and specialist palliative care, inpatient facilities (being open for admission 24 hours/day, 7 days/week), a specialist acute oncology assessment unit and outpatient services, radiology and nuclear medicine.

3.9 To effectively control and successfully implement the TCS Programme it has been arranged into the following seven projects as set out below.

Figure 3-3 Seven TCS Projects



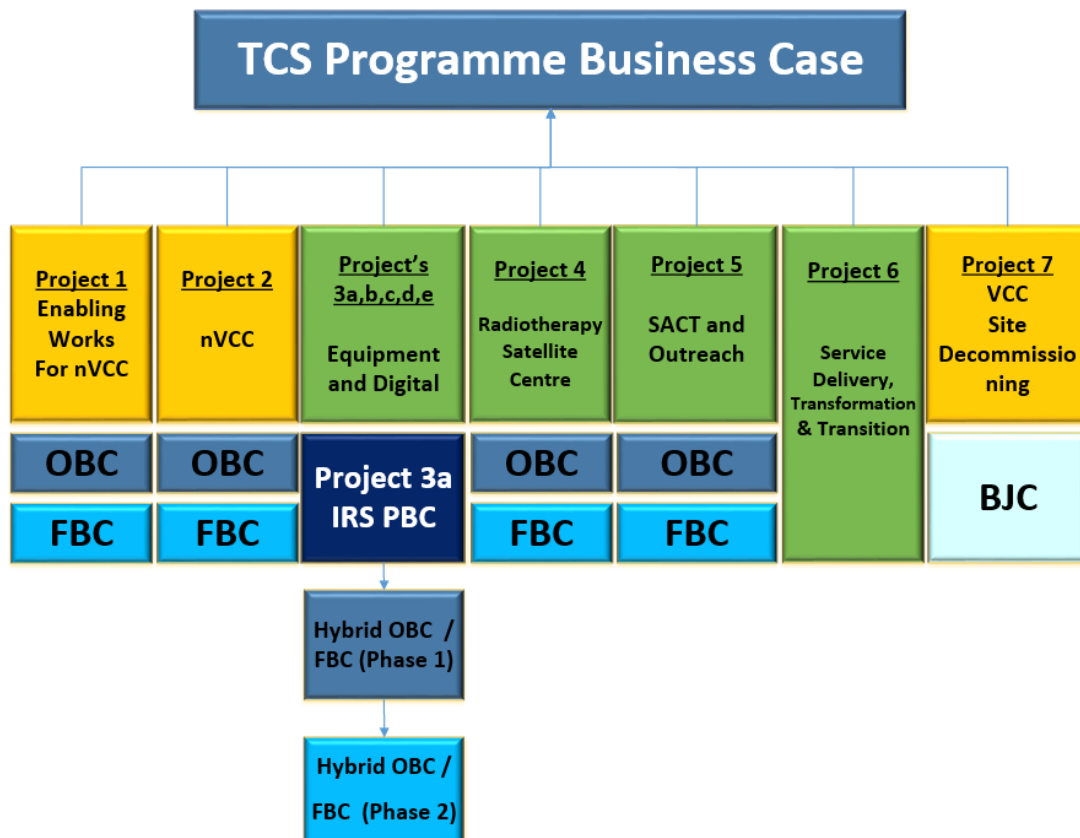
3.10 The seven Projects are structured and described in the table below.

Table 3-1 Project Descriptions

Project Number / Name		Description
1	Enabling Works	All Enabling works needed to provide Primary and secondary access to the new Velindre Cancer Centre Site (includes the provision of utilities).
2	New Velindre Cancer Centre	The re-provisioning of a new Velindre Cancer Centre in the Whitchurch area of Cardiff.
3	Digital and Equipment	The provision of integrated Digital Information and Equipment Services across the TCS Programme. This Project oversees the IRS Project.
4	Radiotherapy Satellite Centre	Provision of a Radiotherapy Satellite Centre at Nevill Hall Hospital.
5	SACT and Outreach	The Provision of SACT and Outpatient services embedded in Local Health Boards. A minimum of two locations and a maximum of four
6	Service Delivery Transition and Transformation	This project is responsible for establishing and transforming all service delivery functions across the clinical model. It is also responsible for planning and implementing the transition between the old and new cancer centre.
7	Site Decommissioning	The decommissioning of the old Velindre Cancer Centre brownfield Site.

- 3.11 To deliver the TCS Programme, as described in the TCS PBC, a suite of Investment Cases is required, and it is important that this business case is seen in the context of the other investment cases that are being developed.
- 3.12 The diagram below sets out the TCS Programmes Business Case Framework and how it aligns to the seven projects.

Figure 3-4 TCS Programmes Business Case Framework



- 3.13 The diagram above sets out the TCS Programme Business Case Framework; the following principles apply following an assessment of cost and complexity relating to the individual projects:

- For all major infrastructure schemes (Projects 1, 2, 4, 5) an Outline and Full Business Case will be developed unless the costs and complexity for Project(s) 5 are deemed to be low cost and non-complex where a Business Justification Case may be more appropriate. If a BJC is to be considered it must have the support of the investment decision maker.
- A BJC is expected to be required for the decommissioning project (Project 7). This assumption will be tested and will need to be agreed by Welsh Government later in the programme.
- Project 6 Service Delivery Transition and Transformation is predominately service change with no infrastructure. These costs will be met by the Trusts commissioners and as such no Capital Business Case will be produced (although justification in other forms will be provided).

- Project 3 Digital and Equipment has five projects in total, of which this IRS Procurement and Implementation Project is project 3a, will have different arrangements. The procurement of the IRS outlined in this business case will be structured in such a way that it can facilitate the delivery of this Project in the event of the business cases for nVCC (Project 2) and RSC (Project 4) gaining approval.

3.14 The capital equipment costs for IRS will also be referenced in the OBCs for the nVCC and RSC Projects. This business case will allow VUNHST to procure the IRS (Phase 1 Implementation), as this is now urgent to maintain safe, resilient and effective services within the VCC, and the rationale for this will be described in later sections.

Trust Radiotherapy Equipment: Strategic Direction

3.15 Given the importance of clinical equipment to the Trust in delivering effective, high quality and safe patient care there have been a number of previous approvals made by the Trust Board that set the strategic direction of travel for equipment, these are:

- The Prime Contractor approach for treatment machines (procurement approach).
- The TCS Equipment Strategy.
- Cognitive by Design (Digital Vision).

The Prime Contractor Approach

3.16 In 2015 members of the Radiotherapy Development Group (RDG) reviewed the impact of running Velindre Cancer Centre (VCC) as a dual-vendor site for treatment machines. The review concluded that operating within the confines of a dual-vendor site detrimentally impacted on a number of areas of the radiotherapy service, including:

- Efficiency and patient flow
- Capacity and the ability to work flexibly
- Workforce and the burden of training (planning and treating patients; and maintaining, running and operating the machines)
- Support services including the Record and Verify (R&V) and IT software
- Resources to undertake a competitive tender process for every new machine
- Resources to manage two commercial contracts and service providers: and
- Limitations on Research and Development capacity.

3.17 This is explored further in the Business Needs section in Chapter 4.

3.18 The Velindre University NHS Trust Board, in September 2016, approved the recommendation that VCC should undertake a compliant and transparent procurement exercise to identify a ‘Prime Contractor’ to meet VCC’s capital radiotherapy equipment needs. The anticipated benefits linked to this decision included:

- Patient Outcome
- Patient experience and satisfaction
- Staff satisfaction
- Service resilience and efficiency
- Business and financial planning
- Research and development
- Reputation

TCS Equipment Strategy

3.19 On the 8th of March 2017 Velindre’s Board approved a TCS Equipment Strategy that set out how Velindre planned its equipment requirements needed to enable the TCS Programme.

3.20 The approved position was as follows:

Table 3-2 Approved Position

Category	Approved Decision
Replacement Options	Extend the operational life of some existing equipment assets, accept some accelerated depreciation (on others) and replace all new in nVCC
Transition Options	Replace all Radiotherapy Treatment Machines using a ‘big bang’ approach
Maintenance Options	Co-produced In-house and Vendor (as now)

3.21 The delivery model adopted in the nVCC OBC was agreed with Welsh Government in 2017 and aligned to this approach.

3.22 It should be noted that as a result of significant slippage in the nVCC Project the approach outlined above needed to be adapted to manage service-related risks. These risks and the potential solution will be described later in this section.

Cognitive by Design

- 3.23 VUNHST has been progressing significant developments in Information Management and Technology (IM&T) systems. These have been a combination of national programmes, internationally used systems and bespoke local developments all of which have enabled an improvement in services for professionals, patients, and donors. The Trust has prioritised the development of its IM&T Strategy to support the identified organisational and clinical priorities and to ensure that next generation IM&T is used to transform service delivery. At the heart of the informatics delivery are the four principles from the “Informed Health and Care: A Digital Health and Social Care Strategy for Wales” (2015).] These are:
- Information for you (the patient).
 - Supporting Professionals (digital tools).
 - Improvement and Innovation (better use of information / whole systems approach).
 - A Planned Future (joint planning regional and national).
- 3.24 VUNHST has produced an ambitious strategic informatics programme, “Digital Excellence”, which over the next five years, will implement a range of national technology solutions, while growing our capacity and capability to embrace innovative technologies. This is based on the fundamental premise that high quality healthcare in the 21st century cannot be delivered with out of date or obsolete legacy systems, and/or paper-based information recording and delivery. TCS has developed a strategic vision for Cancer Services entitled “Cognitive by Design” that underpins the digital programme for future investment.
- 3.25 By utilising IM&T as a critical enabler to support service transformation, Velindre University NHS Trust aims to fundamentally redesign administrative, operational and clinical processes to maintain high levels of data quality, and not only ensure information is accurate and up to date, but also embedding state of the art technologies to deliver exceptional services.
- 3.26 The enablement of, and connectivity of staff and patients is critical to the success of the Digital Programme. To this end the Trust is working with colleagues from across NHS Wales to ensure mobile computing requirements, patient engagement systems, as well as digital staff communication tools are at the forefront of the Digital Programme.
- 3.27 To ensure the Trust continues to provide the most effective informatics services, we will continue to explore further opportunities for standardisation of processes, rationalising systems and solutions, alignment of resources, where possible, and share best practice both from across the divisions, and also externally, by incorporating the lessons from other Health Board/Sector experiences.

- 3.28 The future design of a fully integrated radiotherapy solution is a key aspect of new ways of working, modernising and rationalising the number of digital systems so that clinicians will be trained in one system rather than specialising or only being able to use one or other of the existing applications.
- 3.29 This activity will involve significant process flow mapping and data migration of existing services to ensure that future services are fit for purpose. This will be a complex and resource intensive activity but will be fundamental to the future successes of the service.
- 3.30 Over the last two years and following a separate business case proposal the Trust has implemented an interim radiotherapy treatment planning system to ensure a resilient as possible service due to legacy arrangements no longer being available. The treatment planning system will be an important feature of the transition to the IRS service.
- 3.31 To ensure that the Trust's digital vision has been robustly tested the Trust has commissioned an assurance review of its Digital Vision, development plan and delivery capacity. This assurance has been delivered by an industry leader in this field (Channel 3).
- 3.32 The report provides assurance across the range of areas reviewed. Channel 3 have confirmed that:
- The digital vision aligns with the clinical vision providing clarity in objectives which are generally well understood.
 - The programme plan is being built on solid foundations.
 - The skills and capabilities of the existing team are high.
- 3.33 Specifically, in relation to our Radiotherapy Solution PBC the Channel 3 Report confirms that:
- 'The procurement of the new Radiotherapy Treatment Machines is being well managed according to best practice. The use a competitive dialogue process enables value to be driven out of the procurement. The Programme is engaging expert advice to compliment the "in house" expertise available. Engagement with national Advisory Services is efficient and consistent'.

Links to National Strategy

- 3.34 By enabling delivery of the TCS programme, the project aligns with key national strategies including the **Welsh Government Programme for Government 2021-26** which sets out Welsh Government commitments over the next five years to improve the lives of people across Wales. The project specifically aligns with the following well-being objectives:
- **Provide effective, high quality and sustainable healthcare** by creating a 21st century NHS that tackles health inequalities and focuses on prevention. Specifically, by improving access to Radiotherapy services.

- **Build an economy based on the principles of fair work, sustainability and the industries and services of the future** by building an economy based on sustainable jobs. Specifically, by creating skilled jobs and apprenticeships.
- **Build a stronger, greener economy as we make maximum progress towards Decarbonisation** by developing a modern and productive infrastructure which acts as an engine for inclusive and sustainable growth.
- **Embed our response to the climate and nature emergency in everything we do by delivering a green transformation.** Specifically, through greater green energy.

3.35 **Ministerial Priorities for NHS Wales** published on 9 July 2021, set out the Minister for Health and Social Care's eight priorities for NHS Wales to complement and contribute to the Welsh Government Programme for Government. The projects will directly contribute to these as follows:

- **Covid-19 Response:** Ensuring there is adequate capacity to meet future demand.
- **NHS Recovery:** Long term capacity to meet demand.
- **A Healthier Wales:** Improved access and better patient outcomes.
- **NHS finance and managing within resources:** Providing best value for money.
- **Supporting the health and care workforce:** Improvements to workflow releasing staff time.

4 CASE FOR CHANGE

Introduction

4.1 This section of the business case establishes the case for change for the procurement of an Integrated Radiotherapy Solution (IRS) by providing a clear understanding of:

- The spending objectives (what the proposals seek to achieve);
- Existing arrangements (what is currently happening); and
- Business needs (what is required to close the gap between existing arrangements and what is required in the future).

Spending objectives

4.2 As this business case is facilitative of, whilst also being independent of, the overall TCS Programme Business Case, it is important for this investment case to align and support the delivery of the overall TCS Programme’s spending objectives.

4.3 The Investment Objectives for the IRS therefore been aligned with the TCS Programme spending objectives, refined to fit with the procurement of this type of solution, and also to meet the spending objectives of the existing VCC.

4.4 The Investment Objectives for this proposal are set out in the table below and are matched to the TCS Spending Objectives:

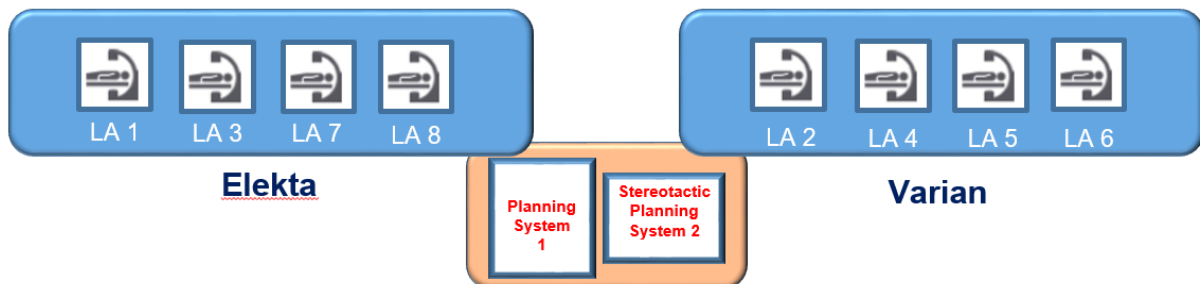
Table 4-1 Spending objectives

Ref	TCS Spending Objective	Ref	IRS Investment Objective
PSO1	To build a new hospital that supports quality and safe services	RIO1	To procure and implement a new Integrated Radiotherapy Solution that supports quality and safe services
PSO2	To provide sufficient capacity to meet future demand for services	RIO2	To provide an Integrated Radiotherapy Solution that has sufficient capacity to meet future demand for services
PSO3	To improve patient, carer and staff experience	RIO3	To deliver an Integrated Radiotherapy Solution that improves patient, carer and staff experience
PSO4	To provide capacity and facilities to support the delivery of high-quality education, research, technology and innovation	RIO4	To provide an Integrated Radiotherapy Solution that promotes capacity and the delivery of high-quality education, research, technology and innovation in Radiotherapy

Existing arrangements

- 4.5 Currently all Radiotherapy Treatment and Treatment Planning services are carried out at the existing Velindre Cancer Centre in Whitchurch, Cardiff.
- 4.6 In 2019/20, the Radiotherapy Department facilitated attendances of patients and delivered 54,899 fractions of Radiotherapy. Activity reduced during 2020/21 and 2021/22 due to the impact of Covid-19 but is expected to increase to 58,464 by 2022/23.
- 4.7 The current radiotherapy service has eight Linear Accelerator machines of varying ages, two of them with advanced (stereotactic) capabilities, two CT Simulators (for RT planning NB: not part of the IRS procurement as recently replaced), a superficial unit and a brachytherapy service. The Linear Accelerators are split equally between two vendors (Elekta and Varian).
- 4.8 The service currently has three treatment planning systems, two for general external beam radiotherapy and one for cranial stereotactic applications. Velindre Cancer Centre does all of its treatment planning in house. Each of the existing vendor's treatment machines operate within their own Oncology Information System environment.
- 4.9 The diagram below sets out the configuration of the Radiotherapy Linear Accelerators and Treatment Planning System at the Velindre Cancer Centre. It illustrates the split of core Linear Accelerators by Vendor and the associated planning systems. The plan is to further harmonise in the new solution to remove variation between vendors.

Figure 4-1 Configuration of the current Radiotherapy Solution



- 4.10 The Radiotherapy Physics service, outside of its treatment planning function, has the specialist expertise to be able to carry out significant elements of system maintenance and support but utilises vendor support in specific instances. There are support contracts in place with the main vendors, however these do vary considerably in terms of parts and labour inclusivity, and do not guarantee performance. There are no contractual obligations placed on either vendor currently with regard to guaranteed uptime and performance of their equipment.

4.11 The existing age profile of Velindre’s treatment machines as of 2021 is set out in the table below.

Table 4-2 Age Profile

Linac Identifier	Type	Age in 2021
LA1	Elekta Synergy	13
LA2	Varian TrueBeam Stx (Stereotactic)	5
LA3	Elekta Synergy	14
LA4	Varian TrueBeam STx (Stereotactic)	7
LA5	Varian Trilogy	9
LA6	Varian Clinac	16
LA7	Elekta Synergy	11
LA8	Elekta Synergy	10

Business needs

4.12 There is an increasingly urgent need to procure the proposed IRS in order to reduce the likelihood of equipment failure, obsolescence and ensure the most up to date treatments are available to our patients. This is critical to providing a safe, efficient and effective Radiotherapy service under existing arrangements and enabling delivery of the TCS programme.

4.13 Predictions with regards to decreasing reliability of aging treatment devices have proven correct. The Trust’s oldest treatment machine LA6 has been prone to significant down time and is also subject to a recently issued end of life notice from the manufacturer.

4.14 The main drivers for change are:

1. The age profile of treatment machines at the existing Velindre Cancer Centre and the increasing risk to service delivery.
2. The complications that arise as result of current dual vendor arrangements.
3. Increasing incidences of cancer and associated increases in demand both now and in the future including the potential for COVID-19 surge due to delays in access to diagnosis.
4. The essential project interrelationships between this procurement and the TCS programme.

Business need 1: Age of Treatment Machines at Existing Velindre Cancer Centre

- 4.15 There is an independent need for VUNHST to re-procure treatment machines and associated Radiotherapy Equipment to ensure that it can continue to deliver safe and effective Radiotherapy Treatments to the population of Southeast Wales. Investment is needed irrespective of whether the RSC and nVCC projects are delayed or not approved to go ahead. This is why Phase 1 implementation of the IRS will concentrate on the replacement of two standard treatment machines in the existing VCC.
- 4.16 Radiotherapy treatment machines have a manufacturer recommended life of 10 years. Beyond this date, they can become more unreliable and maintenance costs can increase, as we have experienced. In line with the recommended 10-year life these assets are depreciated over the same period for financial accounting purposes (straight line depreciation).
- 4.17 The table below sets out the age profile and illustrates whether individual treatment machines are under or over their 10-year life in 2021.

Table 4-3 Age Profile with Years over Recommended Asset Life

Linac Identifier	Type	Age in 2021	Years over Recommended asset Life
LA1	Elekta Synergy	13	+3
LA2	Varian TrueBeam STx (Stereotactic)	5	
LA3	Elekta Synergy	14	+4
LA4	Varian TrueBeam STx (Stereotactic)	7	
LA5	Varian Trilogy	9	
LA6	Varian Clinac	16	+6
LA7	Elekta Synergy	11	+1
LA8	Elekta Synergy	10	

- 4.18 VUNHST has committed as part of its TCS Equipment Strategy to minimise wherever possible the replacement of major medical equipment ahead of the nVCC being delivered, but this has created corresponding risks.
- 4.19 The rationale for this decision was as follows:
- It was believed that some major medical equipment assets could safely be “stretched” thus delivering increased value for money (although due to the delays in the nVCC and RSC projects this is untenable).
 - Replacing new major medical equipment in the nVCC had certain benefits as it removed the need to relocate treatment machines from the VCC which would create treatment capacity issues.

4.20 The increasing age profile of the existing treatment machines and associated equipment (such as Radiotherapy Informatics Solution, and workflow systems) at the existing VCC has become an urgent business driver.

Transition Plan

4.21 The table below sets out a replacement programme of the Trust’s treatment machines as originally planned and integrated with the TCS Programme, it has been updated to reflect the new Project timelines for the RSC and nVCC Projects.

4.22 At the time of issuing final tender:

- The RSC was planned to open (first patient treated) in April 2024 with two standard treatment machines.
- nVCC was planned to open (first patient treated) in April 2025.
- Any increase in the number of Treatment Machines beyond the existing 8 machines will increase staffing and operating costs. These costs will be part of the RSC FBC and managed through normal commissioning discussions with the Trust’s commissioners as part of its Long-Term Agreement (LTA).
- The approach outlined above is consistent with the Radiotherapy Satellite Business case.

Table 4-4 Treatment Machine Ages – Based on RSC 2024 Opening

			Planning Scenario - No Early Replacement of Linacs - wait for RSC 2023 and nVCC 2024 as previously planned																											
Location			2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020		2021		2022	2023		2024		2025	2026		
			Transition YR																Transition YR		Transition YR		Transition YR		Transition YR					
LA10	Std	RSC																						0	1	1	2	3		
LA9	Std	RSC																						0	1	1	2	3		
LA8	Std	VCC							0	1	2	3	4	5	6	7	8	9	9	10	10	11	12	12	13	13	14	0	1	2
LA7	Std	VCC						0	1	2	3	4	5	6	7	8	9	10	10	11	11	12	13	13	14	14	0	1	2	
LA6	Std	VCC	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	15	16	16	17	18	18	19	19	0	1	2	
LA5	Std	VCC							0	1	2	3	4	5	6	7	8	8	9	9	10	10	11	11	12	12	0	1	2	
LA4	Stereo	VCC										0	1	2	3	4	5	6	6	7	7	8	8	9	9	10	10	0	1	2
LA3	Std	VCC			0	1	2	3	4	5	6	7	8	9	10	11	12	13	13	14	14	15	16	16	17	17	0	1	2	
LA2	Stereo	VCC										0	1	2	3	4	4	5	5	6	6	7	7	8	8	9	9	0	1	2
LA1	Std	VCC				0	1	2	3	4	5	6	7	8	9	10	11	12	12	13	13	14	15	15	16	16	0	1	2	
Total											6	7	7	8	8	8	8	8	8	8	8	8	8	8	8	8	8	10	10	10
Avg Age											4.17	4.43	5.43	5.63	6.63	7.625	8.625	9.625	9.625	10.625	10.625	11.625	12.625	12.625	13.625	13.625	14.625	14.625	15.625	
Peak Age											8	9	10	11	12	13	14	15	15	16	16	17	18	18	19	19	20	20	21	

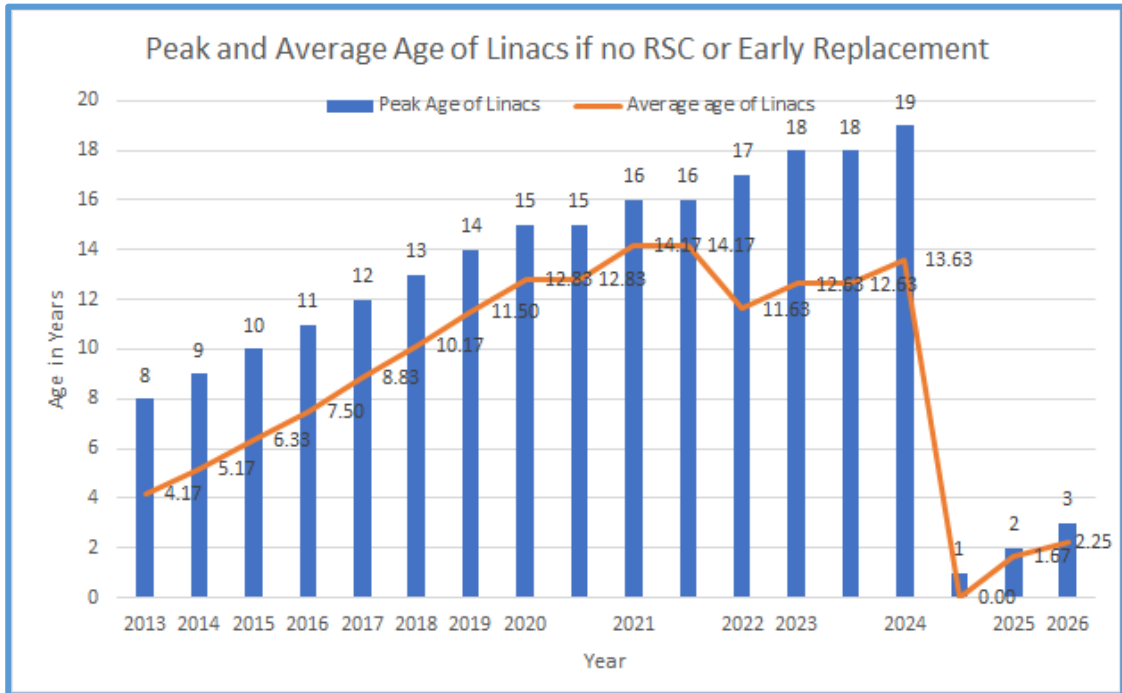
4.23 The table above was based on the Radiotherapy Satellite Centre opening in 2024 and the nVCC in 2025. It shows one treatment machine reaching a peak age of 18 years in 2023 and four of the Trust’s treatment machines being considerably over they recommended life in 2023. Should the RSC not go ahead as planned, and no early procurement of treatment machines approved the situation at Velindre Cancer would worsen.

4.24 The increasing age of the services treatment machines are major drivers described in this business case. A range of options will be developed that will mitigate these scenarios.

- 4.25 In readiness for IRS contract award the service needs to agree the sequencing and prioritisation of machine replacement at VCC considering a number of factors such as machine life expectancy, patient treatment demand and service resilience needs. The service has discussed and considered a number of factors in order to make a recommendation on this.
- 4.26 This sequencing ensures that there are minimal implementation delays following contract award to the successful bidder. This also enables the service to commence service continuity planning readiness in advance and for the estates team to also commence any construction planning readiness for this phase. The prime factors that were considered being machine age, service resilience, obsolescence and any potential IRS bidder outcome which may be seen as influencing any decision in order that this may not be considered as any procurement bias in the future.
- 4.27 Linear accelerators have a recommended service life of 10 years from manufacturers, although many of the machines at VCC are beyond this age.
- 4.28 An end-of-life notice for 2023 has been received on **LA6** which makes this the **first** machine for consideration and also that some limitations of the design on this machine make it obsolete for some more modern treatment techniques.
- 4.29 Due to the current mixed manufacturer design of radiotherapy service at VCC, machines are matched for service with secondary machines in order to ensure treatments can be maintained should there be issues with any particular machine. **LA5** is recommended as the **second** machine to be replaced because this machine is the resilient machine for LA6 and which makes service continuity planning for treatments the next most urgent need to ensure service can be maintained.
- 4.30 Neither of the above recommendations would be altered by the outcome of the IRS award.

4.31 The graph below sets out the peak and average ages of treatment machines

Figure 4-2 Peak and Average Ages of Treatment Machines



Treatment Machine reliability – likely consequences

4.32 It is highly likely that treatment machine reliability will decrease with age and as a result this reduces treatment machine availability (as the burden of repairs increases). Allied to this, there are increasing costs associated with unreliability.

4.33 An illustration of this is that Velindre has previously operated one treatment machine to 14 years of age before a major component failure meant the treatment machine was classed beyond economical repair and required full replacement. With three of the eight treatment machines at Velindre reaching or exceeding this age by 2021 the service wide risks are high. If nothing is done to address this, significant service disruption could easily manifest with long lead times required to procure and commission any replacement treatment machines.

4.34 The increasing age profile of the existing treatment machines and associated equipment (such as Radiotherapy Informatics Solution, and workflow systems) at the existing VCC is becoming more of a critical driver through the passage of time.

Business need 2: Complications of Dual Vendor Arrangements

4.35 As set out in the Strategic Context (Section 3), a review was conducted by the Radiotherapy Development Group in 2015 which was subsequently approved by the Trust Board in 2016. This report highlighted the inefficiencies associated with running a dual vendor site. The impact of dual vendor remains a current issue at the VCC as it creates the following issues:

- Sub optimal efficiency and patient flow.
- Lack of capacity and the ability to work flexibly.
- Increased workforce requirements and the burden of training (planning and treating patients; and maintaining, running and operating the machines).
- Requires complex support services including the R&V and IT software.
- Additional resources are required to undertake a competitive tender process for every new machine.
- Additional resources are needed to manage two commercial contracts and service providers.
- Places limitations on Research and Development capacity.

4.36 These issues are explored in further detail in the paragraphs below.

4.37 **Service resilience:** As a result of compartmentalisation into a dual-vendor environment, service resilience in the event of machine breakdown has been significantly impaired as it is not possible to transfer patients from one machine type to another without an extended re-planning process. This has a prohibitive time and resource overhead for the service and significant disruption or interruption of ongoing treatment courses for patients. Services with a larger number of matched machines are significantly more resilient than those without. Recent assessments undertaken at VCC indicate that a fully matched machine environment with appropriate service resilience capacity would provide uptime improvements in the region of 5%.

4.38 **Service development limitations:** It would be beneficial for the service to develop and implement a single paperless process for the radiotherapy patient pathway, with all information held electronically in a single Oncology Information System. This is not currently feasible while we are running dual systems which have quite distinct operational modes.

- 4.39 **Workforce impacts:** Additional workload results from the commissioning and implementation requirements associated with a dual vendor arrangement. For example, volumetric modulated arc therapy solutions are distinctly different on the Elekta and Varian platforms and these require separate commissioning and clinical implementation plans and resource allocation. The same situation applies for introduction and development of Image Guided Radiotherapy, Respiratory Motion Management and any other new technology requirements. Also, our Treatment Planning Systems require full commissioning datasets for each type of vendor's machines. Several years of work have already been committed in this regard.
- 4.40 These overheads inevitably lead to delays in clinical implementation of new techniques 'across the board' in our centre, not least because the alternative systems require comparative evaluation even before one or other (or the pair) of the options is pursued. This was verified in the Demand and Capacity Review that the Trust commissioned Attain in 2020.
- 4.41 **Radiotherapy Information System support requirements:** Computing staff within the Radiotherapy Physics Department at VCC are required to support both systems. There is effectively a doubling of work in supporting and implementing system upgrades and when these are required. There is also a potential knock-on effect if, and when, Digital Healthcare Wales (DHCW) needed to develop new interfaces to CANISC which is also going end of life and requires replacement.
- 4.42 The complexities of our dual vendor environment have been highlighted with current work to develop links with the national RT Dataset, with interfaces needing to be developed, tested, implemented and supported from both vendors' RT information systems (Aria and Mosaic).
- 4.43 **Training requirements:** All staff involved in delivering the radiotherapy service require full training on each vendor's equipment and associated operating and information systems. There is currently elevated risk of operational confusion and misunderstanding due to the differing ways in which the two systems work. Staff involved include Therapy Radiographers, Clinical Oncologists and Clinical Scientists, Technologists and Mechanical and Computing Engineers in Medical Physics.
- 4.44 **Procurement and commercial:** There are extra costs associated with having two providers and needing to carry out separate tenders to replace treatment machines. In addition, there are costs associated with managing two separate maintenance contracts.
- 4.45 **Estimated cost of the procurement process:** A conventional procurement scenario would be as follows:
- Assume a six-month period for development of business case and equipment selection.
 - This would typically involve 8 senior staff (average mid band 8b = £70K) from the service (4 from Medical Physics, 2 from Radiotherapy, 1 project manager, 1 procurement officer).

- Depending on age of machine and central capital funding availability, machines may be purchased individually or in pairs to maximise resilience.
- For a 10-machine configuration, this may involve procurement of 3 pairs of machines and 4 individual machines, therefore 7 procurement exercises over a 10-year period.

4.46 Due to the rapid evolution of radiotherapy technology older machines are unable to deliver the full range of treatments offered by VCC and other leading centres. Therefore, continuing to operate outdated equipment will have a detrimental effect on patient care.

4.47 As an example, LA6, which has now received an End-of-Life notice, cannot be used for online CT imaging or arc therapies. This reduces availability, capacity and further narrows business continuity options for the service and its patients.

Business need 3: Increasing Cancer Incidences and Radiotherapy Demand

VUNHST has been developing its Business Intelligence (BI) functions to ensure that it can better plan its future services. This includes the ability for the Trust to have advanced notice of Health Board activity by tumour site.

4.48 VUNHST has used a number of recognised methods to inform its RT Planning assumptions:

- Reported Cancer incidences in Wales and UK (retrospective).
- VUNHST own activity data and trends.
- Benchmarking of our findings / Planning Assumptions.

Reported Cancer Incidences

4.49 It should be noted that Cancer Incidence data is reported retrospectively and is often up to three years old at the time of publication. It still however provides a useful tool in identifying trends and is particularly powerful when correlated against actual activity data.

4.50 In 2015, VUNHST contacted the Welsh Cancer Incidence Surveillance Unit (WCISU, Part of Public Health Wales) asking for a comprehensive report to be commissioned that would assist in forecasting the likely demands that would be placed on VUNHST.

4.51 Following on from the detailed analysis of the incidences of cancer carried out by WCISU, combined with the UK population comparisons and expert knowledge both internally and externally to Velindre, a Radiotherapy Growth Planning assumption of 4% was derived. This was made up of 2% growth, 1% Increase in access and 1% attributed to increasing treatment complexity.

- 4.52 VUNHST has, since this point, been monitoring its actual activity verses it's planning assumptions and in 2017 took the decision to revise its planning assumptions from 4% to 2% where it remains today.
- 4.53 Benchmarking VUHNST's planning assumptions with other non-surgical cancer centres validated our approach, this was further strengthened by Cancer Research UK's research findings on predicted future increases in the incidences of cancer as described in their publication "Cancer in the UK 2018". In addition to this, Attain's 2020 Radiotherapy Demand and Capacity Review incorporates more up to date benchmarking data.
- 4.54 The impact of Covid resulted in a reduction of external referrals of 13%. The planning assumptions made for referral activity in 2021/22 was 13% COVID recovery, 10% Growth. In the first two quarters of 2021/22 this recovery and Growth has been achieved. There is suppressed demand in UHB's that may stimulate a further surge in Q3 & Q4 which is monitored monthly particularly in Breast & Colorectal tumour sites

Revised WCISU Incidence Data to 2015 (from data up to 2013)

- 4.55 VUNHST, as part of its research, reviewed new incidence data from WCISU and other registries in UK and Ireland to establish the most up to date incidence information. When reporting incidence data in European Age Standardised Rates (EASR) per 100,000 there is a downturn / or flattening in the incidences of cancer diagnosis across the UK and Ireland. Of note is that the EASR standardises data to facilitate comparison of unlike populations. The Welsh population is increasing, and so is the proportion of the population in advanced age groups. In standardising Welsh cancer incidence data, the impact of an increasing elderly population is partially negated. When crude cancer incidence rates are considered, a sustained growth in disease incidence over time is apparent as shown in the chart overleaf. This ranges from 589.9 (per 100,000) in 2007 – 2011 to 626.5 in 2013 – 2017.

Figure 4-3 Cancer Incidence per 100,000 (Wales)

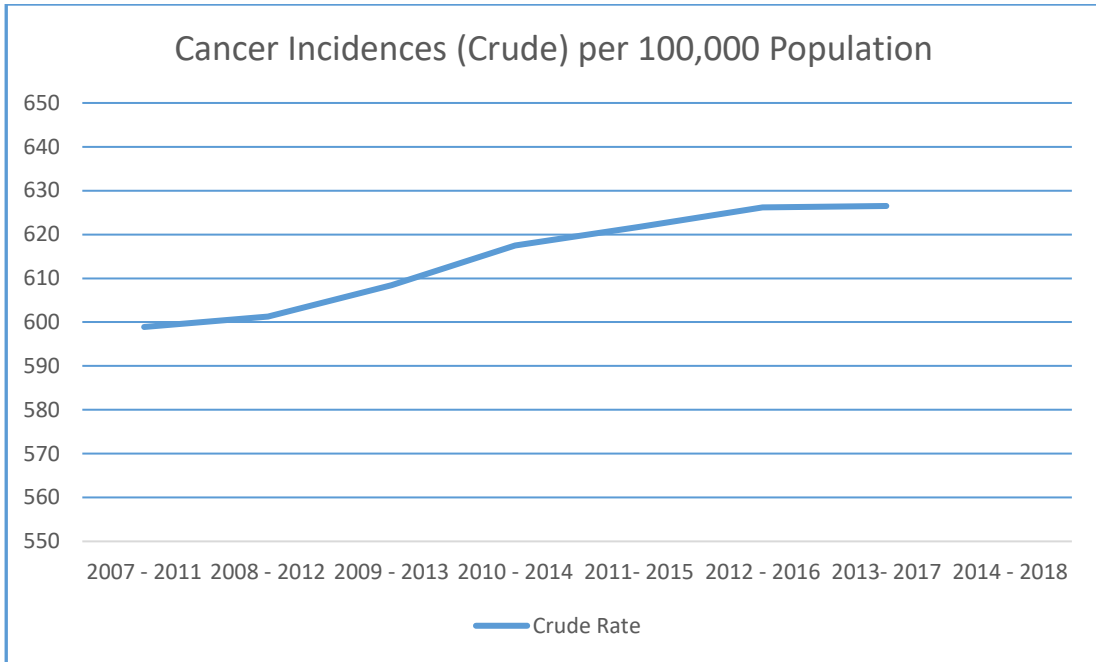


Table 5 - Cancer Incidence per 100,000 2007 = 2017

	2007 - 2011	2008 - 2012	2009 - 2013	2010 - 2014	2011 - 2015	2012 - 2016	2013 - 2017	2014 - 2018
Crude Rate	598.9	601.3	608.4	617.5	621.7	626.2	626.5	
EASR	643.1	639	640	642.4	639.5	637.1	630.6	

4.56 WCISU also concluded the following from its updated research:

- The number of new cases of cancer in residents of Wales continues to rise in men and women – there were 19,026 new cases in 2013, up by over 12 per cent compared to 2004.
- The largest increases in numbers in men and women were in the 65-69- and 70-74-year-old age groups.
- Cancer becomes more common with increasing age, except for the 90+ age group in women – the age specific cancer rate rises more steeply in men than women with increasing age, and for ages 70 years and over, rates in men are over 50 per cent higher than women.
- Age-specific all cancer incidence rates in older age groups reduced dramatically in men from 2004 to 2013 whereas in women there was little change.
- The predicted suppressed demand of 35K referrals (DU) across Wales impacted on UHB's in March and April 2021 with increases in most primary sites. VCC experienced a reduction of 13% referrals in 2020/21 compared against 2019/20. This recovery was factored into 2021/22.

Velindre Radiotherapy Activity (Fractions)

- 4.57 Radiotherapy Velindre Cancer Centre has seen the fractions it delivers increase from 53,948 in 2016/7 to 54,899 in 2019/20 as set out in the table 4-7 below. In addition to this activity increase, the service also experienced an increase in the complexity associated with Radiotherapy planning and treatment delivery.
- 4.58 Using actual activity data from 2016/17 – 2021/22 it has been possible to further uplift the fractions delivered by 2% per annum to illustrate the likely demands the service will need to meet in the future. This allows the Trust to more accurately articulate its Radiotherapy service requirements.
- 4.59 The activity data 2016 – 2021/22 (actuals) and what was forecast demand 2021 – 2032 at the time of developing the FBC is set out in table 4-7 below.

Table 4-6 Activity Data 2016-2032

	2016/17 Actual	2017/18 Actual	2018/19 Actual	2019/20 Actual	2020/21 Actual	2021/22 Actual	2022/23 Forecast	2023/24 Forecast
VCC	53948	51229	54997	54899	36861	40507	58464	47915
Outreach								11719
Total	53948	51229	54997	54899	36861	40507	58464	59634
	2024/25 Forecast	2025/26 Forecast	2026/27 Forecast	2027/28 Forecast	2028/29 Forecast	2029/30 Forecast	2030/31 Forecast	2031/32 Forecast
VCC	48873	49851	50848	51865	52902	53960	55039	56140
Outreach	11953	12192	12436	12685	12938	13197	13461	13730
Total	60826	62043	63284	64550	65840	67157	68500	69870

- 4.60 The decline in activity in 2020/21 and 2021/22 (highlighted in red) relate to the impact of Covid-19. Activity has increased between 2021 and 2022 as the pandemic recedes, but it should be noted that risk based working practices are still artificially suppressing demand.

Velindre Radiotherapy Attendances

- 4.61 The table 4-8 overleaf sets out the number of annual Radiotherapy attendances at Velindre since 2012/13. The service experienced a dip in attendances in 2016 – 2018 which was common across other UK Radiotherapy services but has since reversed.

Table 4-7 Number of Annual Radiotherapy Attendances

	2012/13 Actual	2013/14 Actual	2014/15 Actual	2015/16 Actual	2016/17 Actual	2017/18 Actual	2018/19 Actual	2019/20 Actual	2020/21 Actual	2021/22 Actual
2012/13 attendance with 2% growth	48072	49033	50014	51014	52035	53075	54137	55220	56324	57450
Attendance actual	48072	51951	54981	54591	51467	50564	55522	54899	36861	40618
Attendance actual growth		8	6	-1	-6	-2	10	-1	-33	10

*attendance actual growth figure is a percentage rise or fall

- 4.62 Since 2012/13 there has been an overall increase in attendances from 48,072 to 54,899 in 2019/20, this is an average increase of 975 attendances per year. In 2021 Radiotherapy attendances dropped off dramatically as the impacts of COVID-19 were felt across the health system. In 2021/22 there was a 10% return in attendances even with operational restrictions still suppressing demand.
- 4.63 There are significant fluctuations between the years. It is therefore important as recognised by the National Radiotherapy Advisory Group (NRAG) guidance that when planning radiotherapy services there is a degree of capacity retained to manage fluctuations in demand without impacting on patient experience and waiting list performance.
- 4.64 As described earlier in this section there has been a steady increase in fractions delivered and patient attendances at the Velindre Cancer Centre. It has also been stated that the complexity and time to deliver new techniques are increasing notably.

Benchmarking our Planning Assumptions for Radiotherapy Activity

- 4.65 As alluded to previously and in order to validate Velindre's 2015 planning assumptions for Radiotherapy, a benchmarking exercise was undertaken with similar Cancer Centres across the UK. These centres were identified as good comparators in terms of size, service model and population served. This was confirmed by Attain's 2020 Radiotherapy Demand and Capacity Review.
- 4.66 The comparable tertiary cancer centres involved were:
- The Beatson West of Scotland Cancer Centre.
 - The Clatterbridge Cancer Centre NHS Foundation Trust.
 - The Christie Cancer NHS Foundation Trust.
 - Leeds Teaching Hospital NHS Trust.
 - The Royal Marsden NHS Foundation Trust.

4.67 The anonymised information obtained during the benchmarking exercise is set out in the table below referenced as Peer Sites:

Table 4-8 Benchmarking Exercise

Service	Annual growth assumption/years		Other cancer centres annual growth predictions
	2016/17 - 2022/23	2023/24- 2031/32	
Radiotherapy (Initial Assumption)	4%	2%	Peer Site A – 3.8% Peer Site B 1.5% Peer Site C – 3% Peer Site D – N/A Peer Site E – 4.0%
Radiotherapy (Revised)	2%	2%	

4.68 The benchmarking exercise demonstrated that the Trust’s clinical growth assumptions in 2015 were in line with those from other cancer centres across the UK, where this data was available.

4.69 As previously described in 2017 a review of the 2015 growth assumptions was carried out. This review examined whether predicted growth forecasts had manifested into service activity. The Trust modelled a range of scenarios utilising the integrated activity workforce and finance model and as a result the growth assumption was adjusted from 4% (as shown above) to 2% in line with actual activity from 2014/15 to 2015/16.

Future Planning Requirements

4.70 VUNHST has taken a flexible approach to how it plans its infrastructure projects within the TCS Programme as it is aware that predicting Radiotherapy demand is influenced by many factors, some of which are beyond the control of Velindre as a tertiary provider. Factors such as referral preferences from Multi-Disciplinary Teams, changing clinical indications for radiotherapy, the staging of cancer referrals and the adoption of clinical trials could all have a bearing on Velindre’s Radiotherapy activity. Both the nVCC and RSC Projects have been developed to allow flexibility and adaptability in response to changing activity demands.

4.71 The Velindre Cancer Centre has developed tried and tested methods to calculate its future Radiotherapy requirements. The nVCC and RSC business cases outline how this is achieved by turning research, benchmarking and activity data into future planning requirements using industry standard approaches.

4.72 As a result of this methodology, the following planning assumptions were used within the nVCC and RSC business cases:

1. 2% Growth in Radiotherapy Activity year on year
2. Years 2018 – 2023 current service performance given constraints (no service efficiency machine) was applied
3. Year 2024 onwards calculated on greater efficiency due to availability of service efficiency machine at the nVCC.

4.73 Further to this, the impact of Covid on demand was considered, including the following factors:

- COVID in 2020/21 reduced referral by 13%. Cancer Recovery Programme for VCC was implemented using various parameters.
- Radiotherapy in 2019/20 received 4343 referrals, during COVID 2020/21 this reduced to 3772. As of 30 September 2021, 1997, referrals were received with a forecast outturn of 4387.
- Breast, Colorectal, Lung and Urology have shown 32% growth when compared to 2019/20.

4.74 This was used to identify the number of Treatment Machines required and the resulting planned configuration is set out in the table below.

Table 4-9 Planned Configuration

Location	Number	Type	Notes
VCC / nVCC	6	Standard Machines	Core requirement
VCC / nVCC	2	Advanced Machines	Core requirement
RSC	2	Standard Machines	Contractual option

4.75 This is the same configuration as the existing VCC which has two stereotactic machines and six standard treatment machines but **may vary on the individual bidder’s actual solution.**

Business need 4: Project Interrelationships

4.76 The procurement of an IRS is independently needed as part of the VCC Radiotherapy service business as usual activities. It has been ‘decoupled’ from the RSC and nVCC infrastructure project approvals as the VCC service is required to deliver the Trust’s Radiotherapy Equipment Strategy and refresh its radiotherapy digital equipment as it reaches the end of its recommended life or becomes obsolete.

4.77 In the event of the nVCC and/or the RSC Projects being approved, the procurement of an IRS becomes a major enabler to the smooth implementation, transition and continuity of service for patients.

4.78 The IRS procurement as set out in the table below, enables the nVCC and RSC Projects in the following ways:

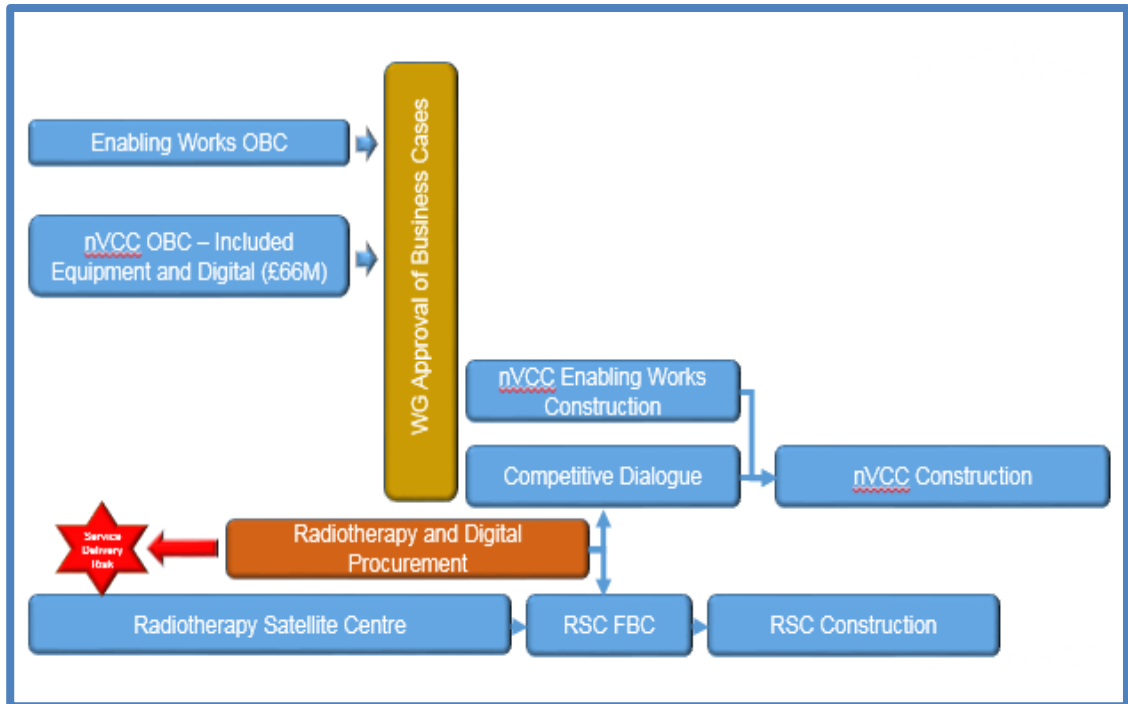
Table 4-10 IRS Procurement

Project	Enabler / Requirement
Project 2. nVCC	<p>There is a contractual requirement for VUNHST to inform the bidders during competitive dialogue the specifications of equipment that will be installed in the nVCC. Different bidders have different bunker and interface requirements.</p> <p>Failure to start the IRS procurement in a timely manner may mean that this contractual requirement cannot be met as the bidders will not be known until the IRS Procurement has been concluded.</p>
Project	Enabler / Requirement
Project 3. RSC	<p>Similarly, to the nVCC there is a requirement for the specification of the IRS to inform the design of the Radiotherapy Satellite Centre.</p>

Key Programme Dependencies

4.79 The diagram overleaf illustrates the complex interdependencies that currently exist and have been set out in the preceding narrative. It shows that the IRS procurement is important to assure delivery of the Radiotherapy Service at the nVCC and at the RSC. The timing and proposed procurement approach has been set down in detail in the Radiotherapy Commissioning paper that supports the nVCC OBC.

Figure 4-4 Complex Interdependencies



Summary of Business Needs

- 4.80 The case for change clearly demonstrates there is an urgent need to procure the IRS to ensure that VUNHST can continue to provide a safe, efficient and effective Radiotherapy service both currently and as part of the TCS programme.
- 4.81 This is summarised in the table overleaf which shows how the existing arrangements and business needs align with the project investment objectives (and by associated the programme spending objectives) and demonstrate that doing nothing is not a feasible option.

Table 4-11 Summary of the case for change

RIO1 To procure and implement a new Radiotherapy Solution that supports quality and safe services	
Existing arrangements	Business needs
<p>Ageing equipment:</p> <ul style="list-style-type: none"> • 8 treatment machines - 5 of which have exceeded the 10-year life expectancy and 1 issued with End of Life Notice. • 3 treatment planning systems - 1 of which is reaching end of life • Each treatment machine vendor operates in its own Oncology Information System 	<ul style="list-style-type: none"> • Reliability reduces with age of machinery increasing the likelihood of equipment failure and obsolescence. • Increasing burden of repairs result in growing costs. • Increased risk to service delivery and ability to provide most up to date treatments. • Need for interim arrangements to support a functional Radiotherapy Informatics Solutions during any transition period.
RIO2 To provide a Radiotherapy Solution that has sufficient capacity to meet future demand for services	
Existing arrangements	Business needs
<ul style="list-style-type: none"> • Increasing incidences of cancer, more access to services and increasing complexity of treatments results in planning assumptions of 2% growth in demand p.a. • All services currently delivered from the existing Velindre Cancer Centre with <ul style="list-style-type: none"> ○ Ageing equipment ○ Dual vendor arrangements (8 linacs split equally between 2 vendors) • From July 2021 a surge impact of 23% was planned, with the Trust running at 31% in September 2021 as more surgery patients are received from Health Boards. 	<ul style="list-style-type: none"> • The unreliability of ageing equipment and inefficiencies resulting from a dual vendor approach combine to reduce availability and capacity, creating risks around business continuity and VUNHST's ability to meet demand. • Given the forecast growth in demand of 2%, these risks will continue to increase over time. • The TCS programme seeks to address these risks with the development of the nVCC and RSC projects. The procurement of an IRS is critical to successful delivery of these.
RIO3 To deliver a Radiotherapy Solution that improves patient, carer and staff experience	
Existing arrangements	Business needs
<ul style="list-style-type: none"> • Ageing equipment • Dual vendor arrangements (8 treatment machines split equally between 2 vendors) 	<ul style="list-style-type: none"> • The dual vendor arrangements result in the need to operate differing systems resulting in suboptimal patient flow, increased workforce and training requirements. • This reduces capacity and flexibility. • Outdated equipment and inefficiencies are detrimental to patient care and experience.
RIO4 To provide a Radiotherapy Solution that promotes capacity and the delivery of high-quality education, research, technology and innovation in Radiotherapy	
Existing arrangements	Business needs
<ul style="list-style-type: none"> • All services currently delivered from the existing Velindre Cancer Centre with <ul style="list-style-type: none"> ○ Ageing equipment ○ Dual vendor arrangements (8 treatment machines split equally between 2 vendors) 	<ul style="list-style-type: none"> • The dual vendor arrangements limit R&D capacity.

	<ul style="list-style-type: none">• In addition to Business-as-Usual needs, in the event of the nVCC and RSC projects being approved, the existing ageing equipment and dual vendor arrangements will not enable successful implementation and realisation of TCS programme benefits.
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5 POTENTIAL SCOPE

Introduction

- 5.1 This section of the business case identifies the potential scope of the Project in terms of the key service requirements that should be considered in designing the future solution and developing options.

Key requirements

- 5.2 Given the business needs, such as the major interfaces, service requirement and inherent risks identified, there is a need for the IRS procurement to deliver the following:

- The identification of a Prime Contractor which, depending on approvals of the associated OBCs, will support the development of the RSC Project and nVCC Competitive Dialogue process.
- The ability of the Trust to have in place a compliant contract to deliver treatment machines to support service delivery activities.
- Requirement to replace critical radiotherapy related clinical informatics systems to support service delivery and improvement.
- Requirement to replace hospital wide, critical clinical informatics systems which are dependent on the new radiotherapy design to support service delivery and improvement i.e., integration with the CANISC replacement.
- The ability to mitigate any procurement challenge or risks to delivery earlier as not to present a critical path delay to the overall programme, hence de-risking, nVCC and RSC.
- The ability to incrementally develop a solution that will be fully functional at the VCC and the RSC ahead of the nVCC commissioning, will reduce integration and service-related risks.
- The ability to mitigate any procurement challenge or risks to delivery earlier as not to present a critical path delay to the overall programme, nVCC and RSC.
- Remedial works for machines that are not replaced in Phase 1 but which need to remain functional until Phase 3.

Procurement scope

- 5.3 The potential scope of the IRS procurement is proposed to include:
- Radiotherapy Treatment Machines / Equipment.
 - Radiotherapy Informatics Solution (including Oncology Information System (OIS) & Treatment Planning System (TPS)).
 - Dosimetry & Quality Assurance Systems.
 - Clinical & Patient Safety Systems.
 - Ancillary equipment, IT and infrastructure.
 - Project Management, Ongoing Support and Development Services.

- Research & Development (including the option of a research machine in a bunker at the nVCC).

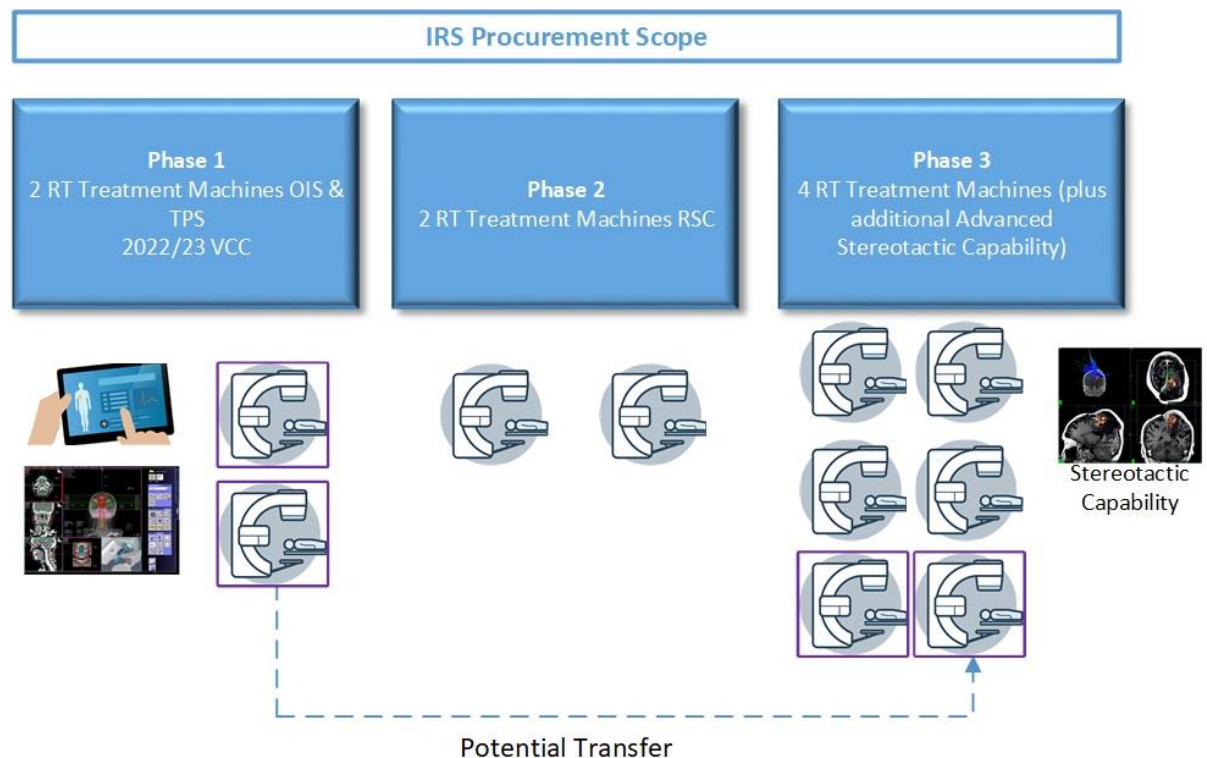
5.4 In addition, there are service requirements (non-hardware) to include:

- Integration with other systems to be advised.
- Professional services for delivery and data migration of existing services.
- Assistance with transition planning will be required.
- Ongoing support and development services.

5.5 The proposed procurement will be implemented in three phases which are described below:

- **Phase 1** – Replacement of the Interim TPS solution and delivery of a new Radiotherapy Informatics Solution and two treatment machines for the VCC to mitigate age related risks. Remedial works for machines which are not replaced but which need to remain functional until Phase 3.
- **Phase 2** – 2 x Standard treatment machines required at the RSC. In the event the RSC business case is not approved this phase will not go ahead.
- **Phase 3** – 6 x treatment machines required. If the nVCC business case is approved, this will involve two (potential) transfers from VCC from Phase 3. In the event the nVCC business case is not approved the treatment machines will be installed at VCC.

Figure 5-1 Proposed procurement phasing



- 5.6 There is a need for the procured IRS to deliver a fully integrated solution, incorporating hardware and an IT system which is a future proofed.
- 5.7 To achieve this, a dedicated Digital and Equipment Project Board accountable to the TCS Programme Delivery Board has been established and this group has established a dedicated IRS Project Team. This IRS Project Team will manage the procurement to progress this integrated solution.
- 5.8 When the nVCC is commissioned, there will be two relatively new treatment machines in the old VCC if this business case is approved. Currently the costed assumption is that these treatment machines will be relocated.
- 5.9 The ages of these treatment machines will range from 3-4 years depending on the date the nVCC is commissioned. A cut off point in terms of cost and risk (component hardening / frailty) of relocating a treatment machine is normally 5 years.

6 BENEFITS AND RISKS

Introduction

- 6.1 This section of the business case identifies the benefits, risks, constraints and dependencies in are considered when developing and assessing the options for an Integrated Radiotherapy Solution (IRS).

Benefits

- 6.2 By addressing the business needs and achieving the spending objectives the project will deliver a range of benefits that align with the NHS Infrastructure Investment Criteria listed below.

Health gain: improving patient outcomes and meeting forecast changes in demand

Affordability: reduction in costs over the long term

Clinical and skills sustainability: reducing service and workforce vulnerabilities and demonstrating solutions that are flexible and robust to a range of future scenarios

Equity: where people of highest health needs are targeted first; and

Value for money: optimising public value by making the most economic, efficient and effective use of resources.

- 6.3 The table presents the benefits that the project is expected to deliver, categorised by type: cash releasing, non-cash releasing, quantifiable and qualitative. Work is underway to develop these further and a final version of this table will be provided in the final submission of the combined OBC/FBC.

Table 6-1 Main benefits

ID	Benefit	Description	Beneficiary	Benefit Type	Metric
B01	Reduced risk of service failure	Reduced risk of catastrophic failure due to more up to date machines	VUNHST	Unmonetisable - Qualitative	Not measurable
B02	Reduced risk of obsolescence	Improved functionality due to more up to date machines	VUNHST	Unmonetisable - Qualitative	Not measurable
B03	Increased flexibility	Better continuity due to the flexibility provided by matched machines	VUNHST	Unmonetisable - Quantifiable	See Bidder's Framework
B04	Better patient outcomes and safety	Better patient outcomes due to the improved functionality and better compliance with good practice	VUNHST	Unmonetisable - Qualitative	See Societal Benefits B16
B05	Benefits of increased automation and use of	(a) Reduced clinical time required for patient scheduling (b) Reduced	VUNHST	Quantifiable	See Bidder's Framework

	integrated systems	appointment times + Other benefits associated with automation and integration			
B06	Environmental benefits	Reduction in energy usage resulting in reduction in carbon emissions	VUNHST	Unmonetisable - Quantifiable	See Bidder's Framework
B07	Community benefits	Job creation	VUNHST	Unmonetisable - Qualitative	See Societal Benefits B17
B08	Improved patient and carer experience	Improved resilience will reduce risk of cancelled appointment resulting in a better experience for patients and carers	VUNHST	Quantifiable	See Bidder's Framework
B09	Improved staff experience	Improved wellbeing of workforce due to more up to date machines	VUNHST	Quantifiable	See Bidder's Framework
B10	Increased R&D opportunities	Increased R&D opportunities as a result of newer equipment and collaboration with a single vendor	VUNHST	Unmonetisable - Qualitative	See Societal Benefits B13 and B14
B11	Better business intelligence	Access to improved analytics and reduction in manual data collection	VUNHST	Quantifiable	See Bidder's Framework
B12	Benefits of service support	Improved service report reduces burden of major system upgrades	VUNHST	Quantifiable	See Bidder's Framework
B13	Additional investment in RD&I	Increased investment in Research, Development & Innovation	VUNHST	Non-Cash Releasing	Additional RD&I income from successful bidder
B14	Future research bunker opportunity	Opportunity to receive a discount on the procurement of a treatment machine for a future research bunker	VUNHST	Non-Cash Releasing	Cost avoidance
B15	Creation of capacity contingency	Advanced technology provides ability to deliver additional fractions creating capacity to deal with additional demand if required in the future	VUNHST	Non-Cash Releasing	Number of additional fractions available
B16	Advanced technology leads to better patient outcomes	Advanced technology contributes to better patient outcomes supporting the TCS Programme aim of improved survival rates	Patient	Societal	Number of additional survivors
B17	Job creation	Implementation of IRS creates new Engineering and Apprentice Engineer roles	Economy	Societal	Number of additional jobs created in UK market

Risks

- 6.4 Risk is the possibility of a negative event occurring that adversely impacts on the delivery of the project and its benefits. The main risks that the project must address are listed in the table below.

Table 6-2 Main risks

ID	Risk	Mitigation	Risk Type
A1	Risk that capital and revenue funding is not available / not agreed	Regular engagement with WG and Trust's commissioners relating to funding levels required. Trust requirements are designed in such a way as to reward bidders to come within an affordability threshold	Implementation Risks
A2	Risk that approvals are delayed	Regular updates, project plan and forward look against Trust and WG business cycles	Implementation Risks
A3	Risk that implementation is delayed because of preferred supplier (including supply chain issues and component delays)	Trust has a contract in place and agreed implementation plan which the bidder would be expected to perform against therefore there is the opportunity to seek liquidated damages	Implementation Risks
A4	Risk that bidder does not specify correct construction design resulting in the building not accommodating the solution	Detailed contract drafting with regards to the interface for the nVCC and RSC projects identifies relevant pass-ups and pass-downs between the contracts. There are also dispute resolution and third-party rights retained. Liquidated damages are available as a remedy. Engagement between the construction partners and bidder	Implementation Risks
A5	Risk of construction delays within VCC, RSC and nVCC phases leading to IRS implementation delays	Detailed contract drafting with regards to the interface for the nVCC and RSC projects identifies relevant pass-ups and pass-downs between the contracts. There are also dispute resolution and third-party rights retained. Liquidated damages are available as a remedy.	Implementation Risks
A6	Risk of implementation delays due to limited capacity and/or capability	Effective workforce planning, clear identification of roles and early recruitment, dedicated WOD/recruitment resource to support the process. Clear governance process in place. Change control measures in place (e.g. change freeze, etc.), where change freeze not possible or acceptable, clear priorities should be in place.	Implementation Risks
A7	Risk that there is a lack of integration with WPAS/WCP (CANISC replacement) interface	Featured within the requirements to mitigate the interface risk issues	Implementation Risks
A8	Risk that bidder is unable to support implementation with the appropriate skilled resource	Evaluation seeks to reward the bidder who can describe their team's capability and skills	Implementation Risks
A9	Ongoing risk of Covid impacting on ways of working (social distancing, travel restrictions, etc.)	Following government guidance, use of relevant PPE, re-planning as necessary (e.g. increased training sessions,	Implementation Risks

		moving face-to-face to online where required)	
A10	Risk that there are IT issues as a result of obsolescence of existing VCC infrastructure	Regular engagement with IT colleagues to identify any gaps with regards to VCC infrastructure versus solution designs and readiness requirements	Implementation Risks
A11	Risk of multiple deliveries/phases converging within narrow timescale impacting on ability to properly resource - overlapping with other Projects' implementation plans	Fully resourced and agreed project implementation plan including milestones and communications	Implementation Risks
A12	Risk that legacy data not available in timeline required / risk to it being lost during implementation	Ensure workarounds are in place to allow access to legacy data to inform new treatments. Back-up/Failover provision for accessing data during Data Migration.	Implementation Risks
A13	Risk that there is an inability to / unwillingness to adopt required changes to ways of working across all services	Change management processes communications, stakeholder plans, etc. Clinical mandate	Implementation Risks
A14	Risks associated with access / storage because of solution moving to cloud	Change control. Contractual mitigations ensuring that Trust has the ability to retrieve its own data from the cloud at the end of the contract. Increased training and adherence to GDPR + NIS within the solution design approvals and contract.	Implementation Risks
B1	Risk that the bidder's technical solution does not fully meet the service requirements (not able to fully procure)	Trust requirements have been developed by Trust specialists and subject to independent internal and external review	Solution Design Risks
B2	Risk that the bidder's technical solution leads to an inefficient solution / poor functionality that does not fully meet the service requirements (cannot be fully delivered)	Trust requirements have been developed by Trust specialists and subject to independent internal and external review. Bidder ownership during implementation to ensure solution design can be fully met.	Solution Design Risks
B3	Risk that the bidder's technical solution leads to a clinically unsafe / unusable solution that needs to be resolved	Trust requirements have been developed by Trust specialists and subject to independent internal and external review. Bidder ownership during implementation to ensure solution design can be fully met.	Solution Design Risks
B4	Risk that a provider announces technical advances after procurement process.	Adequate change control process, contract	Solution Design Risks
B5	Risk that Velindre requires changes due to change in clinical indications or treatments meaning the solution would need to change to accommodate - more specialist treatments	Adequate change control process, contract, remaining aligned to current research trials ongoing	Solution Design Risks
B6	Risk that there are data quality issues as a result of the new design not meeting previous functionality	Trust requirements have been developed by Trust specialists and subject to independent internal and external review. Bidder ownership during implementation to ensure solution	Solution Design Risks

		design can be fully met. Adequate change control process	
B7	Risk that solution does not have the appropriate level of resilience and redundancy	Clearly defined requirement that the solution must be resilient in all main features	Solution Design Risks
C1	Risk of legal challenge from unsuccessful bidder	Robust and legally assured procurement process	Contract Risks
C2	Risk that the preferred supplier becomes insolvent	PQQ process included financial due diligence including Dunn & Bradstreet reports; ability to ask for parent company guarantee; step-in rights	Contract Risks
C3	Poor contract performance - Risk of fitness for purpose of end contract to solve problems (e.g. SLAs for repairs/maintenance etc.) - poor bidder performance	Contractual remedies exist, regular contractual meetings with supplier. Ability to issue early warning and termination notices should performance deteriorate	Contract Risks
C4	Contract not as robust / fit for purpose	Carried out commercial and contractual dialogue over many sessions. The Trust has been in receipt of legal advice in regards to the development of the contract.	Contract Risks
C5	Risk that there is inadequate ongoing contract and performance management - appropriate resource is not in place for future ongoing management of contract and solution (capacity, awareness) - relationship management (note organisation ability to manage process)	Contract management resource has been included within the business case resource plan. Mechanisms in place within the contract and regular service meetings in place.	Contract Risks
C6	Risk that Trust is unable to meet ongoing contractual obligations (e.g., engineering, etc.)	Agreed recruitment plan within the business case for the key resource to manage and maintain the contract	Contract Risks
C7	Risk that any changes to financial treatment for external issues such as CPI, VAT, etc., make the contract unaffordable	Regular engagement with WG and Trust's commissioners relating to funding levels required. Trust requirements are designed in such a way as to reward bidders to come within an affordability threshold. Working with advisors to understand accounting treatment and associated VAT implications.	Contract Risks
C8	Risk of contractual dispute arising	Mechanisms such as escalation arrangements and termination clauses within the contract	Contract Risks
C9	Risk that FBCs for nVCC and RSC are not approved	Minimum number of machines in the contract. Programme master planning and control plans to manage dependencies across the programme and projects.	Contract Risks
D1	Risk that demand and capacity is underestimated	Carried out future planning based on estimated increases in incidences of cancer as per Cancer Research UK. Continually monitor demand and capacity and option of catalogue and change control to buy additional goods and services. Bidders scope for	Operational Risks

		technology improvements over the life of the contract to increase efficiencies.	
D2	Risk that demand and capacity is overestimated	Carried out future planning based on estimated increases in incidences of cancer as per Cancer Research UK. Continually monitor demand and capacity.	Operational Risks
D3	Risk that unable to recruit suitably skilled resource required to deliver the service - availability of applicants	Effective workforce planning and early recruitment, dedicated recruitment campaign	Operational Risks
D4	Risk of increased downtime due to machine failures	Delivery of the preferred option	Operational Risks

Constraints

6.5 Constraints relate to the parameters that the project is working within and any restrictions or factors that might impact on the delivery of a project. For the procurement of an IRS this includes:

- Affordability constraints which are explored within the Financial Case.
- Timelines for the new Velindre Cancer Centre (nVCC) and Radiotherapy Satellite Centre (RSC) projects which have implications for the way in which the IRS contract will be constructed.
- Availability of internal resources to deliver the project.
- Legacy systems to manage through transition.
- Need to engage adequately with partners to ensure there is the appropriate level of buy in order to optimise Research and Development opportunities.
- Public contract regulations drive the timeline of the IRS procurement.

Dependencies

6.6 Dependencies include things that must be in place to enable the project or project phases to be delivered. They typically include links to other projects and funding requirements that are likely to be managed elsewhere.

- Access to adequate capital funding via Welsh Government and revenue funding from the Trust's Commissioner's

7 CONCLUSION

7.1 The Strategic Case demonstrates a compelling case for investment to support the procurement of an Integrated Radiotherapy Solution (IRS). The key factors supporting the case for investment are:

- There is a need to replace treatment machines to reduce service delivery risks regardless of the nVCC and RSC projects.
- Cancer incidences and activity are increasing as is the complexity of treatment and a surge of COVID-19 cases remains a distinct possibility
- The current VCC has a dual vendor approach which is inefficient.