Report Title	**All Wales Positron Emission Tomography (PET) Programme Progress Report**	**Agenda Item**	3.6
Meeting Title	**Joint Committee**	**Meeting Date**	30/01/2024
FOI Status	Public		
Author	Programme Design and Delivery Lead		
Executive Lead	Dr Sian Lewis (All Wales PET Programme SRO)		

Purpose of the Report	The purpose of this report is to provide an update on several issues facing the Projects within the All Wales Positron Emission Tomography (PET) Programme.				
Specific Action Required	RATIFY ☐	APPROVE ☐	SUPPORT ☐	ASSURE ☒	INFORM ☒

Recommendation(s):

Members are asked to:

- **Note** the proposed actions regarding escalation to the Sponsor (Section 3.3.4),
- **Note** the issues and risks facing the projects; and
- **Note** the progress made by the Workstreams and other enabling activities.

ALL WALES POSITRON EMISSION TOMOGRAPHY (PET) PROGRAMME PROGRESS REPORT

1.0 SITUATION

The purpose of this report is to provide an update on several issues facing the Projects within the All Wales Positron Emission Tomography (PET) Programme.

The all-Wales PET Programme is in the implementation stage and while progress is being made, the Projects within the Programme are all realising issues. As such, change control thresholds have been (or are soon likely to be) reached. In line with governance routes, escalation to the Joint Committee (JC) and the Sponsor, the Welsh Government (WG) is required.

This report also updates on the various enabling activities that have been ongoing for the all-Wales PET service.

2.0 BACKGROUND

WHSSC commissions PET scanning as a specialist service. The issues facing the Welsh PET service are longstanding and were first described in several strategic documents published in 2018[1,2]. The national Programme Business Case (PBC) recommended that four new fixed, digital PET scanners should be put in place across Wales in a phased manner over the next five years to answer growing clinical demand.

Following WG scrutiny and receipt of support from all Health Boards (HBs) and Velindre University NHS Trust (VUNT), Ministers endorsed the £25M capital All Wales PET PBC on the 25th of August 2021. Due to the success of the Programme, the Director General/CEO of NHS Wales issued a second mandate[3] (October 2021) requesting that WHSSC take on responsibility for the All Wales PET Programme implementation phase. The Programme formally launched with its revised governance and support from the WG funded Programme Management Office (PMO) in March 2022.

Each Project within the Programme represents an active PET service site and are at various stages of development and complexity. Every Project has a Senior Responsible Owner (SRO), Project Director and Project Manager and each host HB/PET site follows their local change control (threshold limits) in accordance with their respective Standing Financial Instructions (SFIs).

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[1] Welsh Government, Imaging Statement of Intent (Mar 2018)
[2] Auditor General for Wales (Wales Audit Office), Radiology Services in Wales (Nov 2018)
[3] Goodall, A. 2021. Letter to Sian Lewis. 28 October

However, given the oversight and assurance function of the All Wales PET Programme Board, change thresholds are monitored because the consequential effects of unmanaged change in one area, may be far-reaching within the Programme and affect business-as-usual activities and service provision. Indeed, looking at the Projects in their entirety permits a long-lens view on the impact of significant changes against the ongoing increase in clinical demand. Certainly, Wales continues to realise a substantial increase in clinical demand for PET scanning which is in line with the original Programme Business Case (PBC). This is likely to become an increasing pressure on the services as developments for Alzheimer's treatments progress through NICE appraisal - where PET scans are determined as the appropriate diagnostic and monitoring tool. However, even without additional scanning for eligible patients with Alzheimer's disease, we expect the demand in the south east of Wales to outstrip capacity in either 2025/26 or 2026/27.

3.0 ASSESSMENT

3.1 Programme Milestones

The original proposed timelines are included in ***Table 1*** below, with the impact of changes summarised and marked in a RAG status.

Table 1. Summary of Project status

Project	Proposed date of Business Case completion	Proposed "go live" dates		Impact of change
Project 1 – Cardiff				
BJC	APPROVED	PET Scanner	July 2023	COMPLETE
		Ion Source replacement	Feb 2024	DELAYED
		Hot Cell replacement	Jan 2025	DELAYED
Project 2 – Betsi				
SOC	APPROVED	Aug 2025		UNKNOWN
OBC	Aug 2023			
FBC	May 2024			
Project 3 – Swansea				
BJC	Nov 2023	Nov 2024		Business case: Q3 2024/25 Go live: Q3 2025/26

3.2 Project Updates

3.2.1 Project 1 (Positron Emission Tomography Imaging Centre (PETIC))

- The GE Omni Legend System scanner installation work is now complete and image optimisation work is completed also. The scanner is producing exceptionally high quality images and reducing patient scan time. The Positron Emission Tomography Imaging Centre (PETIC) scanning capacity has increased from 75 to 91 scans/week,
- In the original business case, several items requiring replacement or investment had been identified by PETIC, including: PET scanner, hot cell replacement and ion source replacement. The case included the expansion of uptake rooms to further increase scanning capacity, however the business model in the original business case identified that PETIC would be able to fund these uptake room amendments from increasing revenue. The funding approved by WG included:

PHASE	DESCRIPTION	BUDGET	CURRENT STATUS
1	Replacement of existing PET scanner (Includes revenue from sale of existing scanner)	£2,650k	Complete (July 31st 2023)
2	Cyclotron replacement	£330k	Due to commence
3	Radiopharmaceutical Production Suite refresh	£1,670k	Due to commence

- However, recently additional requirements have been identified by PETIC. Specifically, a Capital shortfall of £1.84M for phases two and three (cyclotron ion source and hot cell replacement within the PET radiopharmaceutical manufacturing facility, and expansion of uptake rooms) was raised by the PETIC Project Board in early October 2023,
- Cardiff University subsequently submitted an Options Paper to WHSSC (as Commissioners) for consideration (11.10.23). This paper noted that *"PETIC is now operating on a financially unsustainable basis due to a combination of recent changes in the economic landscape, aging facilities, resource issues, regulatory changes and an underfunded Capital Replacement Programme. Specifically: Commercial companies are increasing production capacity to meet the increasing demand for radiopharmaceuticals (thereby reducing PETIC's ability to generate revenue from sales). This situation will change again from 2025, further eroding PETIC's ability to compete"*,
- These Options are now being considered by WHSSC, the WG and Cardiff University, with facilitation by the Programme PMO, and include:
  - Do nothing – Continue commissioned scanning contract supported by current production capacity and delaying Capital Replacement Programme for 2-3 years,
  - Continue with existing Capital Replacement Programme identifying funding for any shortfall,
  - CU/PETIC terminates service by ceasing radioisotope production and transfers scanning to the NHS,
  - CU/PETIC terminates service by transferring radioisotope production to commercial supplier and scanning to the NHS,

- In developing these options, a transfer of clinical scanning to a third party (assumed to be the NHS) and retaining radioisotope production in PETIC has been discounted,
- Several meetings have taken place between representatives of PETIC, WHSSC and the WG since the Options Paper was put forward. The WHSSC team summarised their understanding of current uncertainties related to ongoing isotope production, which includes:
  - Uncertainty regarding UK supply of PSMA and potential future licensing of PSMA products,
  - The likely markets for different PSMA isotopes,
  - The feasibility of introducing a Gallium production unit into Wales (potential resilience to the PSMA service),
  - The interdependency between scanning and production infrastructure,
  - Limitations of refurbishing a manufacturing unit on a hospital site,
  - Opportunities regarding the financial model,
  - Work on planning for the hot cell replacement work and uptake room capacity review is commencing this September,
- There is agreement across all parties that that there are several key aspects to the PETIC function that require review to inform next steps for this unique Welsh resource. As such, ***Table 2*** outlines next steps.

Table 2 - Proposed stages of the Review of Project 1 (PETIC): Phases 2 & 3

Stage	Requirement and consideration	Role and Responsible Party(ies)
1.	Reach absolute clarity and transparency on the infrastructure requirements of the manufacturing facility at PETIC. This is required with an expert view of the UK-wide commercial and RD&I landscape.	Detailed external review and advisory report conducted by an independent expert in radiopharmaceutical production.
2.	Clarity and transparency are required on the future financial model, plans and strategy of the manufacturing facility.	Financial models to be developed by Cardiff University (with assistance and challenge from WHSSC Finance Director).
3.	Assurance should be sought regarding the form and function of the Project Board, so that any future working within the Project is conducted appropriately.	The PMO and Cardiff University to undergo an interim Programme/Project Assurance Review.
4.	A strategic decision is required as to whether the PETIC facility is: 1. Best placed as a whole, or split by scanner vs production facility, 2. Best run by an academic institution (Cardiff University), a commercial supplier or by NHS Wales.	WHSSC (as commissioner) to work with Cardiff University (as asset owner) to consider all information provided from the above sources and make recommendations to the Welsh Government (as Sponsor and Capital funder) to inform a strategic decision on the future of the scanning and manufacturing facilities.

- Terms of reference for the external review of the manufacturing facility at PETIC are nearly finalised, with the PMO working to identify appropriately qualified, independent person(s) and budget to carry this out,
- Stuart Davies (Interim Programme Director, WHSSC) is engaging with PETIC and Cardiff University on their financial model; and
- The group plan to meet in mid-January to work through next steps.

3.2.2 Project 2 (BCUHB)

- The Preferred Way Forward for the Nuclear Medicine Consolidation project has been agreed by Project Board to be a single consolidated unit at Glan Clwyd Hospital,
- The draft OBC was set to be completed in Q3 of 2023-24 and an engagement session took place in September 2023 to update stakeholders on progress, details of the proposed service model, and next steps as the project moved towards the Full Business Case stage,
- The December all-Wales Programme Board was informed that the OBC outline costs are now significantly higher than those at the SOP level. BCUHB are in the process of reviewing what options might be available to reduce costs,
- The Project Director informed Programme Board that clarity on costings will be reached in January 2024, following review of the electrical supply issues,
- As there is potential change to costs and time, the Programme Board will await formal update from the BCUHB Project SRO and Project Director in January 2024; and
- The PMO will then ascertain if level of change requires escalation to Sponsor.

3.3.3 Project 3 (SBUHB)

- In the last update to the JC, the SBUHB Project Board were nearing completion of their fully tendered single business case and there were minimal issues facing this Project,
- The plan was to construct a modular PET building alongside the existing Cancer Centre. The project had approval for a direct award for the procurement of the building supplier,
- When undertaking due diligence for the modular build, SBUHB found that the cost differential between a traditional and a modular route prompted their change management to go with traditional but longer build solution which is far less costly,
- The SBUHB project board has not moved this risk into a red category, but they have recognised the impact to time and cost,
- A Change Request Form was received and reviewed at the December 2023 Programme Board meeting (***Appendix 1***),
- Please note that the Capital cost is greater than what was stated in the PBC (~£6m) as the PBC described refurbishing a facility. Instead, a detailed options appraisal led to a new build being the preferred option,
- The estimated traditional build outturn capital costs could be as low as £10.8m - a considerable reduction in capital costs of between £2m - £2.5m

compared with the modular route. A traditional build would not be operational until the end of 2025, rather than the end of 2024 under a modular route. There is no difference in the appearance and quality of the building,

- The December 2023 Programme Board recognised the proposed change, and propose for the sponsor to give approval, which includes:
  - Planned submission of business case to WG is now Qtr3 2024/25,
  - The Unit was planned to be operational Qtr3 2023/24. It is now planned to be operational Qtr3 2025/26; and
  - Progressing a traditional solution to RIBA stage 3 (fully designed and tendered stage) would involve the HB funding an additional £130k design team fees. This is a risk to the HB, as it would need to fund from its own discretionary capital programme which is under financial pressure.

3.3.4 Actions

With approval and commentary from the JC, the SRO will write and escalate to the WG(Sponsor) and inform them of all of the issues facing the three Projects, recommending a review and requesting direction for the following actions:

1. Request that PETIC submit a formal Change Request Form to Programme Board,
2. For WHSSC and the PMO to continue working on the external review of the PETIC Manufacturing facility (actions in ***Table 2***) to reach a strategic decision on its future position, role and function,
3. Await further feedback from Project 2 (BCUHB) on the costings for the OBC; and
4. Approve the Change Request Form submitted by Project 3 (SBUHB).

Furthermore, the SRO will also request WG review the original PMO funding business case and enact the planned extension of PMO funding to facilitate the ongoing Programme.

3.4 Workstream Updates

3.4.1 Workstream 1 (Procurement)

- COMPLETE.

3.4.2 Workstream 2 (Workforce)

- In response to this Workstream's case, Health Education and Improvement Wales (HEIW) has incorporated the pipeline needs outlined by the PET Programme into the national Education and Training Plan for 2024/25. This includes the need for new graduate Clinical Technologists and Radiographers and new postgraduate Clinical Scientists to fill vacancies in wider Radiology and Medical Physics services as existing experienced staff move to work within PET-CT. For Radiologists, the CCT/sixth year in Nuclear Medicine is supported when trainees are identified to take this on (***Appendix 2***); and

- The Workstream continues to implement the approved training, including the set-up of a Fast-Track MPE Training Scheme which shortens the training process from 6 to 3 years.

3.4.3 Workstream 3 (Radiopharmaceuticals)

- The NIHR Innovation Observatory has supporting the workstream and produced a Horizon Scan and Landscape Analysis of Innovations for PET Radiopharmaceuticals (***Appendix 3***); and
- The wider review of infrastructure associated for PET Radiopharmaceuticals has now been drawn into the scope of the external review of PETIC (see above).

3.4.4 Workstream 4 (Centres of Excellence)

- Given the issues facing the Projects within the Programme, work on this workstream has been halted until there is more clarity and progression.

3.4.5 Other enabling work – electronic referral form (ETR)

- A discrete task and finish group, led by the WHSSC PET PMO, was set up to develop an Electronic Test Referral (ETR) form for PET. WG approved the reallocation of the PMO underspend (£32,000) for Digital Health and Care Wales (DHCW) to develop the form. Through collaboration with DHCW and stakeholders within the PET service, the ETR form has been developed. However, an issue has recently arisen due to RADDIS no longer developing forms in light of the roll-out of RISP. The PMO are looking into whether anything can be done on this key enabling work and will escalate appropriately,
- Significant advancements in data and reporting standardisation have been accomplished, through joint working across sites, the PMO and WHSSC Planning and Information Teams;
- Staff satisfaction and patient satisfaction questionnaires are soon to be launched on an all-Wales basis. This have been accomplished, through joint working across sites, the PMO and the WHSSC Quality Team,
- Programme Benefits are being further assessed to develop a best practice methodology for defining the cash-releasing benefits; and
- Plans are underway to define a potential research project to understand the changes to a patient pathway following the accurate diagnosis of a PET scan.

4.0 RECOMMENDATIONS

Members are asked to:

- **Note** the proposed actions regarding escalation to the Sponsor (Section 3.3.4),
- **Note** the issues and risks facing the projects; and
- **Note** the progress made by the Workstreams and other enabling activities.

Governance and Assurance	
Link to Strategic Objectives	
Strategic Objective(s)	Governance and Assurance
Link to Integrated Commissioning Plan	
Health and Care Standards	Governance, Leadership and Accountability Effective Care
Principles of Prudent Healthcare	Public and professionals are equal partners through co-production
NHS Delivery Framework Quadruple Aim	Reducing the per capita cost of health care Improving Patient Experience (including quality and Satisfaction)
Organisational Implications	
Quality, Safety & Patient Experience	Informed decisions are more likely to impact favourably on the quality, safety and experience of patients and staff.
Finance/Resource Implications	There are potential direct impacts arising from this report.
Population Health	-
Legal Implications (including equality & diversity, socio economic duty etc)	There are no direct impacts arising from this report.
Long Term Implications (incl WBFG Act 2015)	-
Report History (Meeting/Date/ Summary of Outcome	**-**
Appendices	Appendix 1 - Change Request Form – SBUHB – Project 3 Appendix 2 - HEIW Letter: Request for Workforce Training Appendix 3 - NIHR IO PET Radiopharmaceuticals Report

Appendix 1

All Wales PET Programme Change Control

Change control is the process through which all requests to change the approved baseline of a project, programme or portfolio are captured, evaluated and then approved, rejected or deferred. To avoid unnecessary administration, it is important for the process of change control to be appropriate for the level of change impact. Thresholds in which formal change control is required when these tolerances are breached can define this.

At the point in which a threshold may be breached, a formal change control is required. This is a formal, written request that occurs after the parameters of the project have been agreed to or baselined and after the project is underway. Change requests may arise as a result of issues that occur from the management of work or external sources. Issues that result in changes to scope or any other part of the baseline plan are progressed through change control.

Change control is of particular importance when the project is part of a larger programme or portfolio, such as the All Wales PET Programme because the consequential effects of unmanaged change may be far-reaching within the Programme and to business-as-usual activities.

For clarity, local threshold limits for each host Health Board/PET site will be in accordance with their respective SFIs. However, it is expected that notification of the threshold breaches are included in the regular reporting to Programme Board. The Programme Board role will be to inform both the Joint Committee and Welsh Government (Sponsor), as detailed in the Table 1 below. The process for change management typically has the following steps:

- Project/Programme Manager log the change in relevant change log.
- Initial evaluation where the change is reviewed.
- Necessary approval routes sought, in accordance with PET site respective local threshold limits and notification to the Programme Board as described in Table 3.
- A formal Change Request includes detailed evaluation of the impact on baseline success criteria, benefits, scope, quality, time, resources, costs, risks, stakeholder engagement or any other criteria important to achieving the business case are considered.
- A recommendation is made to the Local Governance and/or Programme Board, Joint Committee or Sponsor to approve, reject or defer the change.
- The schedule and budget plan is updated if a change is approved.
- Implementation where the necessary actions are taken and monitored.

Table 1: Thresholds and routes to review of formal change requests

Impact of change (threshold)	Programme Board function
Less than one month change to schedule, and/or ≤£5,000 budget impact	Informed through regular highlight reporting.
Between 1-3 months change to schedule, and/or £5,001 - £25,000 budget impact	Informed through regular highlight reporting. To be formally noted in Programme Board minutes.
Between 3-6 months change to schedule, and/or £25,001 - £100,000 budget impact	Informed through regular highlight reporting. The Programme Lead to ensure notification is included in Programme Board minutes and Programme report to Joint Committee. Programme Manager to assure that local change controls are actioned.
More than 6 months change to schedule, and/or £100,001 - £250,000 budget impact	Noted by Programme Manager or Programme Lead at Project meetings or through 1:1 meetings with key Project/Workstream personnel. Alternatively, informed through regular highlight reporting. The Programme Lead to ensure notification is included in Programme Board minutes and Programme report to Joint Committee. Programme Manager to assure that local change controls are actioned. Programme Lead to ensure that the Sponsor is notified.
More than 9 months change to schedule, and/or ≥£250,001 budget impact	Noted by Programme Manager or Programme Lead at Project meetings or through 1:1 meetings with key Project/Workstream personnel. Alternatively, informed through regular highlight reporting. The Programme Lead to ensure notification is included in Programme Board minutes and Programme report to Joint Committee. Programme Manager to assure that local change controls are actioned. Programme Lead to ensure that the Sponsor is notified.

Appendix 1

All Wales PET Programme Change Request Form

Project:	*SWANSEA PET CT PROJECT*	Change ID:	*C1*

Change Request			
Change Title:	*Change in Procurement Route*	**Identification Date:**	*06/11/2023*
Requested by:	*Christine Morrell*	**Date received at PMO:**	
Change threshold:	☐ Between 3-6 months change to schedule, and/or £25,001 - £100,000 budget impact ☐ More than 6 months change to schedule, and/or £100,001 - £250,000 budget impact ☑ More than 9 months change to schedule, and/or ≥£250,001 budget impact		

Change Description & Details

Situation:

The All Wales PET CT Programme Business Case (PBC) identified approx. £6m capital to develop a predominantly refurbished static facility in Swansea. Following detailed option and site appraisals we progressed development of Swansea's single business case based upon a new build modular build, which we anticipated would be operational by the end of 2024.

Design activities have now concluded and indicative outturn capital costs confirm the modular solution capital costs are £13.3m. We therefore undertook a due diligence review of alternative and less costly routes to delivering a quality new build static PET CT unit with the assistance of our independent Cost Advisor. This review has concluded the following potential changes:

Cost - The estimated traditional build outturn capital costs could be as low as £10.8m - a considerable reduction in capital costs of between £2m - £2.5m compared with the modular route.

Indicative Timeline – A traditional build would not be operational until the end of 2025, rather than the end of 2024 under a modular route.

Quality - There is no difference in the appearance and quality of the building.

Impact or Risks:

1. Business Case submission will be delayed whilst the traditional design solution is worked up. We had planned to submit the (modular build) business case to WGov at the end of November 2023. Planned submission to WGov is now Qtr3 2024/25.
2. The Unit was planned to be operational Qtr3 2023/24. It is now planned to be operational Qtr3 2025/26

3. Progressing a traditional solution to RIBA stage 3 (fully designed and tendered stage) would involve the Health Board funding an additional £130k design team fees. This is a risk to the Health Board, as it would need to fund from its own discretionary capital programme which is under financial pressure.

Risk of not implementing this Change: Progressing a modular procurement (with a significantly higher value compared to a traditional solution) may not be approved by WGov, further delaying the programme.

Scope:

Timely internal and external approval of our completed business case.

GIG CYMRU NHS WALES
Addysg a Gwella Iechyd Cymru (AaGIC)
Health Education and Improvement Wales (HEIW)

Addysg a Gwella Iechyd Cymru (AaGIC)
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Date: 21/07/2023

To: Sian Lewis,
Managing Director of Welsh Health Specialist Services Committee
and Chair of All Wales PET Programme Board

Sent by email.

Dear Sian Lewis, All Wales PET Programme Board

Re: All Wales PET Programme Request for Workforce Training

HEIW received from a set of papers created by the PET Programme Workforce Workstream of the all Wales PET Programme. These described the need for additional workforce training in order to meet the requirements of the PET services under development across Wales. These papers were comprehensive and well-reasoned and clearly demonstrate a multi-professional input across all PET services and projects in their creation.

Current training routes
Commissioned education funded via the annual NHS Wales Education and Training Plans are as follows and include current cohorts underway and proposed numbers for 2024/25. The Education and Training Plan for 2024/25 is due to be submitted to Welsh Government shortly.

Commissioned Education	20/21 Entry	21/22 Entry	22/23 Entry	23/24 Entry	Planned 24/25
BSc Diagnostic Radiography (3yrs) and Radiography Associate	140	166	166	150	139*
PTP Clinical Technologist Nuclear Medicine (3 yrs)	3	6	3	6	3**
STP Medical Physics – all areas (3 yrs)***	7	13	7	13	4
HSST Medical Physics – all areas (5 yrs)	1	1	3	2	*tbc*
Reporting Radiography	10	10	10	20	20
Nuclear Medicine CCT	0	0	0	****	****

** Recommended commissioning above the 115 identified in IMTPs. This is in recognition of increasing workforce requirement and HEI pre-registration contracts. Work underway to address significant placement capacity constraints.*
***No IMTP requests, however, identified need in Positron Emission Tomography (PET) workforce plan and engagement directly with service has shown support needed. Contract range of 1-3 places.*
****Including both the formal Scientist Training Programme and the "Route 2" approach. Training made available by services.*
*****Nuclear Medicine ST6/CCT is available where a candidate is identified to take this on.*

The PET Programme papers suggested that the current training routes commissioned by HEIW through the annual Education and Training Plan are providing a level of effective pipeline of professions into these specialist services.

It was of interest to understand the dependence on wider Radiology and Nuclear Medicine/Medical Physics services in taking on new graduates/postgraduates completing commissioned programmes. PET services then offer extended and advanced practice roles for their progression.

As is shown in the above table and notes added, the details of pipeline need have been timely in enabling decisions regarding commission of the Radiography and Clinical Technologist Nuclear Medicine degrees in 2024/25, where Health Board/Trust IMTP submissions were lower than expected.

Additional training needs requested.
The PET Programme papers describe additional training needs across 9 themes:

1. Additional Clinical Technologist Training Capacity
2. New Clinical Technologist Fast-Track Training
3. Train existing Nuclear Medicine and Medical Physics Staff on PET
4. Existing Radiographers
5. Facilitative investment for training Clinical Radiologists
6. Additional Training for SBUHB Cardiologists
7. Additional Training for Administrators and Clinical Support Staff
8. Continue Support for Clinical Scientists (Medical Physics)
9. Additional Medical Physics Experts (MPEs)

Four specific requests to HEIW were included within the recommendations:

- For HEIW to advise on existing mechanisms for phased funding of training needs outlined
- For HEIW to commission a PET-CT educational and experiential opportunity for all services, with a proposal provided for provision of this by the Manchester Christie PET-CT Academy
- For HEIW to consider training time within funding for healthcare scientist routes to registration
- For HEIW to continue work with Medical Physics services to develop an accelerated training approach, starting urgently in 2023/24, and to also work with the PET Programme to consider a new fast-track training route for Clinical Technologists.

A detailed picture was also provided of current workforce and gaps against service specification need. Whilst the required increases may appear small, it is striking that they are a substantial increase on existing establishment for these services.

Advice on funding for Healthcare Science training
Funding in relation to continued professional development (CPD) training for NHS staff is the responsibility of the local services. A CPD strategy is in the process of being developed by HEIW, which includes description of the responsibilities of staff, services, and HEIW.

An “Extended Practice/Advanced Practice” budget is also provided to all NHS Wales Health Boards and Trusts to support health professionals develop towards extended practice or advanced practice roles. This is available to Nurses, Midwives, Allied Health Professionals and Healthcare Scientists. This is not available to universities; however, it is understood that PET Imaging Centre includes staff on honorary contracts with Cardiff and Vale University Health Board and supports training with Velindre NHS Trust.

Due to additional registration and regulatory requirements, those professions within Healthcare Science in NHS Wales also have access to an annual budget to support "equivalence" and other in-service routes to professional registration. This "Equivalence funding" is designed to enable progression to the multiple points of registration throughout the Healthcare Scientist career pathway. Specialist examinations such as Medical Physics Expert are also funded due to services relying on these for regulatory compliance, and therefore Health Boards/Trusts reliance upon these to meet patient needs.

This latter funding previously supported formal education, formal training schemes, and fees for degree assessment or equivalence funding portfolio. This had previously been available to a budget of £75,000 annually, although in 2022/23 HEIW supported requests totalling over £200,000.
The national Scientist Training Programme is also available for staff within NHS Wales to undertake.

Needs outlined by the PET Programme relating to Healthcare Science:

1. Additional Clinical Technologist Training Capacity
2. New Clinical Technologist Fast-Track Training
3. Train existing Nuclear Medicine and Medical Physics Staff on PET
4. Existing Radiographers
7. Additional Training for Administrators and Clinical Support Staff
8. Continue Support for Clinical Scientists (Medical Physics)
9. Additional Medical Physics Experts (MPEs)

The types of clearly articulated needs from the PET Programme have also been echoed from other national strategic programmes including Healthcare Science, Imaging and Pathology. Therefore, there have been changes made to the criteria and approach for the Healthcare Science Equivalence Funding in 2023/24 as follows:

Inclusion criteria: All professions that are included within healthcare science in Wales are now expressly stated as included via an online form - this now includes Radiographers. The wider range of registration routes and training schemes are also expressly stated, with an option to state others.

Speciality training: Specialty examinations included to enable specialty and regulatory compliance are now expressly stated. In 2023/24, specialist training has also been supported to enable the PET-CT training requirements.

Capacity for meeting professional requirements: Inclusion of ability to request funding for time away from role against each of the criteria has been supported for 2023/24 and is also included within the 2024/25 Education and Training Plan for submission to Welsh Government.

New training schemes for Wales: This support for training capacity has enabled novel accelerated training to be requested towards specialty examinations (e.g. MPE) or registration routes (e.g. Clinical Technologists). Further development will be required to ensure all Wales approaches.

Following a delay whilst these developments were implemented, the application window for 2023/24 was opened from 30th May to 12th June 2023. Applications were received from all services involved in the PET Programme. With costings of the fast-track Medical Physics Experts being finalised, currently the total "Equivalence funding" across the healthcare science profession is estimated at £560,000. All the needs from the PET Programme for healthcare science in 2023/24 have been met via this funding.

Advice on funding for Radiologist training

Wales has two separate schemes – one based in north Wales and one in the south. The programme is well established and offers structured teaching and training in the many University Hospitals across Wales. Radiology training in South Wales is supported by National Imaging Academy Wales (NIAW), with training time divided between the Academy and clinical placements. The South Wales scheme has capacity to train 100 trainees. The North Wales scheme includes training mainly delivered in Betsi Cadwaladr University Health Board (BCUHB), with teaching supported by the Northwest of England

School of Radiology. The North Wales scheme has 11 trainees currently in post.

Training is split into three years of core training in all disciplines of clinical radiology, followed by two years of subspecialty training. An additional sixth year of training is provided for those pursuing an interest and career in nuclear medicine.

Needs outlined by the PET Programme relating to Radiologists/Cardiologists:

1. Facilitative investment for training Clinical Radiologists
2. Additional Training for SBUHB Cardiologists

The CCT/sixth year in Nuclear Medicine is supported when medical trainees are identified to take this on, and HEIW is keen to liaise with services where individuals may be interested to do so. Funding for existing Radiology and Cardiology Consultants to undertake a Postgraduate Diploma is the responsibility of the service.

Medical Deanery trainees in Radiology undertaking training with the National Imaging Academy for Wales are commissioned by HEIW. Additionally, trainer capacity is funded across services in Wales in line with all other specialties. The proposed trainer capacity increases would be out of proportion with other specialties, and it is suggested that consideration is given for other funding sources to support capacity within the National Imaging Academy for Wales. Funding the Hermes software for Radiology reporting is also the responsibility of the service.

Proposed PET-CT educational and experiential training needs

The need for additional specific PET-CT training was also explained, with a particular supplier proposed of The Christie PET-CT Academy (based at The Christie NHS Foundation Trust) who offer training in PET-CT essentials and IV cannulation, and both training and experience in management of increased patient numbers and new Medical Physics requirements within the service specifications. It is understood that this is not available in Wales due to services either being in development, or running at lower capacity than will be the case when the new scanners are brought into commission.

HEIW will liaise with the Christie Academy to explore funding the short-term PET-CT educational and experiential training needs in 2023/24 and will work with the PET Programme to review the benefit of this for the future in the context of wider NHS Wales developments in training skills academies.

Summary

The national Education and Training Plan for 2024/25 has incorporated the pipeline needs outlined by the PET Programme. This includes the need for new graduate Clinical Technologists and Radiographers and new postgraduate Clinical Scientists to fill vacancies in wider Radiology and Medical Physics services as existing experienced staff move to work within PET-CT. For Radiologists, the CCT/sixth year in Nuclear Medicine is supported when trainees are identified to take this on.

Advice has also been provided on existing mechanisms for phased funding of training needs outlined.

Four funding streams are available to Healthcare Scientists within services:

- CPD funding which is the responsibility of the Health Board/Trust
- Enhanced Practice/Advanced Practice funding supplied by HEIW to Health Boards/Trusts
- Healthcare Science Equivalence Funding for all routes to registration, speciality examinations and regulatory training requirements – time away from role has been included within this funding in 2023/24 and is proposed for the future via the national Education and Training Plan
- The Scientist Training Programme is also open to existing staff.

Additionally, there is agreement for 3 fast track Medical Physics Expert trainees to be supported starting in 2023/24, with details to be finalised to ensure an all-Wales approach and to review future needs. The

proposed fast track Clinical Technologists approach will be explored further with the PET Programme Workforce Workstream whilst awaiting the outcome of the Education and Training Plan for 2024/25.

Funding for existing Radiology and Cardiology consultants to undertake a Postgraduate Diploma is the responsibility of the service, as is the responsibility for funding the software for Radiology reporting. The proposed trainer capacity increases would be out of proportion with other medical specialties.

HEIW will liaise with the Christie Academy to explore funding the short-term PET-CT educational and experiential training needs in 2023/24 and will work with the PET Programme to review the benefit of this for the future in the context of wider NHS Wales developments in training skills academies.

Yours sincerely

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Horizon Scanning Report: Identification of innovations for PET radiopharmaceuticals in the context of the Welsh Health Service

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Contents

List of abbreviations

177-Lu	Lutetium-177
18F	Fluorine-18
64CuCl2	Copper (II)-64 chloride
AI	Artificial Intelligence
ARSAC	Administration of Radioactive Substances Advisory Committee
ATSM	Copper(II)-diacetyl-bis(N(4)-methylthiosemicarbazone)
CT	Computed Tomography
CTR1	Copper Transporter 1
Cu	Copper
DFO	Deferoxamine
EMBASE	Excerpta Medica Database
ESCC	Esophageal Squamous Cell Carcinoma
FDG	Fludeoxyglucose
Ga-68	Gallium-68
ID	Identification
IO	Innovation Observatory
ISTR	International Symposium on Trends in Radiopharmaceuticals
MDT	Metastasis Directed Therapy
MM	Multiple Myeloma
MPI	Myocardial Perfusion Imaging
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
MRS	Magnetic Resonance Spectroscopy

N-13	Nitrogen-13
NICE	National Institute of Health and Care Excellence
O-15	Oxygen-15
PD-L1	Programmed Cell Death Ligand 1
PET	Positron Emission Tomography
PSMA	Prostate-Specific Membrane Antigen
RAM	Ramucirumab
Rb-82	Rubidium-82
RIS	Research Information Systems
ROW	Rest of World
Sc	Scandium
SPECT	Single Photon Emission Computed Tomography
TFR1	Transferrin Receptor Protein 1
URL	Uniform Resource Locator
VEGFR2	Vascular Endothelial Growth Factor Receptor 2
VOSViewer	Visualisation of Similarities Viewer
WHSSC	Welsh Health Specialised Services Committee
Zr	Zirconium

Glossary

Positron emission tomography (PET): is a form of nuclear imaging technology which is based on the particular properties of positron emitter radionuclides (also called 'beta plus rays')

Radiopharmaceutical: is a radioactive compound used for diagnosis and therapeutic treatment of human diseases. A radiopharmaceutical consists of two components: a radionuclide and a pharmaceutical

Computed Tomography: sometimes called "computerised tomography" or "computed axial tomography" (CAT), is a non-invasive medical examination or procedure that uses specialized X-ray equipment to produce cross-sectional images of the body.

Radionuclide: is a substance that degrades in a very constant manner over time and emits one or several radiations. This degradation or decay is defined by a constant, the period (or half-life) corresponding to the time it takes for half of the remaining substance to disappear. This half-life is specific for each radionuclide.

Nuclear medicine: is a specialized field of medicine covering all aspects of the use of radioactive substances that are either injected in or ingested by humans with the aim to diagnose or treat a disease.

Introduction

Positron emission tomography (PET) radiopharmaceutical is composed of a biologically active pharmacophore and a positron-emitting radionuclide and belongs to a unique species in the pharmaceutical field.[1] PET is a non-invasive molecular imaging technique used to study and visualise human physiology with the detection of probes labelled by positron-emitting radionuclides.[2] It is permissible in most countries worldwide to manufacture and prepare PET radiopharmaceuticals on a commercial scale within the radiopharmaceutical industries and in hospitals' radio pharmacies. However, PET radiopharmaceuticals are potentially hazardous. The level of risk depends on the types of radiation emitted and the half-lives of radioactive isotopes. In addition, because of the short half-lives of PET radiopharmaceuticals, quality control tests prior to human administration within such a short period are extremely challenging.

The most common radionuclides for PET radiopharmaceuticals include carbon-11 (C-11), oxygen-15 (O-15), nitrogen-13 (N-13), fluorine-18 (F-18), gallium-68 (Ga-68), and rubidium-82 (Ru-82). F-18 (t ½ = 110 min) is the most widely used radionuclide in PET, and it is often referred to as the "radionuclide of choice" because of its favourable physical and nuclear characteristics.[2] It is the first PET radiopharmaceutical to be included in the United States Pharmacopoeia USP 1989.[3] F-18 has a half-life of only two hours. The advantage of this very short half-life means that the radioactivity in the patient completely disappears by the end of the day. However, it is also the most constraining property influencing the manufacturing and application of Fludeoxyglucose (FDG).[4]

In addition to providing multidisciplinary functionality and molecular diagnostic information, PET offers enhanced morphological features when combined with structural imaging modalities such as computed tomography (CT). As a result of improved diagnostic performance and guidance of clinicians toward better patient management, PET/CT has gained wide acceptance among nuclear medicine practitioners and the scientific community.[5] The application of PET in clinical oncology is increasing since many molecular targets relevant to cancer can be labelled with positron emitter radionuclides.[4]

Identifying PET radiopharmaceuticals early in the development process is imperative in order to make informed decisions and to prepare for the future development of these innovations. Traditionally, clinical studies of drugs proceed through phase 1, phase 2 and phase 3 before regulatory approval. However, with PET radiopharmaceuticals an initial step called Phase 0, pre-phase 1, microdosing (Europe) or exploratory Investigational New Drug (IND, USA) is often employed.[1] It is commonly known that phase 1 studies are typically carried out in small numbers, phase 2 studies are proof of principle studies to demonstrate that the proposed treatment targets the intended organ or disease process, and phase 3 studies are the definitive efficacy studies required to receive marketing authorization.

Regulation of PET radiopharmaceuticals

PET radiopharmaceuticals are a special class of medicinal formulations used in nuclear medicine for the diagnosis of specific diseases.[2] The formulations contain both a radionuclide and a drug. From the regulatory standpoint, this distinctive character may pose a challenge due to the need

to balance pharmaceutical good manufacturing practices (GMP) and radiation safety concerns.[6] Furthermore, there are a variety of other regulations, some of which are conflicting, which need to be addressed. Among them are the protection of workers, patients, and the general public from the effects of radiation and the handling of radioactive waste.

In the USA, the Food and Drug Administration (FDA) regulates the production of PET radiopharmaceuticals, while the Nuclear Regulatory Commission (NRC) regulates the use of PET radiopharmaceuticals. Therefore, manufacturers must ensure compliance with both sets of regulations. In consideration of the unique nature of PET radiopharmaceuticals, FDA instituted specific current good manufacturing practice (CGMP) requirements in 21 Code of Federal Regulations (CFR) part 212.[4] These requirements ensure that the PET radiopharmaceuticals are manufactured, processed and stored in a safe and appropriate manner. These requirements also cover the labelling, packaging and distribution of the PET radiopharmaceuticals. According to Section 212.30(a), PET drug production facilities must provide adequate facilities for maintaining orderly handling of materials and equipment, preventing mix-ups, and preventing contamination of equipment or product caused by substances, personnel, or environmental conditions which could adversely affect the quality of the product.[7] In order to verify compliance with relevant regulations, the FDA inspects manufacturers or processors of FDA-regulated products. An FDA inspection typically focuses on activities that end at the point of final release of a PET drug product in order to ensure compliance with CGMPs.[4]

In Europe, radiopharmaceuticals have been recognized as a special group of medicines. Thus, the preparation and clinical use of PET radiopharmaceuticals have been regulated and variously adopted by member states.[6] A manufacturing authorisation may be issued by the EMA or by a national authority. Additionally, "in-house" small-scale preparation of PET radiopharmaceuticals is allowed without the requirements of a marketing authorization based on various national laws of European countries. The first official recognition of the special status of radiopharmaceuticals came in the EU Clinical Trials Regulations of 2014, wherein it was acknowledged the clinical trials of diagnostic radiopharmaceuticals did not fall within the regulations.[1] Clinical trials are therefore conducted according to the guidelines of the International Conference on Harmonisation (ICH) for pharmaceutical trials. Trials must also be conducted according to good clinical practice (GCP), which ensures the quality of data obtained from the trial and ensures the safety of trial subjects.[8] According to Nuclear Medicine Europe (NMEU) "current regulatory guidelines do not take account of the particular needs of radiopharmaceuticals (microdoses, half-lives, production specificities) when it comes to developing new products. These regulatory obstacles delay Europe's market access to radiopharmaceuticals (compared to the US), and result in a) fewer new product approvals in recent years, and b) many EU patients lacking access to new diagnoses, therapies and treatments for unmet medical needs.[9] The United Kingdom is unique in having a "specials" licence under which a wide range of products that are not commercially viable can be manufactured.[4]

In recognition of this background and to best inform future developments in service provision, the all-Wales PET Programme within the Welsh Health Specialised Services Committee (WHSSC) requested that the NIHR Innovation Observatory (IO) conduct horizon scanning

activities to identify PET radiopharmaceuticals that meet stakeholder requirements. Table 1 details the inclusion criteria for this scan.

Table 1. PET Radiopharmaceuticals in scope

Technology name	Technology use or application	Technology stage of development	Regulatory status and region
18F pharmaceuticals Fluorine-18 pharmaceuticals Fluorine-18 radionuclides N-13 pharmaceuticals O-15 pharmaceuticals Ga-68 pharmaceuticals Rb-82 pharmaceuticals Zr radiopharmaceuticals Cu radiopharmaceuticals Sc radiopharmaceuticals	Diagnostic (PET; PET CT)	Preclinical Phase 2 Phase 3	Not approved Unable to find Investigational Medicinal Product Special License

Methods

Horizon Scanning for PET Radiopharmaceutical Technologies

The horizon scanning methodologies developed by the IO to identify the pipeline of PET radiopharmaceutical technologies currently in clinical trials and at pre-clinical stage, involved the identification of information sources that detected 'signals' for PET radiopharmaceuticals technologies. The collection of primary and secondary sources was systematically scanned using a combination of traditional scanning methods (manual), automated and novel AI/machine learning techniques.

Search Strategy and Sources

For the scans performed, specific search strategies were developed, and key terms were combined with Boolean operators (where applicable). This allowed the searches to be more precise and targeted, which in turn yielded higher quality results. By using Boolean operators, it was possible to exclude irrelevant results and find more relevant information. A comprehensive list of keywords was compiled by the IO Team, based on project proposal terminology and further reading on the topic. In addition, members of the IO Team attended

the International Symposium on Trends in Radiopharmaceuticals (ISTR-2023) to gain an insight of the pipeline of emerging radiopharmaceuticals in April 2023 which led to the identification of main manufacturers in this field globally.

Information sources used as part of these scans included:

- Clinicaltrials.gov trial registry, used to identify clinical trials in development largely in the US but also in global trial locations
- ScanMedicine[a],the IO's clinical trial database containing information from 11 registries across the globe (e.g. UK, Europe, USA) was used to identify European trials
- BiomedTracker
- Embase
- MHRA products database
- EMA website

Clinical trials

Following an agreed project proposal in May 2023, we undertook searches for clinical trials in early phase 1[b], phase 2 and 3 in the US clinical trial register and IO's searching system, ScanMedicine. Our searches identified 5,816 clinical trials which were downloaded for screening as an Excel spreadsheet. Through the sifting process we identified 818 relevant clinical trials investigating PET radiopharmaceutical technologies mentioned in figure 1 in development for diagnostic purposes. After consultation with the stakeholders, early phase 1 were excluded. The final analysis included 644 relevant clinical trials. Search strategy for the clinical trial searches is presented in Appendix 2. For the purpose of analysis, clinical trials that were investigating more than one radionuclide or radiopharmaceutical, were split into rows. 644 rows based on unique clinical trial IDs after splitting clinical trials based on radionuclides led to a row count of 663. A further splitting of rows based on radiopharmaceuticals led to a row count of 699.

News

News scanning is a method for capturing recent most up-to-date events in the field of study. News sources also provide an opportunity to gather a variety of perspectives on the topic, which can inform the research findings. A search on BiomedTracker, a third-party database provided by Informa[10], was used to search for soft intelligence in 'radiopharmaceuticals' emerged within the last year (August 2022 – August 2023). The searches were undertaken by one information specialist on 15 August 2023 and results were downloaded into a spreadsheet for further analysis. An overview of recent activity captured through news scanning is presented in the results section of this report.

[a] https://scanmedicine.com/

[b] Early phase 1 clinical trials are conducted before phase 1 clinical trials and after preclinical studies. These were included in the first instance as preclinical studies were in remit.

Preclinical studies

The process of PET radiopharmaceutical development can be broadly divided into two stages: preclinical and clinical. Preclinical stage involves synthesizing the radionuclide, testing its characteristics and stability, and evaluating its safety and dosimetry. The clinical stage involves testing the safety and efficacy of the product in humans. A bibliographic database search strategy for pre-clinical studies in the radioisotopes of interest was devised and run on Embase (Ovid). The search strategy was designed by one information specialist and checked by a second information specialist. No date, language or publication type limits were imposed. The search was designed to identify research activity at pre-clinical stage, broadly defined as the pharmaceutical development stages before entering in human clinical trials. The searches were run on 29th of August 2023 and records were exported into a reference management system (EndNote 20, Clarivate Analytics, US) for de-duplication. The full Embase search strategy is provided in Appendix 1.

A total of 2,620 records were retrieved and used for the final analysis. A total of nine subgroups were generated from searching the name of the radioisotope of interest in the title of the record. The following subgroups were created for records that contained any of the radioisotopes of interest in title (F18=885, 13N=8, 15O=22, 68G=264, 82Rb=4, Cu=91, Sc=9, Zr=51), the remaining 1,289 records that did not contain any of the radioisotopes names in title but may contain relevant key words in the abstracts or key word fields, were grouped together for analysis.

The analysis of pre-clinical research activity was conducted using VOSViewer, an open access software developed by van Eck and Waltman of Leiden University that employs the visualisation of similarities (VOS) method to cluster terms based on their frequency counts and their relationships.[11] As a result, we have produced network visualisations for each of the following subgroups of records: F-18, Ga-68, Cu and Zr. It was determined that it would not be appropriate to perform network analyses for the remaining sub groups (Rb-82, Sc, O-15, N-13) due to the small number of records. A list of records is included in Appendix 4 for reference. The remaining group of records, those without relevant radioisotopes in the title, were analysed using a density map to determine high term aggregation and emerging research areas in the periphery of the map. More information can be found in the results section.

Inclusion criteria

All radiopharmaceutical technologies included in the scan had to meet the criteria outlined in table 1. All technologies were further classified, and a pilot data extraction form was shared with stakeholders for approval in June 2023. This was done to ensure that the data extraction form would accurately capture the different technologies to be evaluated and that stakeholders would have the opportunity to review and provide feedback.

Classification of PET radiopharmaceutical technologies:

- General information: trial title and trial status (as agreed on project proposal)

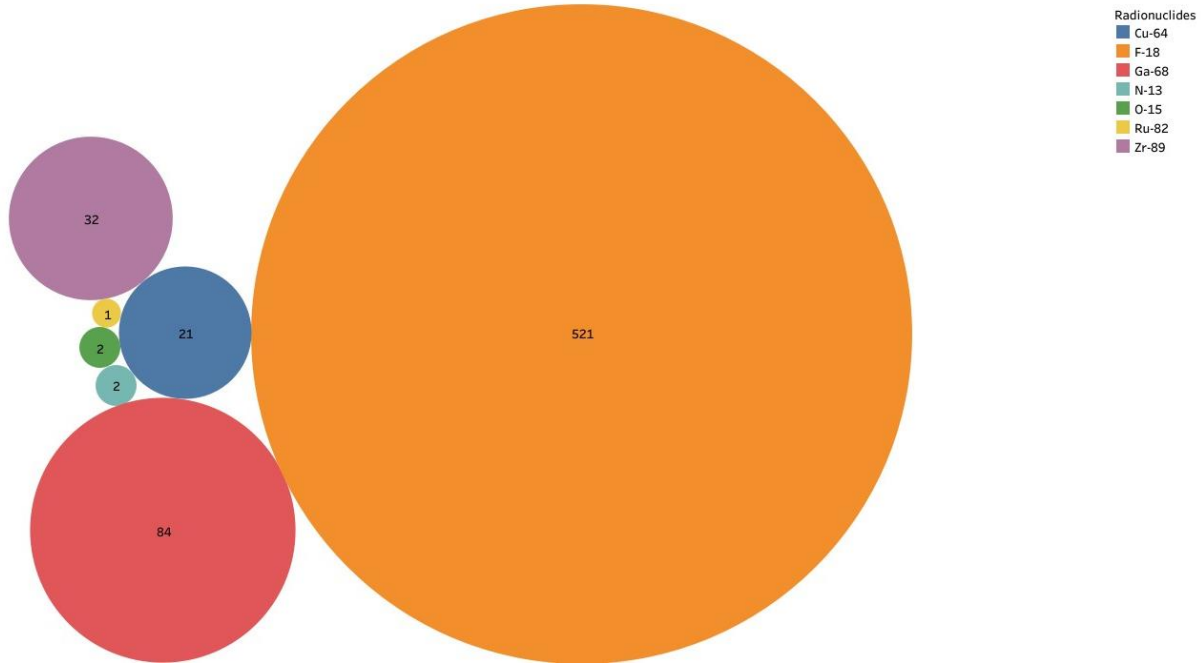
- Product information: name of intervention, name of radioisotope, and classification of radiopharmaceutical
- Patient group: indication, therapeutic area (NICE categories), cancer or non-cancer, gender and age of participants
- Trial information: trial ID, phase, availability of trial results, outcome measures, N of enrolled participants or target, further study design information, date of start and end of trial, sponsor, funding organisations, location of trial recruitment and URL.
- Regulatory information of technology in trial, later enriched with information gathered from MHRA and EMA websites.

Results

Product Pipeline

Out of the 644 clinical trials identified, a large majority were investigating F-18 (521, ~81%) for diagnostic purposes (Figure 1). This is likely due to the fact that F-18 is the most widely used radionuclide for PET imaging in clinical setting for several indications. This was followed by Ga-68 (84, ~13%) and Zr-89 (32, ~5%), which are used in lower quantities in clinical settings. Cu-64 (21, 3%), O-15 (2, 0.3%), N-13 (2, 0.3%), and Rb-82 (1, 0.1%) are used in much lower quantities, hence the small number of trials involving these radionuclides. No clinical trials were identified for scandium. This may be because there is a lack of scientific evidence that this element has beneficial effects on human health. Additionally, scandium may be too expensive or difficult to obtain for use in clinical trials. Furthermore, our scan identified 151 radiopharmaceuticals being investigated in clinical trials which have been categorised according to radionuclides in figure 2-5.

Figure 1: Volume of ongoing trial activity for radiopharmaceutical technologies Cu-64, F-18, Ga-68, N-13, O-15, Rb-82, Zr-89



F-18

We found 521 clinical trials investigating radiopharmaceuticals when radiolabelled with F-18. Majority of those clinical trials (359) included radiopharmaceuticals that were not licensed for the indications being investigated. Certain licensed radiopharmaceuticals such as fluorodeoxyglucose (FDG), florbetapir, fluorocholine, piflufolastat, fluoromisonidazole and fluoroestradiol showed a higher volume of clinical trials. Several of the indications that they are being investigated in are already licensed by the MHRA/EMA, however, the scan identified some new indications in clinical development. A few of these new indications include, cervical cancer, stomach cancer and renal cancer for FDG; neurological conditions, diabetes and endocrine disorders and mental health conditions for florbetapir; and thyroid cancer, liver cancer, breast cancer and cardiovascular conditions for fluorocholine. Other new indications for already licensed or unlicensed radiopharmaceuticals radiolabelled with F-18 identified in this scan can be seen in figure 2.

Figure 2: Indications in clinical trials for F-18

Radiopharmaceuticals	Indications	Regulatory authority	Regulatory status: Licensed	Regulatory status: Not licensed
92 probe	Neurological conditions	N/A		1
A-85380	Neurological conditions	N/A		1
AIF-NOTA-neurotensin	Prostate cancer	N/A		1
AIF-NOTA-octreotide	Others	N/A		2
APN-1607	Neurological conditions	N/A		3
Arabinosyl guanine	Mulitple cancers	N/A		1
	Lung cancer	N/A		1
AZD4694	Neurological conditions	N/A		1
C-SNAT4	Lung cancer	N/A		1
CETO	Diabetes and other endocrinal, nutritio..	N/A		1
Choline	Prostate cancer	MHRA	1	
		N/A		4
	N/A	N/A		1
	Mulitple cancers	N/A		1
	Diabetes and other endocrinal, nutritio..	N/A		1
	Cardiovascular conditions	N/A		1
	Brain cancer	N/A		1
	Bladder cancer	N/A		1
CTT1057	Prostate cancer	N/A		2
DCFBC	Prostate cancer	N/A		1
	Metastases	N/A		1
Dota-noc	Respiratory conditions	N/A		1
DPA-714	Neurological conditions	N/A		7
	Infections	N/A		2
	Breast cancer	N/A		2
	Brain cancer	N/A		1
DTBZ	Neurological conditions	N/A		7
Durvalumab	Head and neck cancer	N/A		1
EF5	Head and neck cancer	N/A		1
Fallypride	N/A	N/A		1
FAPI-74	Mulitple cancers	N/A		1
FAZA	Renal cancer	N/A		1
	Others	N/A		1
	Lung cancer	N/A		1
	Brain cancer	N/A		1
FB-IL2	Neurological conditions	N/A		1
FCPHA	Cardiovascular conditions	N/A		1
FDDNP	Neurological conditions	N/A		2
FDHT	Metastases	N/A		5
	Breast cancer	N/A		1
FE-PE2I	Neurological conditions	N/A		1
FHBG	Neurological conditions	N/A		1
Florastamin	Prostate cancer	N/A		1
Florbenazine	Neurological conditions	N/A		3
	N/A	N/A		1
Florbetaben	Neurological conditions	MHRA	10	
	Cardiovascular conditions	N/A		3
Florbetapir	Neurological conditions	MHRA	24	
		N/A		7
	Mental health, behavioural and neurod..	N/A		1
	Diabetes and other endocrinal, nutritio..	N/A		1
Florilglutamic acid	Brain cancer	N/A		1

Number of clinical tri.. 1 24

Flortaucipir	Neurological conditions	MHRA	5	
		N/A		11
	N/A	N/A		2
Fluciclatide	Mulitple cancers	N/A		5
	Renal cancer	N/A		1
Fluciclovine	Prostate cancer	EMA	9	
		MHRA	4	
	Metastases	EMA	2	
		N/A		4
	Brain cancer	N/A		4
Fludeoxyglucose	Lung cancer	EMA	1	
Fluorochlorine	Prostate cancer	N/A		1
Fluorocholine	Prostate cancer	EMA	5	
		N/A		8
	Diabetes and other endocrinal,	EMA	1	
	nutritional and metabolic conditions	N/A		4
	Thyroid cancer	N/A		2
	Multiple conditions	EMA	1	
		N/A		1
	Metastases	N/A		2
	Liver cancer	N/A		2
	Blood and bone marrow cancers	N/A		2
	Cardiovascular conditions	N/A		1
	Breast cancer	N/A		1
Fluorodeoxyglucose	Mulitple cancers	MHRA	9	
		N/A		3
	Lung cancer	MHRA	11	
	Breast cancer	MHRA	9	
	Blood and bone marrow cancers	MHRA	6	
		N/A		3
	Metastases	MHRA	6	
		N/A		1
	Respiratory conditions	MHRA	2	
		N/A		4
	Neurological conditions	MHRA	4	
		N/A		1
	Head and neck cancer	MHRA	4	
	Cervical cancer	MHRA	1	
		N/A		3
	Others	EMA	1	
		N/A		2
	Cardiovascular conditions	N/A		3
	Skin cancer	MHRA	2	
	Renal cancer	N/A		2
	Musculoskeletal conditions	MHRA	1	
		N/A		1
	Multiple conditions	N/A		2
	Gynaecological conditions	N/A		2
	Bladder cancer	MHRA	1	
		N/A		1
	Thyroid cancer	MHRA	1	
	Stomach cancer	N/A		1
	Penile and testicular cancer	N/A		1
	Ovarian cancer	MHRA	1	
	Digestive tract conditions	N/A		1
	Diabetes and other endocrinal, nutritio..	N/A		1
	Colorectal cancer	MHRA	1	
	Brain cancer	MHRA	1	
	Blood and immune system conditions	N/A		1

Fluorodopa	Diabetes and other endocrinal, nutritional and metabolic conditions	EMA	4	
		N/A		1
	Brain cancer	N/A		5
	Others	EMA	2	
		N/A		2
	Thyroid cancer	EMA	1	
		N/A		1
	Multiple conditions	EMA	2	
	Neurological conditions	EMA	1	
	Mulitple cancers	EMA	1	
	Metastases	N/A		1
Fluoroerytronitroimidazole	Cervical cancer	N/A		1
Fluoroestradiol	Breast cancer	EMA	4	
		MHRA	2	
		N/A		6
	Metastases	EMA	2	
		N/A		4
	Ovarian cancer	N/A		2
	Gynaecological conditions	EMA	1	
Fluoroethoxybenzovesami..	Mental health, behavioural and neurod..	N/A		2
	Neurological conditions	N/A		1
Fluoroethylcholine	Prostate cancer	N/A		4
Fluoroethyltyrosine	Brain cancer	N/A		4
Fluorofuranylnorprogeste..	Gynaecological conditions	N/A		1
	Breast cancer	MHRA	1	
Fluoromisonidazole	Brain cancer	EMA	7	
	Mulitple cancers	EMA	3	
		N/A		1
	Head and neck cancer	EMA	3	
	Prostate cancer	EMA	1	
		N/A		1
	Lung cancer	EMA	2	
	Liver cancer	EMA	1	
		N/A		1
	Neurological conditions	N/A		1
	Cervical cancer	EMA	1	
Fluoropivalate	Mulitple cancers	N/A		1
Fluorothymidine	Breast cancer	N/A		4
	Blood and bone marrow cancers	N/A		3
	Mulitple cancers	N/A		2
	Lung cancer	MHRA	1	
		N/A		1
	Brain cancer	N/A		2
	Renal cancer	N/A		1
	Pancreatic cancer	N/A		1
	Metastases	N/A		1
Fluorthanatrace	Breast cancer	N/A		1
Flurpiridaz	Cardiovascular conditions	N/A		4
Flutematamol	Cardiovascular conditions	N/A		1
Flutemetamol	Neurological conditions	MHRA	13	
		N/A		2
	N/A	N/A		1
	Mental health, behavioural and neurod..	MHRA	1	
	Diabetes and other endocrinal, nutritio..	MHRA	1	
	Cardiovascular conditions	MHRA	1	
	Breast cancer	MHRA	1	
FPCIT	Neurological conditions	N/A		1
FPPRGD2	Mulitple cancers	N/A		1
FPyGal	Mulitple cancers	N/A		1
FSPG	Mulitple cancers	N/A		1
	Lung cancer	MHRA	1	
	Digestive tract conditions	N/A		1
	Cardiovascular conditions	N/A		1

FTC 146	Blood and bone marrow cancers	N/A		1
GEH120714	Neurological conditions	N/A		1
Gozetotide	Prostate cancer	N/A		4
	Thyroid cancer	N/A		2
GP1	Cardiovascular conditions	N/A		1
GTP1	Neurological conditions	N/A		1
HBED-CC PSMA	Thyroid cancer	N/A		1
HX4	Mulitple cancers	N/A		3
	Head and neck cancer	N/A		1
	Cervical cancer	N/A		1
Hydroxyl Dendrimer	Neurological conditions	N/A		1
JK-PSMA-7	Prostate cancer	N/A		1
K5-RGD	Metastases	N/A		1
LBT-999	Neurological conditions	N/A		1
lortaucipir	Neurological conditions	MHRA	1	
MC225	Neurological conditions	N/A		1
Meta-fluorobenzylguanidi..	Others	N/A		4
	Cardiovascular conditions	N/A		1
mFBG	Others	N/A		1
MFES	Breast cancer	N/A		1
MK-6240	Neurological conditions	N/A		3
	Diabetes and other endocrinal, nutritio..	N/A		1
ML-10	Metastases	N/A		2
	Mulitple cancers	N/A		1
NAV4694	Neurological conditions	N/A		3
PBR06	Neurological conditions	N/A		4
PEG folate	Ovarian cancer	N/A		1
	Neurological conditions	N/A		1
PI-2620	Neurological conditions	N/A		6
Piflufolastat	Prostate cancer	EMA	21	
	Metastases	EMA	2	
		N/A		1
	Liver cancer	N/A		2
	Pancreatic cancer	N/A		1
	Mulitple cancers	N/A		1
Piflufolastat, PSMA	Prostate cancer	EMA	1	
PM-PBB3	Neurological conditions	N/A		2
PMPBB3	Neurological conditions	MHRA	1	
		N/A		1
PSMA	Prostate cancer	EMA	1	
		N/A		3
	Mulitple cancers	N/A		2
PSMA-617	Prostate cancer	N/A		1
PSMA-1007	Prostate cancer	N/A		14
	Mulitple cancers	N/A		1
	Metastases	N/A		1
	Brain cancer	N/A		1
RGD-K5	Mulitple cancers	N/A		1
rhPSMA-7.3	Prostate cancer	EMA	5	
		N/A		2
RO6958948	Neurological conditions	N/A		1
Sodium fluoride	Metastases	EMA	5	
	Cardiovascular conditions	N/A		3
	Blood and bone marrow cancers	N/A		2
	Renal cancer	N/A		1
	Neurological conditions	N/A		1
	Multiple conditions	N/A		1
SYN2	Cardiovascular conditions	N/A		1
THK-5351	Neurological conditions	MHRA	1	
		N/A		3
	Mental health, behavioural and neurod..	N/A		1
Thretide	Prostate cancer	N/A		1
Triphenylphosphonium	Cardiovascular conditions	N/A		1
Water	Cardiovascular conditions	N/A		1
XTR003	Cardiovascular conditions	N/A		1
XTR004	Cardiovascular conditions	N/A		1

Ga-68

Ga-68 had the second most number of clinical trials identified as shown in figure 1. Only three radiopharmaceuticals namely dotatate, edotreotide, and gozetotide are licensed by MHRA/EMA for certain conditions shown in figure 3. Our scan includes thirty-three radiopharmaceuticals that are not yet licensed for diagnostic purposes when radiolabelled with Ga-68.

Figure 3: Indications in clinical trials for Ga-68

Radiopharmaceuticals	Indications	Regulatory authority	Regulatory status: Licensed	Regulatory status: Not licensed
ABY-025	Mulitple cancers	N/A		1
	Breast cancer	N/A		1
Deferoxamine	Infections	N/A		1
Dolacga	Liver cancer	N/A		1
Dota-E-(cRGDfK)2	Head and neck cancer	N/A		1
Dota-MGS5	Mulitple cancers	N/A		1
Dota-noc	Multiple conditions	N/A		1
Dota-SSTR	Blood and bone marrow cancers	N/A		1
Dotatate	Thyroid cancer	N/A		2
	Others	N/A		1
	Neurological conditions	N/A		1
	Mulitple cancers	N/A		1
	Metastases	N/A		1
	Head and neck cancer	MHRA	1	
	Diabetes and other endocrinal, nutritio..	N/A		1
	Brain cancer	N/A		1
Edotreotide	Mulitple cancers	MHRA	3	
	Diabetes and other endocrinal, nutritio..	N/A		1
	Cardiovascular conditions	N/A		1
FAP-2286	Mulitple cancers	N/A		1
FAP-CHX	Mulitple cancers	N/A		1
FAP-RGD	Mulitple cancers	N/A		1
FAPI	Digestive tract conditions	N/A		1
FAPI-04	Ovarian cancer	N/A		1
FAPI-46	Pancreatic cancer	N/A		2
	Mulitple cancers	N/A		1
	Lung cancer	N/A		1
Gozetotide	Prostate cancer	EMA	3	
		MHRA	17	
	Metastases	MHRA	2	
	Liver cancer	N/A		2
	Lung cancer	MHRA		1
HBED-CC PSMA	Prostate cancer	N/A		10
MAA	Lung cancer	N/A		1
NeoB	Stomach cancer	N/A		1
	Breast cancer	N/A		1
NeoB, PSMA-R2	Prostate cancer	N/A		1
NODAGA-exendin-4	Diabetes and other endocrinal, nutritio..	N/A		1
NODAGA-RGD	Metastases	N/A		1
NOTA-AE105	Bladder cancer	N/A		1
NOTA-Anti-HER2 VHH1	Mulitple cancers	N/A		1
NY104	Metastases	N/A		1
ODAGA-RGD	Cardiovascular conditions	N/A		1
P16-093	Breast cancer	N/A		1
PEG-αvβ3-Integrin Adhesi..	Breast cancer	N/A		1
Pentixafor	Diabetes and other endocrinal, nutritio..	N/A		1
PSMA	Prostate cancer	N/A		2
PSMA-617	Prostate cancer	N/A		1
RGD	Lung cancer	N/A		1
RM2	Prostate cancer	N/A		1

Number of clinical tri.. 1 17

Cu-64

Out of the 21 clinical trials identified for Cu-64, two trials were found to be investigating already licensed radiopharmaceuticals, copper chloride and dotatate. We identified nine new radiopharmaceuticals that are being investigated for diagnostic purposes when radiolabelled with Cu-64 (figure 4).

Figure 4: Indications in clinical trials for Cu-64

Radiopharmaceuticals	Indications	Regulatory authority	Regulatory status	Number of clincial tri..
ATSM	Colorectal cancer	N/A	Not licensed	1
Copper chloride	Diabetes and other endocrinal, nutritional and metabolic conditions	MHRA	Licensed	1
	Metastases	MHRA	Licensed	1
	Penile and testicular cancer	MHRA	Licensed	1
	Prostate cancer	MHRA	Licensed	3
Dota-trastuzumab	Breast cancer	N/A	Not licensed	1
Dotatate	Cardiovascular conditions	MHRA	Licensed	1
	Metastases	N/A	Not licensed	1
	Others	N/A	Not licensed	1
FBP8	Neurological conditions	N/A	Not licensed	1
Fluorodeoxyglucose	Cardiovascular conditions	MHRA	Licensed	1
Granzyme B	Mulitple cancers	N/A	Not licensed	1
PSMA I&T	Metastases	N/A	Not licensed	1
SAR-bisPSMA	Prostate cancer	N/A	Not licensed	3
SAR-Bombesin	Prostate cancer	N/A	Not licensed	2
SARTATE	Others	N/A	Not licensed	1
Thiosemicarbazone	Cardiovascular conditions	N/A	Not licensed	1

Number of clincial tri.. 1 3

N-13, O-15, Ru-82, Zr-89

We performed a combined analysis of N-13, O-15, Ru-82, and Zr-89, since the number of trials investigating these radionuclides were few (figure 5). N-13 ammonia is being trialled for two new indications and has not been licensed for use by MHRA/EMA. O-15 water is being used to diagnose cardiovascular conditions in two clinical trials and is not licensed for any regulatory authority either.

Zr-89 is being investigated for diagnosis in several clinical trials when conjugated with therapeutic drugs like monoclonal antibodies. Some of these drugs have been marked as licensed for use in figure 5. This is because they are licensed for the indications they are in trials for; however, they are not licensed for diagnosis of those conditions.

Figure 5: Indications in clinical trials for N-13, O-15, Ru-82, Zr-89

N-13, O-15, Ru-82, Zr-89

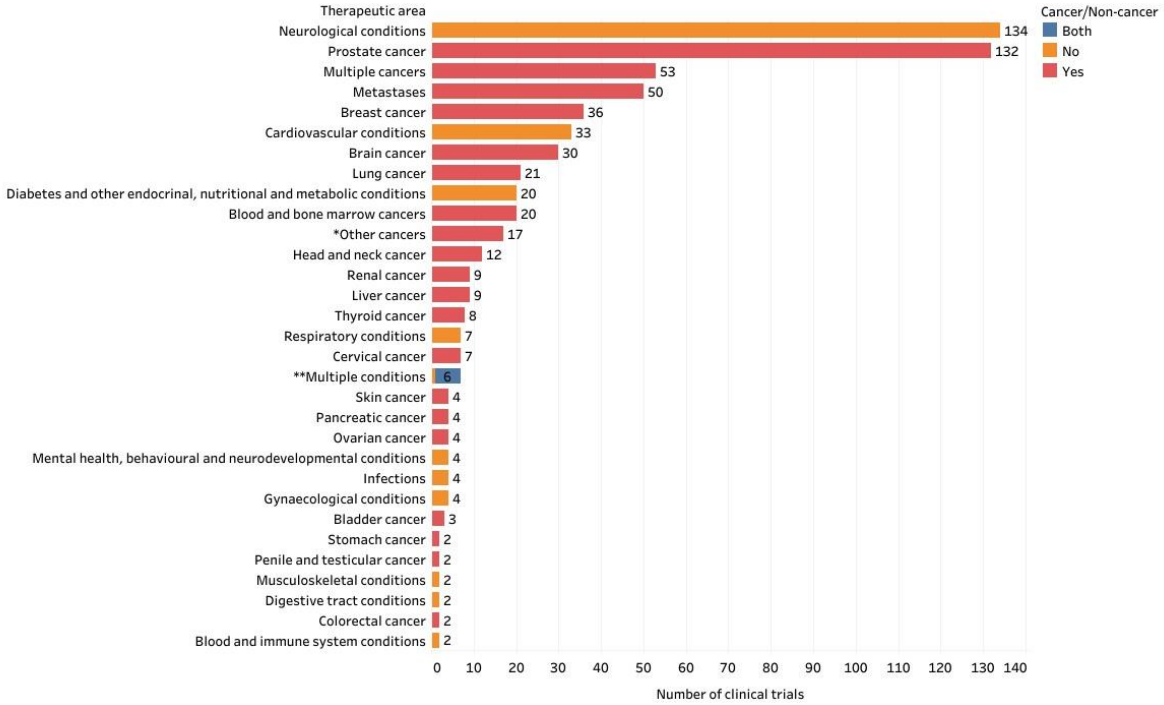
Radionuclides	Radiopharmaceuticals	Indications	Regulatory authority	Regulatory status: Licensed	Regulatory status: Not licensed
N	Ammonia	Respiratory conditions	N/A		1
		Blood and immune system conditions	N/A		1
O	Water	Cardiovascular conditions	N/A		2
Ru	Chloride	Cardiovascular conditions	MHRA	1	
Zr	Atezolizumab	Blood and bone marrow cancers	N/A		1
	Bevacizumab	Neurological conditions	N/A		1
		Cardiovascular conditions	N/A		1
	Crefmirlimab	Skin cancer	N/A		1
		Mulitple cancers	N/A		1
	Crefmirlimab Berdoxam	Mulitple cancers	N/A		1
	Daratumumab	Blood and bone marrow cancers	MHRA	2	
	Df-IAB2M	Prostate cancer	N/A		2
		Metastases	N/A		1
	Df-IAB22M2C	Mulitple cancers	N/A		1
		Infections	N/A		1
	DFO-Atezolizumab	Renal cancer	N/A		1
	DFO-fianlimab	Metastases	N/A		1
	DFO-huJ591	Prostate cancer	N/A		1
	DFO-MSTP2109A	Prostate cancer	N/A		1
	DFO-Nimotuzumab	Mulitple cancers	N/A		1
	Durvalumab	Lung cancer	MHRA	1	
	GC1008	Brain cancer	N/A		1
	Girentuximab	Renal cancer	N/A		3
		Mulitple cancers	N/A		1
		Breast cancer	N/A		1
	Ipilimumab	Skin cancer	MHRA	1	
	Ofatumumab	Blood and bone marrow cancers	N/A		1
	Panitumumab	Head and neck cancer	N/A		1
	Pembrolizumab	Lung cancer	MHRA	1	
	Rituximab	Blood and bone marrow cancers	N/A		1
	Trastuzumab	Metastases	N/A		2
		Breast cancer	MHRA	1	

Number of clinical tri.. 1 3

Therapeutic Area Landscape

A breakdown of the different therapeutic areas for which these technologies are currently being investigated is presented in figure 6. This figure helps to illustrate which areas are receiving the most attention when it comes to advancing the development of these technologies. It also highlights which areas are lagging in terms of research and development.

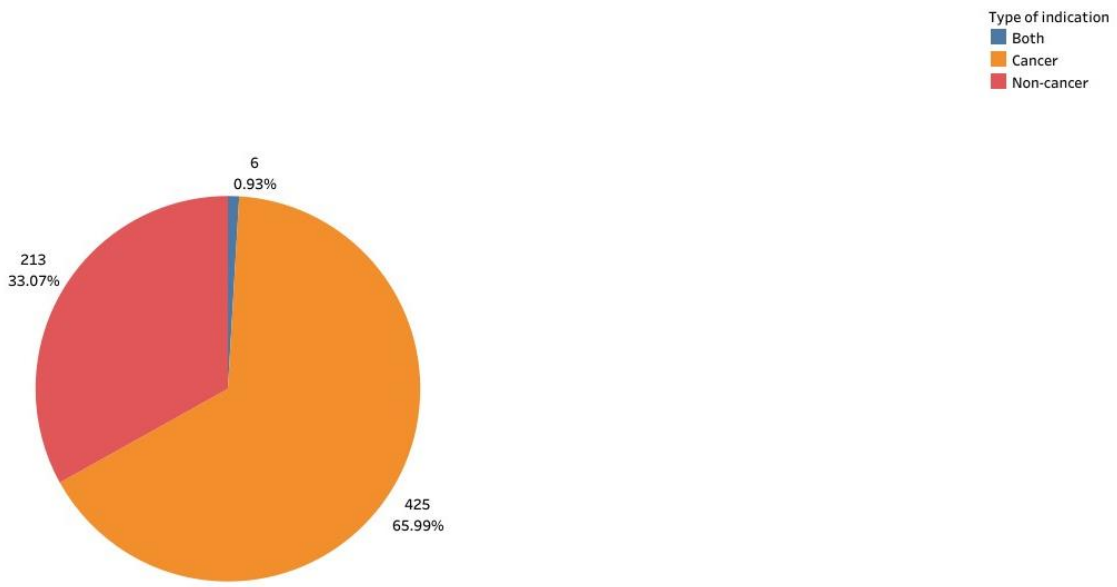
Figure 6: Therapeutic areas being investigated for each radiopharmaceutical in clinical trials according to NICE categorisation



*Others: Trials that included cancer indications that did not appear to fall under the NICE cancer categories; e.g. neuroendocrine tumours, neuroblastomas.
**Multiple conditions: Trials which included both cancer and non-cancer indications or non-cancer indications in more than one organ

Majority of the 644 clinical trials (~66%), were investigating cancer indications while 33% were investigating non-cancer indications (Figure 7). Seven (<1%) clinical trials were found to be investigating both cancer and non-cancer indications.

Figure 7: Number of clinical trials investigating cancer and non-cancer indications



A majority of the clinical trials investigating cancer indications were for prostate cancer, metastatic conditions, multiple cancers, breast cancer, and brain tumours as shown in figure 8. This figure also shows that cancer indications are being diagnosed using radiopharmaceuticals radiolabelled with F-18, Ga-68, Cu-64, and Zr-89. F-18 is the most used radionuclide followed by Ga-68 with very few clinical trials for Cu-64 and Zr-89.

Figure 8: Number of clinical trials for radiopharmaceuticals being investigated for diagnosing cancer indications

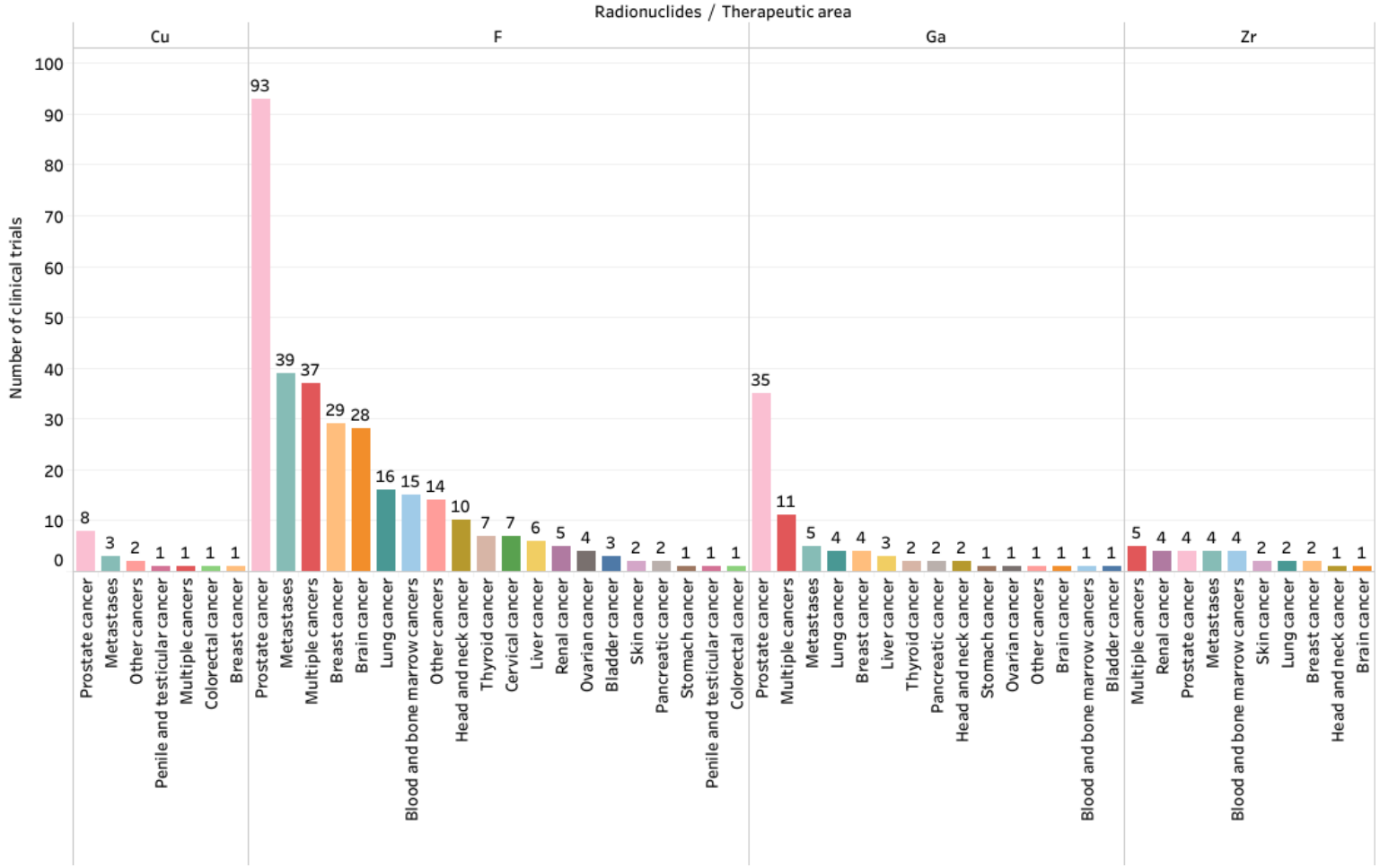


Figure 9: Number of clinical trials for radiopharmaceuticals being investigated for diagnosing non-cancer indications

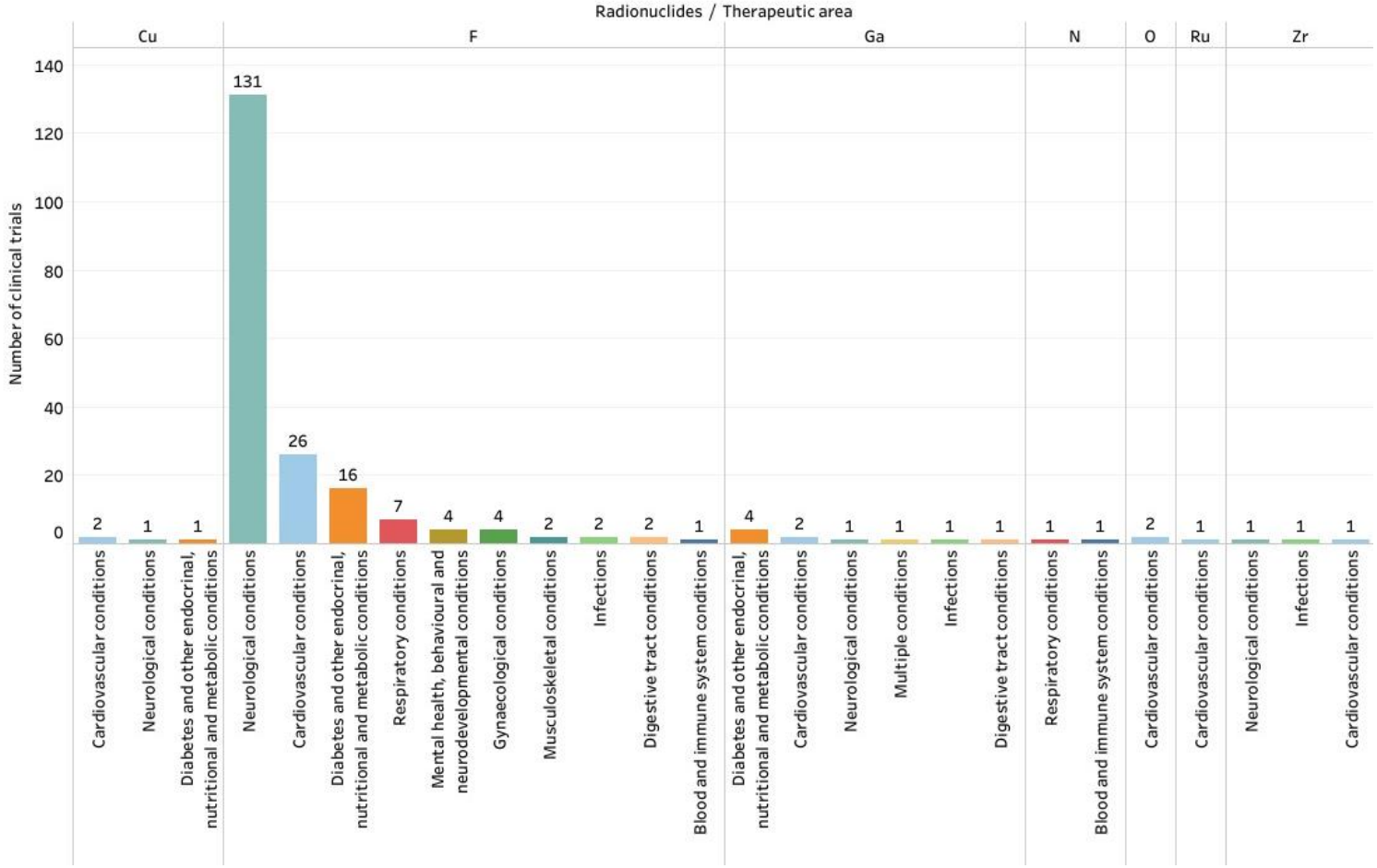
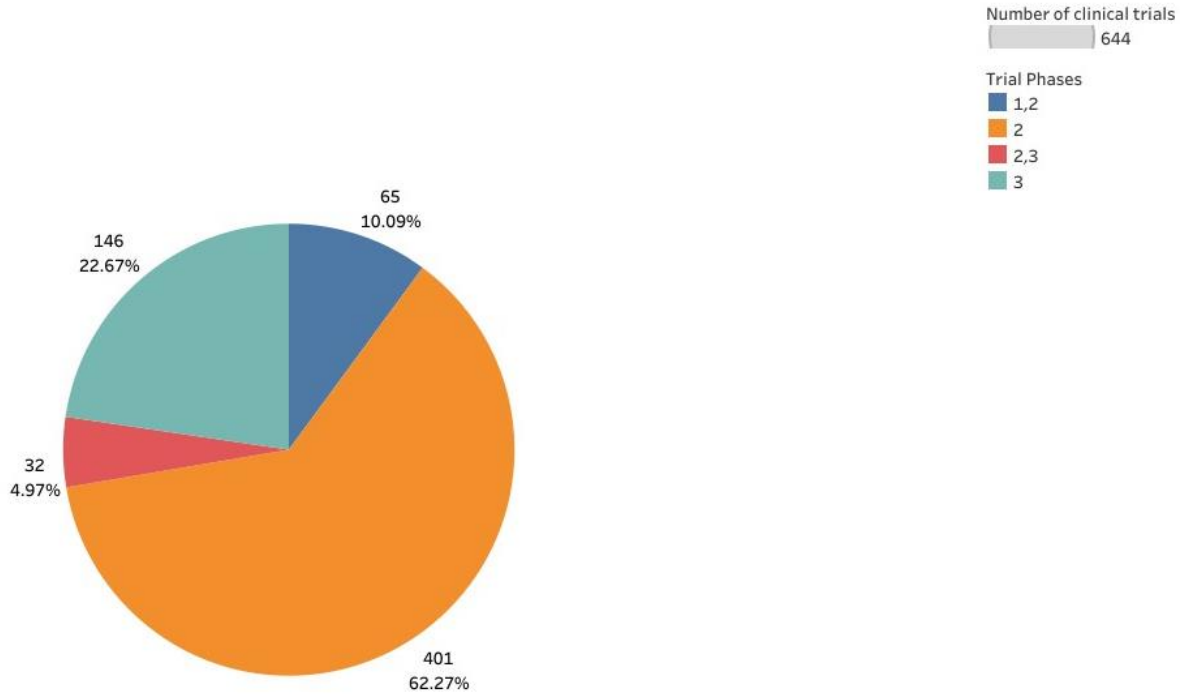


Figure 9 shows non-cancer indications diagnosed with N-13, O-15, and Ru-82, in addition to F-18, Ga-68, Cu-64, and Zr-89, across a wide spread of non-cancer indications. Neurological conditions, cardiovascular conditions, and diabetes and other endocrinal, nutritional and metabolic conditions were the most common non-cancer indications investigated by PET imaging. F-18 was the radiopharmaceutical used the most for diagnosis in the afore-mentioned non-cancer indications, followed by Ga-68, Zr-89 and Cu-64. In fact, F-18 was used the most for imaging for all cancer and non-cancer indication headings.

Clinical Trial Landscape

All radiopharmaceuticals identified have been classified based on their stage of development (phase 1,2 and 2, and phase 2,3 and 3). The majority (401, 62%) of these radiopharmaceuticals were in phase 2 development stage while phase 3 consisted of nearly a quarter of the clinical trials (146, ~23%) (Figure 10).

Figure 10: Number of clinical trials in different stages of development

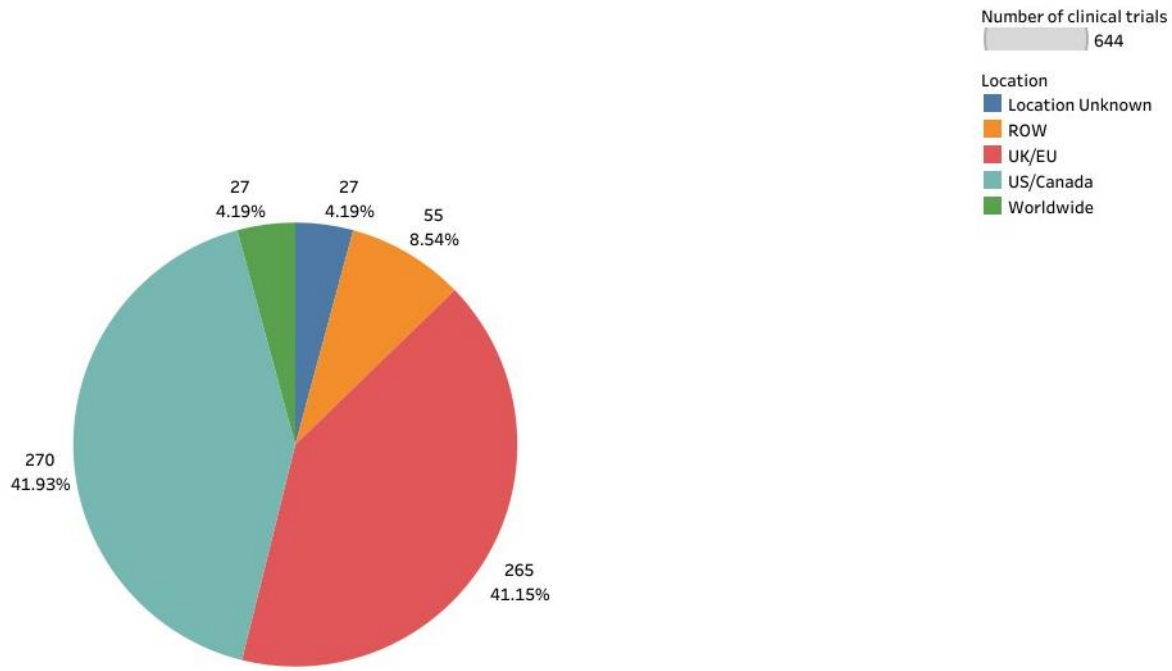


These numbers as illustrated in figure 8,9, and 10 above are important as they reveal the progress being made in terms of clinical trials for new treatments and therapies. They give us an idea of which treatments may be available in the near future and which ones may take longer to develop.

Trial location

An almost equal number of the clinical trials were conducted in locations of US and Canada (271, ~42%), and UK/EU (265, ~41%) while those in ROW (rest of world) locations constituted (56, ~9%) in number (Figure 11). Worldwide locations included trials that had trial locations in more than one of the above location groups and were (27, 4%) in number. The trial locations could not be found for (27, 4%) clinical trials.

Figure 11: Locations of clinical trials



As shown in figure 12, clinical trials being conducted in the UK/EU area are investigating all relevant radiopharmaceuticals.

Figure 12: Locations of clinical trials investigating PET radiopharmaceuticals

Radionuclides	Location Unknown	ROW	UK/EU	US/Canada	Worldwide
Cu-64		2	9	10	
F-18	26	43	217	210	25
Ga-68	3	12	27	41	1
N-13				2	
O-15			1	1	
Ru-82			1		
Zr-89			15	15	2

Location

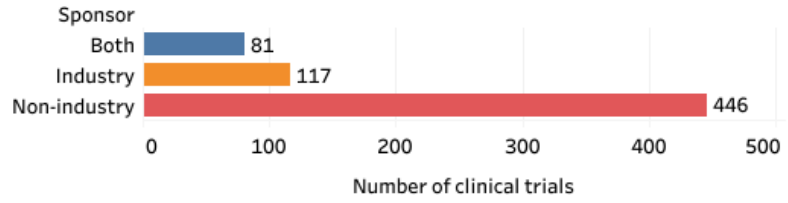
Number of clinical tri..
1 217

Sponsor Information

Our analysis showed that 446 clinical trials (69%) were sponsored by non-industry sponsors. Industry sponsored 117 (18%) clinical trials while 81 (12.5%) clinical trials involved both

industry and non-industry sponsors (Figure 13). These results suggest that non-industry sponsors are more likely to fund clinical trials, while industry sponsors typically collaborate with other entities to fund clinical trials.

Figure 13: Type of sponsors in clinical trials



Our analysis also found that non-industry is more involved in testing radiopharmaceuticals that are not currently in use in clinical practice for the purposes of diagnosis such as Cu-64, O-15, Ga-68, and Zr-89 (Figure 14). This is likely due to the fact that industry is more focused on developing products that are already in use, while non-industry researchers are more likely to be interested in exploring new avenues of research and testing new radiopharmaceuticals.

Figure 14: Number of clinical trials investigating radiopharmaceuticals with sponsor

Radionuclides	Sponsor type: Both	Industry	Non-industry
Cu-64	3	10	8
F-18	65	97	359
Ga-8	5	5	74
N-13		1	1
O-15	1		1
Ru-82		1	
Zr-89	10	6	16

Count of Radionuclid.. 1 359

Manufacturer landscape

From our analysis we have identified industry sponsors conducting clinical trials investigating radiopharmaceuticals. Avid Radiopharmaceuticals is shown to be a key player in the field, sponsoring the vast majority of industry-led clinical trials, as shown in figure 15. Table 2 further summarises which of the various radionuclides under investigation by industry sponsors, as well as the locations of trials conducted by each industry sponsor.

Figure 15: Top 20 industry sponsors

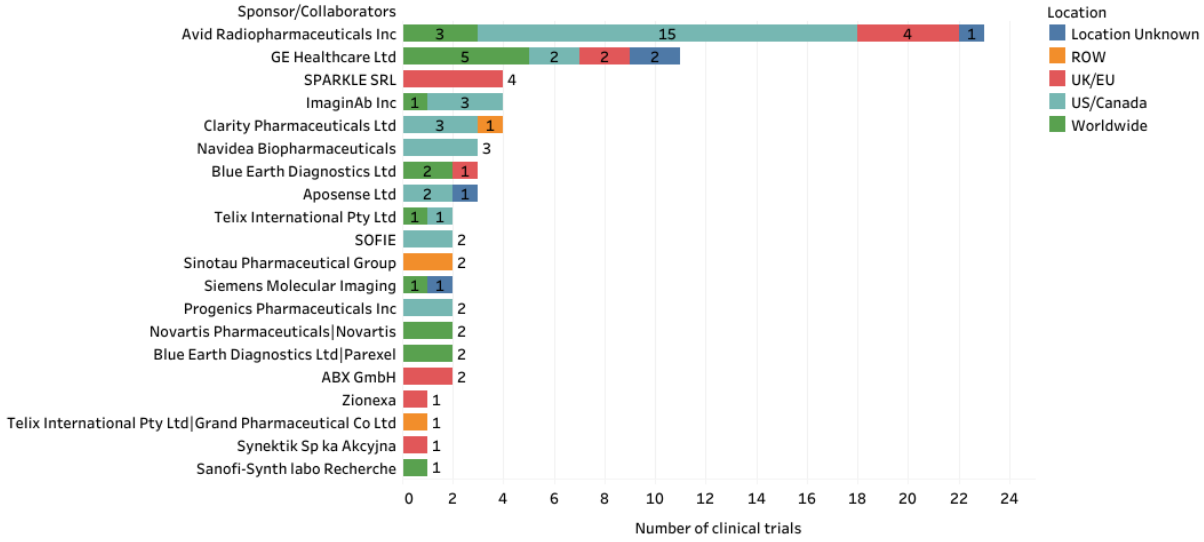


Table 2: List of radionuclides being investigated by industry sponsors identified from clinical trial analysis

Sponsors	Radionuclides	Location	EU or UK
ABX advanced biochemical compounds GmbH	F	Worldwide	
ACR Image Metrix, LLC	F	Worldwide	
Advanced Accelerator Applications	F, Rb	UK/EU	Both
Advanced Imaging Projects, LLC	Ga	ROW	
Advanced Nuclear Medicine Ingredients (acquired by Telix Pharmaceuticals)	F, Ga	UK/EU	EU
Affibody AB	Ga	UK/EU	EU
Amgen	F	US/Canada	
Aposense Ltd.	F	US/Canada	

Sponsors	Radionuclides	Location	EU or UK
APRINOIA Therapeutics	F	Worldwide	
Ashvattha Therapeutics, Inc.	F	US/Canada	
Astellas Pharma Europe Ltd.	F	US/Canada	
AstraZeneca	F, Zr	Worldwide	
Avid Radiopharmaceuticals	F	Worldwide	
Bayer	F, N	US/Canada	
Biokosmos S.A.	F	UK/EU	EU
Blue Earth Diagnostics	F	Worldwide	
Bristol-Myers Squibb	F, Zr	UK/EU	EU
BV Cyclotron VU	F	UK/EU	EU
Cell Point LLC	F	US/Canada	
CellSight Technologies, Inc.	F	US/Canada	
CHU de Bordeaux	F	UK/EU	EU
Cis Bio International	F	UK/EU	EU
Clarity Pharmaceuticals Ltd	Cu	Worldwide	
Curium Pharma	Cu	US/Canada	
Cyclopharma	F	UK/EU	EU
FluoroPharma Medical	F	UK/EU	EU
GE Healthcare	F	Worldwide	
Genentech, Inc.	F, Zr	Worldwide	
Genzyme	F, Zr	Worldwide	
GlaxoSmithKline	F, Zr	Worldwide	
HTA Co., Ltd.	F	ROW	

Sponsors	Radionuclides	Location	EU or UK
IASON GmbH (acquired by Curium Pharma)	F	UK/EU	EU
ICNAS Produção Unipessoal Lda	Ga	UK/EU	EU
ImaginAb, Inc.	Zr	Worldwide	
Innervate Radiopharmaceuticals LLC	F	US/Canada	
Instituto Tecnológico PET	F	UK/EU	EU
IQVIA (formerly Quintiles)	F	US/Canada	
ITEL Telecommunications S.r.l.	F	EU	EU
Janssen Pharmaceuticals	F	UK/EU	EU
Lantheus Medical Imaging, Inc.	F	Worldwide	
Life Molecular Imaging GmbH (formerly Piramal Imaging)	F	Worldwide	
LiteCure LLC	F	US/Canada	
MedTrace Pharma A/S	O	Worldwide	
Merck KGaA	F	UK/EU	EU
Merck Sharp & Dohme LLC	F, Zr	Worldwide	
Navidea Biopharmaceuticals	F	US/Canada	
Novartis Pharmaceuticals	Ga, F	Worldwide	
PETNET Solutions, Inc.	F	UK/EU	UK
Pfizer	F	US/Canada	

Sponsors	Radionuclides	Location	EU or UK
Piramal	F	UK/EU	EU
Pozitron-Diagnostics Ltd.	F	UK/EU	EU
Progenics Pharmaceuticals, Inc.	F	US/Canada	
Proportional Technologies, Inc.	Cu, O	US/Canada	
RadioMedic S.R.O.	F	UK/EU	EU
Radiomedix, Inc.	Cu	US/Canada	
Regeneron Pharmaceuticals	Zr	UK/EU	EU
Roche	F, Zr	Worldwide	
Sanofi	F	Worldwide	
Siemens Molecular Imaging	F	Worldwide	
Sinotau Pharmaceutical Group	F	ROW	
SOFIE	F	US/Canada	
Sparkle SRL	Cu	UK/EU	EU
Synektik SA	F	UK/EU	EU
Telix Pharmaceuticals	F, Zr, Ga	Worldwide	
Threshold Pharmaceuticals (acquired by Molecular Templates)	F	UK/EU	UK
Zionexa	F	UK/EU	EU

Members of the IO team attended the ISTR-2023, which has led to the identification of main manufacturers in this field globally. Table 3 details the list of exhibitors from this conference, along with the radionuclide produced by each exhibitor and the locations in which they operate and/or supply to. It may be important to note that none of the companies from the list of exhibitors have sponsored industry-led clinical trials identified from our scan.

Table 3: List of exhibitors presented at the ISTR-2023 and which radionuclide they produce

Company	Radionuclide Produced	Location
AI4R	N/A	Worldwide
Berthold Technologies GmbH	N/A	EU
Best Cyclotron Systems Inc	^{18}F, ^{13}N, ^{68}Ga, ^{89}Zr, ^{15}O, ^{64}Cu	Worldwide
China Isotope & Radiation Corporation	^{18}F	Worldwide
COMECER	^{82}Rb, Cu, ^{89}Zr, ^{68}Ga, ^{44}Sc,	Worldwide
Eckert & Ziegler Radiopharma GmbH	^{18}F, ^{68}Ga, ^{89}Zr, ^{64}Cu	Worldwide
Eichrom Technologies	^{18}F, ^{68}Ga, ^{44}Sc, ^{89}Zr	Worldwide
Fluidomica Lda.	Other	EU
IBA Radiopharma Solutions	^{18}F, ^{68}Ga, ^{89}Zr, ^{64}Cu, ^{13}N, ^{15}O	Worldwide
Institute of Isotopes Co. Ltd	Other	Worldwide
iPHASE Technologies	^{18}F, ^{68}Ga, ^{89}Zr, ^{64}Cu	Worldwide
Isotopia Molecular Imaging Ltd	^{18}F, ^{68}Ga	Worldwide
Isotope JSC	^{85}Rb, ^{87}Rb, Zr, Cu, ^{68}Ga	Worldwide
ITM Isotope Technologies Munich SE	^{18}F, ^{68}Ga	Worldwide
LabLogic Systems Ltd	N/A	Worldwide
Mediso Medical Imaging Ltd	N/A	Worldwide
MOLECUBES	N/A	Worldwide
Ontario Power Generation	N/A	USA & Canada
Pars Isotope Company	^{18}F, ^{68}Ga, ^{67}Ga	ROW
Ridgeview Instruments AB (Ligand Tracer)	N/A	Worldwide
Rotem GmbH	^{18}F, ^{68}Ga	Worldwide

Scannix	N/A	EU
Shimadzu Handels GmbH	N/A	Worldwide
Sylvia Fedoruk Canadian Centre for Nuclear Innovation Inc.	^{18}F, ^{64}Cu, ^{89}Zr	Canada
Tema Sinergie	^{18}F, ^{68}Ga, ^{64}Cu	Worldwide
TrisKem International	Cu, Sc, Ga, Zr	Worldwide

N/A: company produce instrumentation/hardware for radiopharmaceutical tracing/use

Regulatory information

We identified 151 radiopharmaceuticals in our scan, out of which 126 were not licensed for any indication by MHRA/EMA (Figure 16). Only 25 radiopharmaceuticals identified were licensed. Out of the 25 licensed radiopharmaceuticals, 20 (listed in Figure 16) were licensed by the MHRA, while 5 were only licensed by EMA (Figure 17).

Figure 16: Regulatory status of radiopharmaceuticals

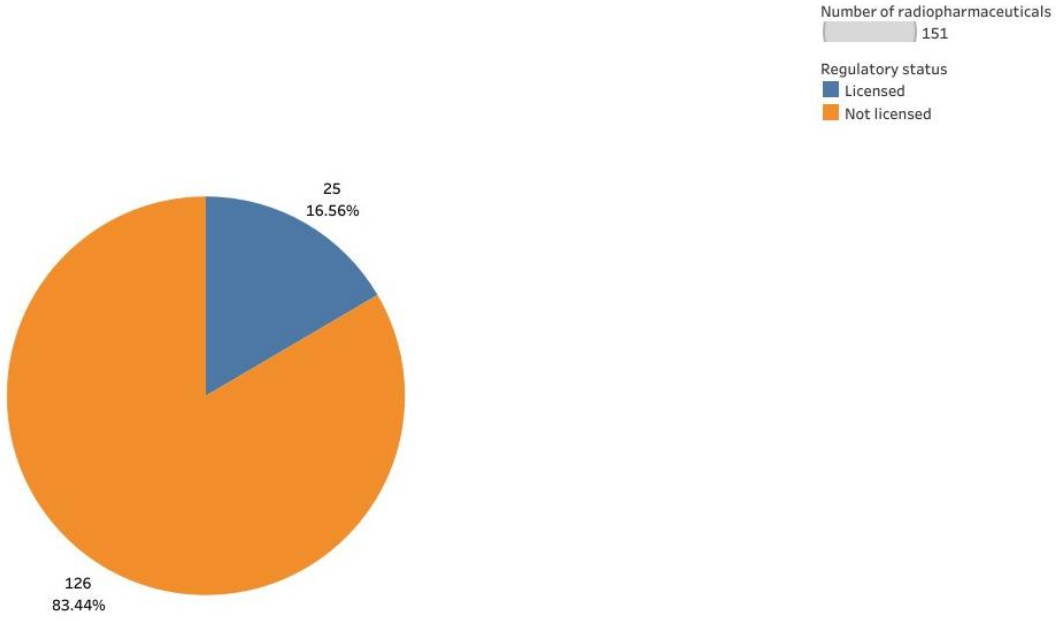


Figure 17a: Regulatory status of radiopharmaceuticals

Regulatory status	Regulatory authority	
Licensed	EMA	5
	MHRA	20
Not licensed	N/A	126

Number of radiophar..
5 126

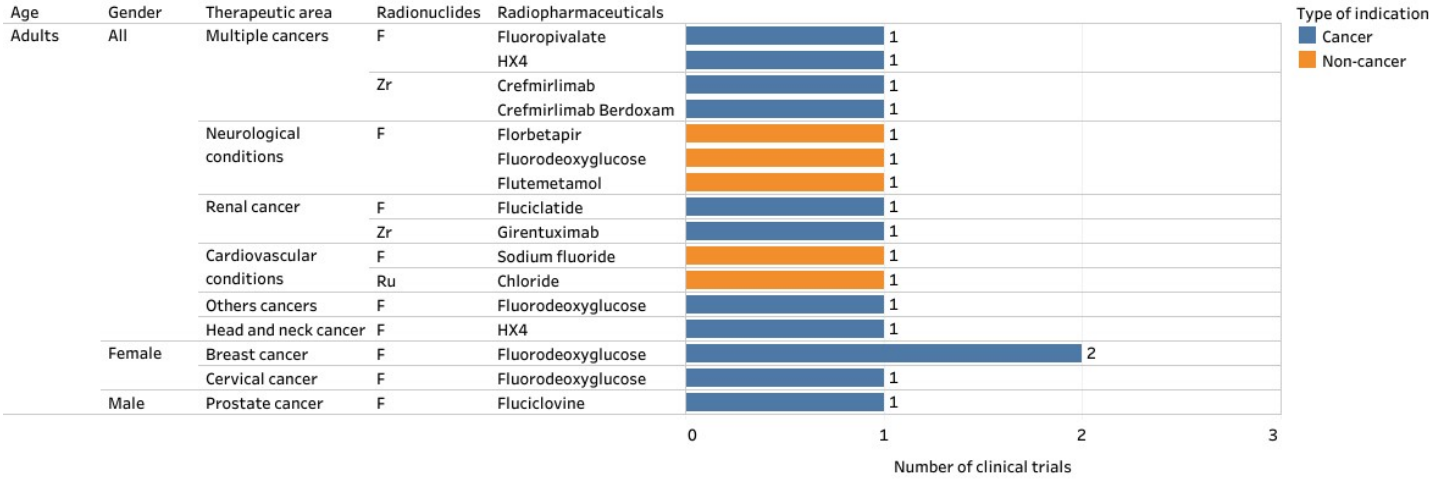
Figure 17b: Licensed radiopharmaceuticals

Radiopharmaceuticals	Regulatory authority
Chloride	MHRA
Copper chloride	MHRA
Daratumumab	MHRA
Dotatate	MHRA
Edotreotide	MHRA
Florbetaben	MHRA
Florbetapir	MHRA
Flortaucipir	MHRA
Fluciclovine	MHRA
Fludeoxyglucose	MHRA
Fluorodopa	EMA
Fluoroestradiol	EMA
Fluorofuranylnorprogesterone	MHRA
Fluoromisonidazole	EMA
Fluorothymidine	MHRA
Flutemetamol	MHRA
FSPG	MHRA
Gozetotide	MHRA
Ipilimumab	MHRA
Iortaucipir	MHRA
Pembrolizumab	MHRA
Piflufolastat	EMA
PMPBB3	MHRA
PSMA	MHRA
Sodium fluoride	EMA

UK Landscape

Narrowing our analysis down to UK trial locations led to a very small subset of 17 clinical trials. All clinical trials were for adult population. Three clinical trials were investigating female population for cervical and breast cancer. One clinical trial was investigating prostate cancer. All cancer and non-cancer indications are shown in figure 18.

Figure 18: UK Landscape of radiopharmaceuticals and therapeutic areas



F-18 was the most used radiopharmaceutical in clinical trials while a very small number was using Zr-89 for diagnosis. One trial was identified in the entire scan that was investigating Ru-82 for cardiovascular conditions (Figure 18).

News and events landscape

As part of our news and events scan, we identified activity in radiopharmaceuticals at various stages of development within the last year (August 2022 to August 2023) (preclinical, investigator-initiated studies, and approved products). Most of these events have focused on the announcement of trial progress (publication of results or the initiation of new trials), however, some have also covered new partnerships or company asset acquisitions that will accelerate the global expansion of some of their pipeline products into new markets.

In 2022 there were a total of 17 events for approved (n=13), investigator initiated trials (n=2) and preclinical studies (n=2). Amongst the approved events of note is the positive CHMP (Committee for Medicinal Products for Human Use) opinion gained in October 2022 for Pluvicto (lutetium Lu 177 vipivotide tetraxetan - Novartis Pharmaceuticals) a Breakthrough designated drug for the treatment of prostate cancer, and subsequent regulatory approval for Europe in December 2022 for the treatment of adult patients with prostate-specific membrane antigen (PSMA)–positive metastatic castration-resistant prostate cancer (mCRPC) in combination with androgen deprivation therapy (ADT) with or without androgen receptor (AR) pathway inhibition.[12] In October 2022, Illuccix (68Ga-HBED-CC-PSMA-11 - Telix Pharmaceuticals Limited, Australia) was approved in Canada for prostate cancer imaging.[13] Top line trial results were announced for Pylarify (PYLCLARI, piflufolastat, 18F-DCFPyL PET/CT - Lantheus Holdings, Inc. US) and Xofigo (Radium-223 Dichloride – Bayer AG) an FDA approved

(2013) radiopharmaceutical for the treatment of men with symptomatic late-stage (metastatic) castration-resistant prostate cancer that has spread to bones but not to other organs.

Furthermore, in 2022 Isoray, Inc. (USA) registered two separate phase 1 and phase ½ investigator initiated trials for neuroendocrine tumours – Imaging and two innovative radiopharmaceuticals for solid tumours present data at two international conferences namely CLR-12120 (Phospholipid Ether + 212b, Cellectar Biosciences, Inc. - US) and PNT2001 (177Lu-PNT2001, POINT Biopharma Global Inc. – Canada).

Between January and August 2023 there were a total of 20 events for approved drugs in prostate cancer and prostate cancer imagining. For the treatment of prostate cancer, Pluvicto became the first targeted radioligand therapy for the treatment of PSMA-positive mCRPC in Canada[14] and Xofigo announced the completion of trial recruitment for their on-going phase 3 clinical trial PEACE III (NCT02194842) for asymptomatic or mildly symptomatic castration resistant prostate cancer patients metastatic to bone.

For prostate cancer imaging, Posluma (18F-rhPSMA-7 PET Imaging, flotufolastat F 18 injection– Bracco Spa., Italy), the first radiohybrid PSMA-targeted PET imaging agent, was approved by the US FDA for PET of PSMA positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.[15] Pylarify received positive CHMP opinion in May 2023 with subsequent regulatory approval gained in July for the detection of PSMA positive lesions with PET in adults with prostate cancer in primary staging of patients with high-risk PCa prior to initial curative therapy and to localize recurrence of prostate cancer in patients with a suspected recurrence based on increasing serum prostate-specific antigen (PSA) levels after primary treatment with curative intent.[16] In March 2023 Illuccix received an FDA approval for a supplementary New Drug Application to enable its use for the selection of patients with metastatic prostate cancer for whom lutetium-177 PSMA-directed therapy is indicated.[17]

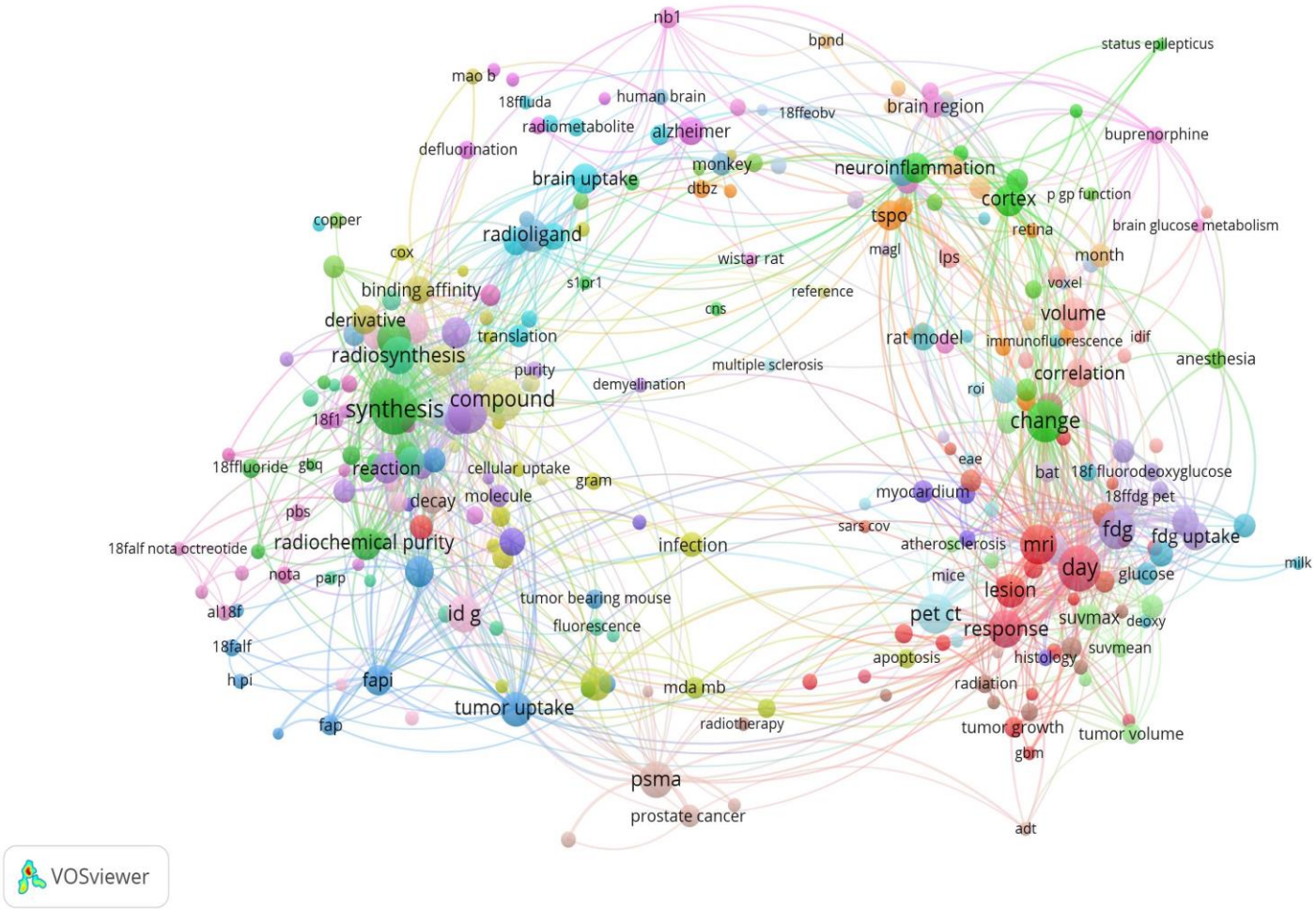
In the preclinical research arena, between January and August 2023, a total of 5 new radiopharmaceuticals announced or demonstrated progress. In summary, two innovative biologics such as AT-02 (Actinium Pharmaceuticals) an anti-HER3 AC225 monoclonal antibody for non-small cell lung cancer that targets ErbB3/HER3[18] and TLX300 (Eli Lilly and Co.) a radiolabelled olaratumab for sarcoma imaging that targets platelet-derived growth factor receptor (PDGFR)[19]; two New Molecular Entities such as FPI-2059 (Fusion Pharmaceuticals Inc.) that targets NT1 (Neurotensin receptor type 1) for colorectal cancer[20] and LNTH-1558 (Lantheus Holdings, Inc.) a small molecule that targets PSMA for prostate cancer imaging[21] and an undisclosed Glypican-3 Targeted Radiopharmaceutical (RayzeBio, Inc.) for Hepatocellular (Liver) Cancer (Including Secondary Metastases).[22]

Preclinical research landscape analysis through network visualisation analyses

A bibliographic database search in Embase (Ovid) was undertaken on 29th August 2023 to identify recent (2020-2023) research activity on radionuclides and PET, no language limits were imposed and conference abstracts were included. A detailed search strategy is included in Appendix 1.

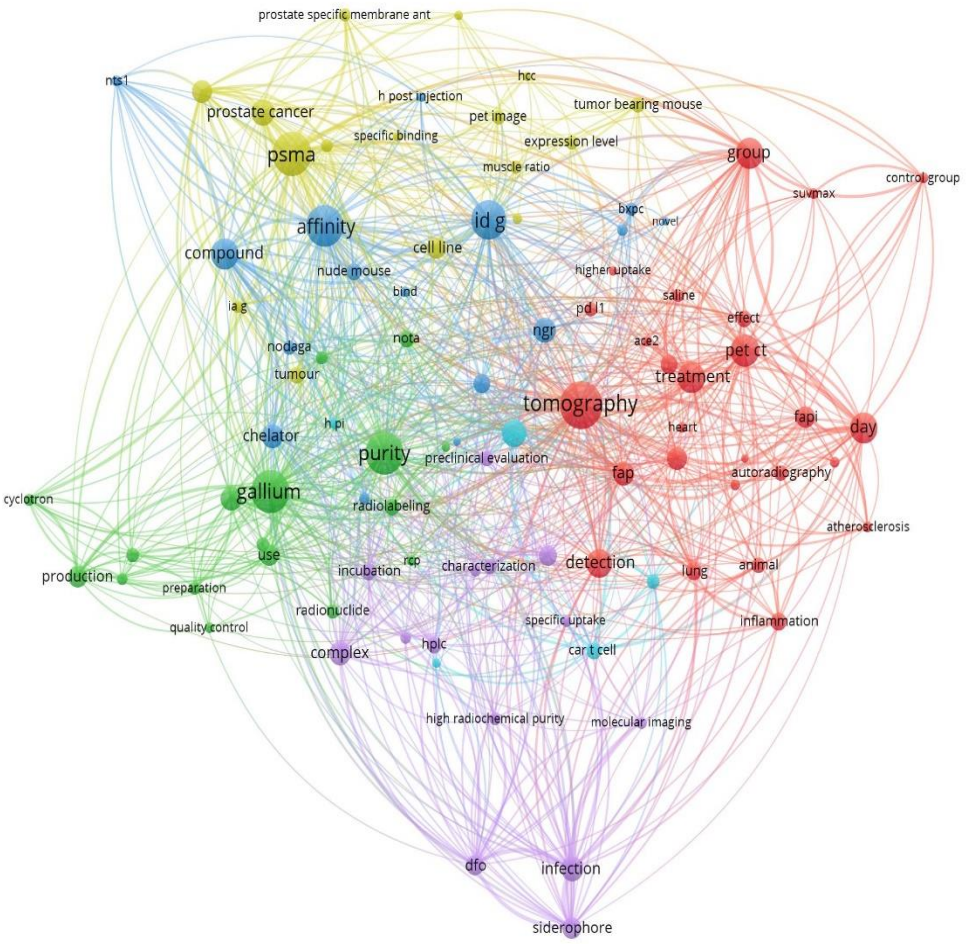
The search identified a total of 2,620 records that were imported into Endnote 20 for further assessment. No screening for inclusion/exclusion was undertaken since the aim of this task was exploratory however, some classification by radioisotope name in title was undertaken by one reviewer and performed in Endnote 20. A total of eight groups were created one per each of the included radioisotopes (F18=885, 13N=8, 15O=22, 68G=264, 82Rb=4, Cu=91, Sc=9, Zr=51). Additionally, one more group was created for all the remaining records (1289) that did not include any of the known radioisotopes in title but included synonymous terms in the abstract and keywords fields. The records were then exported on RIS (Research Information Systems) file format into a visualisation of similarities software (VOSViewer), a free software tool for creating network and density maps based on term co-ocurrence and keyword frequency count. We constructed graphical networks to understand the clustering of the keywords and their degree of dissimilarity to study the connections between keywords in relation to articles that contained the relevant radioisotopes in scope. We excluded *empty* words such as 'article', 'conference abstract' and 'non human'. Figures 19 to 23 present a visual overview of the recent research by radioisotope.

Figure 19: Preclinical research overview for F-18 in title (publication year 2020-2023)



F-18 was included in the title of 885 records retrieved from Embase. A network visualisation analysis of the terms in title and abstract of those records generated thirty-seven different clusters which contained at least 5 terms each. The distance between the clusters represent their relatedness and the size of the labels is determined by the weight of the item. The heavier the weight of an item, the larger the label and the circle of the item. In this instance, the clusters for 'synthesis' and 'radiosynthesis', 'tumour uptake', 'psma', 'lesion' and 'response' appear to have greater weight in the network of related terms. Scattered within the network there are terms with less weight such as 'neuroinflammation' that appears in green in a network with other terms such as 'status epilepticus' and 'cortex' and not distantly related to terms such as 'brain region' which indicates the early research landscape in the field of PET and F-18 for monitoring neuroinflammation.[23-26]

Figure 20: Preclinical research overview of Ga-68 in title (publication year 2020-2023)

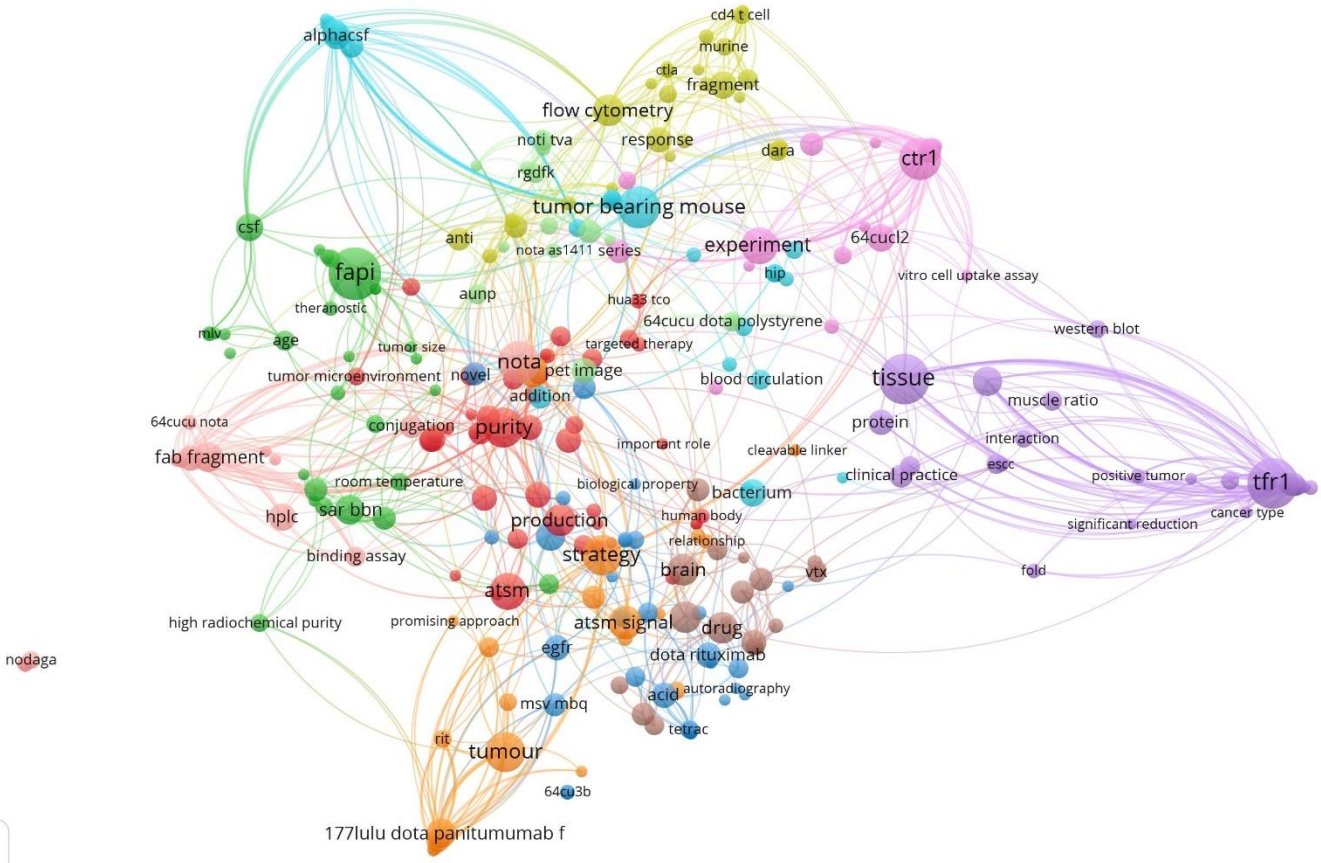


VOSviewer

A total of 264 records were identified that included Ga-68 or a synonym in title. The network visualisation for Ga-68 presents 6 clusters with the smaller cluster including at least 5 related terms. The higher weight in the network is for 'tomography', 'gallium', 'affinity', 'psma' and 'purity'. Distant related terms appear in the periphery of the network and present less weight denoted by the size of the labels. The terms 'cyclotron' and 'production' appear in the same network with 'gallium' and 'purity' although distantly related. Of note, the term 'atherosclerosis' appears in the periphery of a network for 'tomography' 'PET-CT' and 'PET ct imaging' (all in red) indicating the relatedness of these terms in the early scientific landscape.[27-31] Further in the network periphery the term 'siderophore' (purple) appears closely related to 'infection' and 'molecular imaging' all on the same network with 'gallium' and 'PET-CT'. This relationship in the network may signal early research in the use of siderophores radiolabelled with Ga-68 for the identification of bacterial infections via molecular imaging by positron emission tomography (PET).[32-39] Bridging these two networks sits the term 'inflammation' closely related to

'detection' and 'PET-CT' and more distant but still within the same network with 'infection' and '68ge 68ga generator' (which cannot be seen in the picture due to size of node).[40,41]

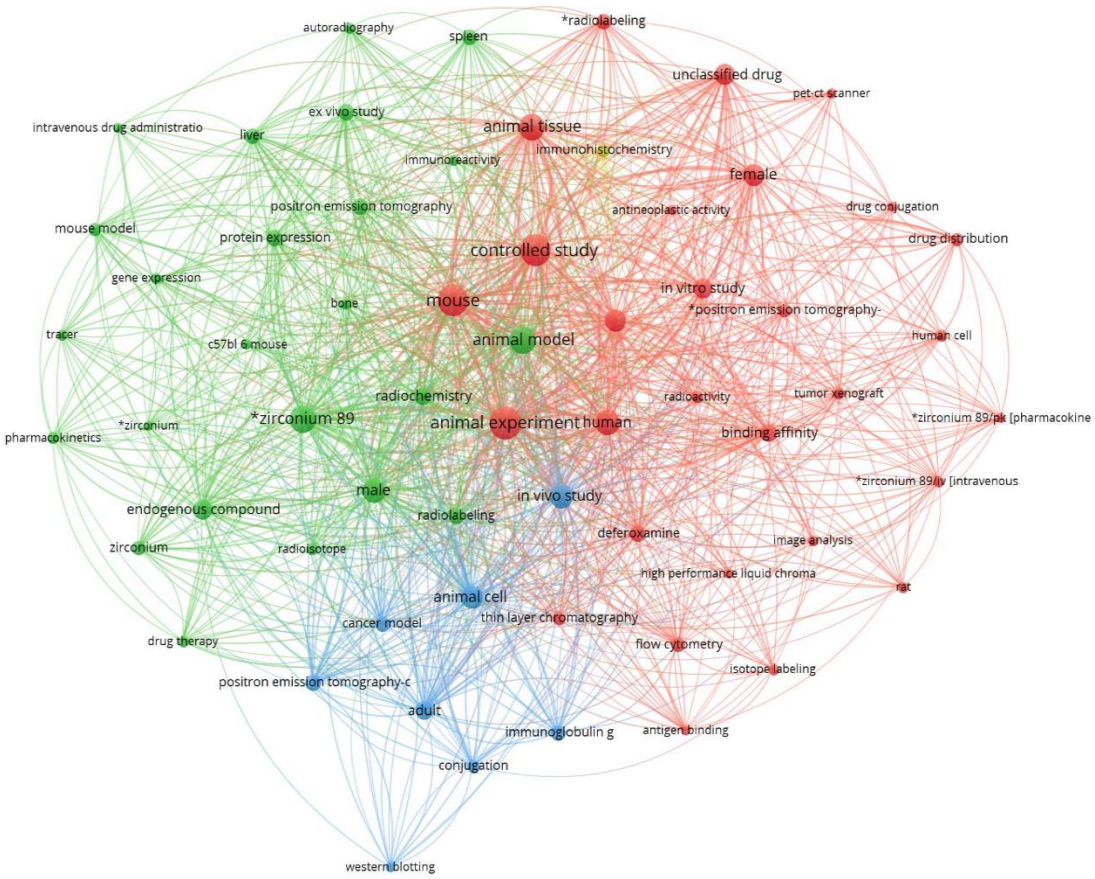
Figure 21: Preclinical research overview of Cu-64 in title (publication year 2020-2023)



Ninety-one records that contained the word Cu or synonymous terms in title were grouped to be analysed in VOSViewer. Due to the small sample of records the threshold for terms repetition was set at 5 which means that words repeated in the title or abstracts of those ninety-one records less than five times would not appear in the cluster visualisation. A total of four clusters were generated. Lowering the threshold for word repetition has allowed to visualise deeper the content of those records however, the clusters and the weight of those labels in fig 16 are smaller and the network looks more dispersed. Of note are the association of '177Lu-lu panitumumab f' with words such as 'tumour', 'promising approach' and 'atsm signal'.[42] In purple, the term 'tfr1' (transferrin receptor protein 1), appears strongly related with terms such as 'tissue' 'protein', 'escc' (esophageal squamous cell carcinoma), 'clinical practice', 'significant reduction' and 'cancer type' signalling the research field of new applications of Copper-64 in ferroptosis induction.[43,44] The node labelled as 'atsm' (Copper(II)-diacetyl-bis(N(4)-methylthiosemicarbazone)) signals a PET tracer (Cu-ATSM) developed for hypoxia imaging that could potentially be used to identify cancers susceptible to redox-directed

therapies.[45] Furthermore, the relationship with terms such as 'production' and 'purity' reveals research in the field of production and radiosynthesis methods for this candidate for imaging of tumour hypoxia.[46] The node labelled 'ctr1' (copper transporter 1), in pink, shows a strong relationship with other pink terms such as 'experiment' and '64cucl2' (copper (II)-64 chloride) signalling the level of experimental research for 64Copper chloride as PET tracer and/or theragnostic agent for a number of different cancers such as lung, thyroid, prostate and hypoxic tumours.[43,47-52] The green node 'FAPI' (fibroblast activation protein inhibitors) signals research into tumour uptake of 64Cu radiolabelled DOTHA2-FAPI-04 and 64Cu-FAPI-04 for prostate cancer imaging and theranostics applications in pancreatic cancer mouse models respectively.[53,54]

Figure 22: Preclinical research overview of Zr in title (publication year 2020-2023)

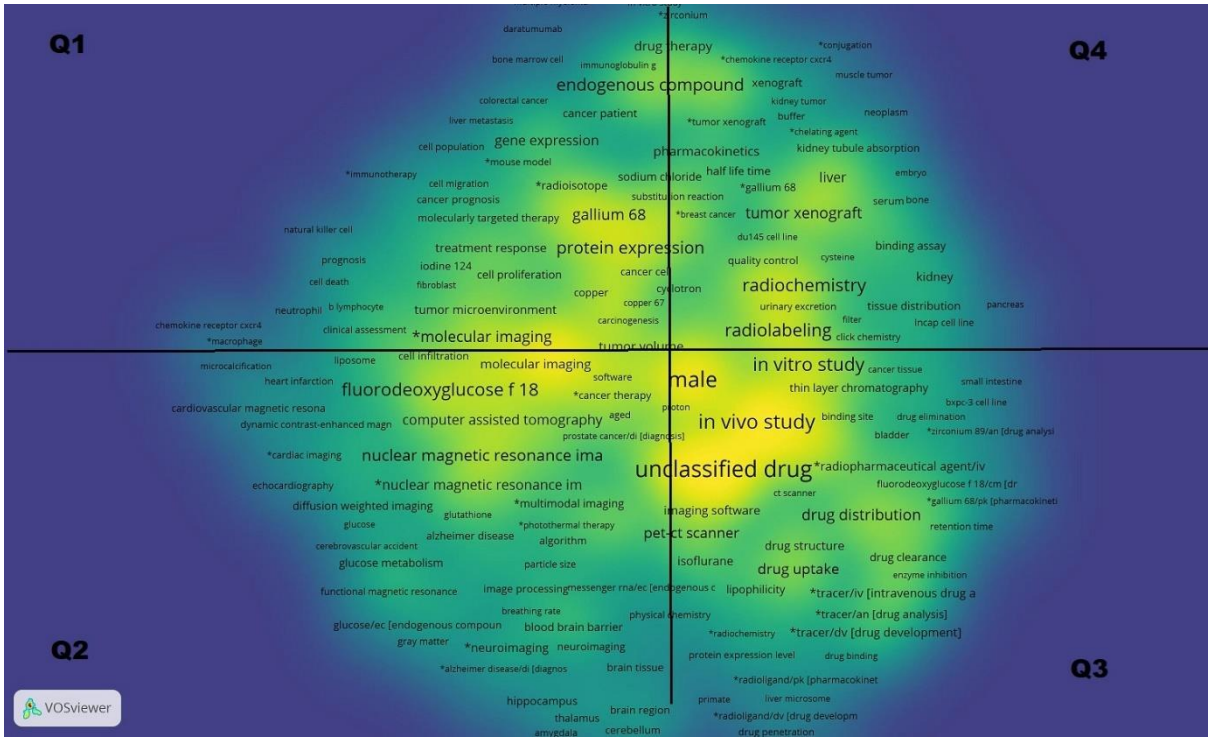


Fifty-one records that included Zr or synonymous terms were grouped and exported into VOSviewer for network visualisation of terms and their relationship within. Minimum term repetition count was set at 5 and four clusters were generated with a minimum of 1 term in cluster 4 'immunohistochemistry'. Of note are frequent terms represented in red such as 'controlled study', 'mouse', 'animal experiment' and 'animal tissue' all of those terms have links across most of the terms in the network signalling the type of animal studies, both 'in vitro' and

'in vivo' studies in 'animal tissue' and 'animal cell'. The term 'Zirconium 89' appears in the network several times. Zirconium radiolabelling studies appear in the relationship with the term 'radiolabelling' indicating preclinical research of novel applications of Zr in PET imaging studies for cancers such as multiple myeloma (MM) where Zr is labelled with elotuzumab as PET imaging agent for MM[55], in the study of ramucirumab radiolabelled with 89Zr ([89Zr]Zr-DFO-RAM) potency to target and image VEGFR2-positive tumours[56], in cancers overexpressing sialic acid-binding immunoglobulin-like lectin 15 (Siglec-15) for which a novel anti-Siglec-15 monoclonal antibody (NC318) was radiolabelled with zirconium-89 to synthesize [89Zr]Zr-DFO-NC318[57], in colorectal cancer PET-imaging and radiotherapy study of a novel anti-DR5 monoclonal antibody CTB006[58] or in chronic kidney disease imaging studies where 89Zr is studied as novel non-invasive method for assessing whole-body alpha-klotho distribution.[59] The immunohistochemistry node reveals pre-clinical research in the field of 89Zr radiolabelling, such as the study of Zr-89 labelled anti-CD11b antibody for evaluating CD11b+ myeloid cells in gastric cancer imaging with PET[60] or the use of [89Zr]DFO-Anti-PDL1, a monoclonal antibody targeting the programmed death-cell ligand (PD-L1) radiolabelled with 89Zr, for non-invasive imaging whole-body mapping of PD-L1 sites to improve the assessment of tumoural PD-L1 expression.[61]

A total of 43 (13N=8, 15O=22, 82Rb=4 and Sc=9) records comprised the group of remaining records for which one of the included radionuclides was mentioned in title. Due to the small number of records per radionuclide a network visualisation was deemed not useful as there were not enough term repetitions to reveal relationship of terms and networks of relevance. Alternatively, a list of these records has been included in Appendix 4.

Figure 23: Density visualisation of preclinical research for all included radioisotopes (in abstract, 2020-2023)



A total of 1,289 records that did not contain any of the included radionuclides of interest in the title but may be included in the abstracts or key word fields were exported into a RIS file to be analysed in VOSviewer. A density visualisation map was generated after removing publication type related keywords such as (conference abstracts, review or preclinical study) and animal and human related tissue or cell related key words. The threshold for word repetition was set at 5 (minimum number of keyword repetition) which produced a total of 974 items distributed across four clusters. The yellow and orange colour designates higher concentration of key words such as 'in vivo' or 'in vitro study', 'fluorodeoxyglucose F18', 'positron emission tomography', 'unclassified drug', 'male', 'protein expression', 'radiolabelling', 'radiochemistry', 'gallium 68' and 'endogenous compound'. Anticlockwise, located in the outer area of the map (Q1) are less frequent terms such as 'multiple myeloma', 'glioblastoma', 'liver metastasis', 'breast carcinoma', 'melanoma' and 'prostate cancer' which could signal early research activity in these cancers. Moving onto Q2 still in the periphery of the map there are terms such as 'microcalcification', 'ischemia', 'heart infarction', 'heart left ventricle ejection', 'heart function', 'brain ischaemia' and 'Alzheimer disease' which could be an indication other non-cancer conditions in which the included radionuclides are being investigated. Q3 includes terms related to the study of pharmacokinetics of some radioligands and 'drug distribution', 'synthesis' and 'uptake' of 'radiopharmaceutical agents'. In Q4 terms such as 'kidney', 'liver', 'pancreas', 'spleen', 'bone', 'muscle', 'heart' and 'stomach' appear alongside other terms such as 'tissue distribution', 'circulation time', 'blood distribution', 'dose response' and 'dosimetry' amongst others.

Discussion

We identified 25 radiopharmaceuticals that were licensed by the MHRA/EMA. Several radiopharmaceuticals like FDG, florbetapir, fluoroclovine are already licensed for use for diagnosis for a number of indications.[62]

FDG is a globally recognised radiopharmaceutical for imaging in several cancer indications. However, there were a few new indications for FDG and other radiopharmaceuticals that this scan was able to identify as shown in figures 2-5. FDG has shown to have limitations in the assessment of a few conditions like prostate cancer. In our analysis, prostate cancer was the cancer indication that was being investigated the most. Some of the non-licensed radiopharmaceuticals that are being investigated for prostate cancer diagnosis identified in this scan include fluorocholine, fluoroethylcholine, and gozetotide when radiolabelled with F-18.[63]

There are several indications mentioned in the 2022 guidance published by the Royal College of Radiologists (RCR)[64], that the radiopharmaceuticals are not licensed for but are recommended for diagnostic purposes for those indications. Some of these indications align with those identified in our scan. For instance, choline is not licensed for any indication, however, it is in clinical trials for diagnosis of prostate cancer and is also mentioned in the RCR guidance as a potential indication and an alternative to other licensed radiopharmaceuticals like gozetotide when radiolabelled with Ga-68.

We identified only one clinical trial investigating Ru-82 for diagnosis of cardiovascular conditions. This appears to be the only indication Ru-82 is licensed for with a recent date of approval from the MHRA in March 2023.[65]

Our scan identified quite a few Ga-68 fibroblast activation protein inhibitors (FAPIs) namely FAPI-2286, FAP-CHX, FAP-RGD, FAPI, FAPI-04, and FAPI-46. They are being investigated for broad cancer indications, and a few specific cancer indications, such as ovarian cancer, pancreatic cancer, and lung cancer. These FAPIs are being considered promising especially for targeted therapy.[66] These appear to be very new in the radiopharmaceutical space. The trials included in this scan for these FAPIs were all posted between 2020 -2023 and none these radiopharmaceuticals are mentioned in the RCR guidance.

Cu-64 is being recognised as a promising radiopharmaceutical in preclinical studies.[67] However, this appears to be a recent development. Most of the trials identified in the scan for Cu-64 were posted after 2020. The RCR guidance does not include any indications recommended for use for Cu-64 as well.

All clinical trials identified for Zr-89, used monoclonal antibodies conjugated with Zr-89, also referred to as radioimmunoconjugates.[68] The use of radioimmunoconjugates in PET imaging allows better understanding of uptake in tumours which can prove vital to determine which patients benefit from treatment. While Zr-89 has been investigated in several clinical trials in the last decade, it is still not licensed by MHRA/EMA or recommended for any indication by RCR. More evidence might be required to understand if Zr-89 is beneficial to patients.

Ammonia as N-13, not licensed for any indication by MHRA/EMA, has been recommended in the RCR guidance for myocardial perfusion imaging.[64] The clinical trials identified in the scan were for respiratory conditions and blood and immune system conditions as shown in figure 5. We can speculate the reasons why ammonia is being investigated albeit in a small number of trials, however, that is beyond the scope of this scan and would need to be investigated separately.

Conclusion

Our scan showed that most of the identified clinical trials were investigating the use of F-18 for diagnosing cancer indications using PET imaging procedures. Ga-68 was also found to have a considerable number of clinical trials, but a relatively small number of clinical trials were testing Rb-82, Cu-64, Zr-89, N-13, and O-15. No clinical trials were found for scandium. Cancer indications were being investigated in a majority of the clinical trials identified. There were more clinical trials at phase 1/2 and 2 stage of clinical development compared to phase 2/3 and 3. Most of the clinical trials are being sponsored by non-industry and most of the clinical trials are being conducted US, Canada, UK/EU areas.

Based on the guidance produced by the UK Health Security Agency for Administration of Radioactive Substances Advisory Committee (ARSAC), which can be considered to be a guide to good clinical practice in the UK for nuclear medicine, there are several indications where radiopharmaceutical technologies are being used in the UK for therapeutic and diagnostic

purposes[3]. Many of these are for diagnostic use for F-18 including imaging for hepatocellular cancer, prostate cancer, neuroendocrine and brain tumours along with a few indications for Ga-68 and one indication for Rb-82. However, there are no indications mentioned against Cu-68, O-15, Zr-89. These could be new radiopharmaceutical technologies for use in diagnosis and would require preparation for adoption into clinical practice.

Our global horizon scan provides not only the all-Wales PET Programme and WHSSC, but also other organisations/bodies, with information on the opportunities for discovering new indications for the radiopharmaceutical technologies of interest. The knowledge of these new and upcoming clinical indications of interest and radiopharmaceuticals could support in future planning for inclusion of radiopharmaceuticals currently in use for other indications. It will also allow health organisations to prepare for the adoption of new radiopharmaceutical technologies in clinical use for the purpose of diagnosis.

The visualisation of similarities technique used to study the preclinical research field for the included radionuclides of interest has provided a relatively rapid approach to understanding the research landscape by aiding with the discovery of some early research applications. Although this method cannot replace the robustness of a systematic literature review, it can support the identification of research leads to follow more systematically in a literature review. As a caveat is worth mentioning that having specialist knowledge in the field would allow for better interpretation of results and study of associations in research field of study.

References

1 Huang Y-Y. An Overview of PET Radiopharmaceuticals in Clinical Use: Regulatory, Quality and Pharmacopeia Monographs of the United States and Europe. *Nuclear Medicine Physics*. 2018.

2 Lodi F, Boschi S. Quality Control of PET Radiopharmaceuticals. In: Khalil MM, ed. *Basic Science of PET Imaging*. Cham: Springer International Publishing; 2017: 105-26.

3 Biricova V, Kuruc J. *Synthesis of the radiopharmaceuticals for positron emission tomography*. International Atomic Energy Agency; 2007. Available from: https://inis.iaea.org/collection/NCLCollectionStore/_Public/38/059/38059371.pdf.

4 Hung JC. Regulatory Aspects of PET Radiopharmaceutical Production in the United States. In: Khalil MM, ed. *Basic Science of PET Imaging*. Cham: Springer International Publishing; 2017: 145-70.

5 Khalil MM. Basics and Advances of Quantitative PET Imaging. In: Khalil MM, ed. *Basic Science of PET Imaging*. Cham: Springer International Publishing; 2017: 303-22.

6 Ballinger JR, Koziorowski J. Regulation of PET Radiopharmaceuticals Production in Europe. In: Khalil MM, ed. *Basic Science of PET Imaging*. Cham: Springer International Publishing; 2017: 127-43.

7 Code of Federal Regulations. *Part 212 - Current good manufacturing practice for positron emission tomography drugs*.

8 European Commission. The rules governing medicinal products in the European Union. *EudraLex - Volume 10*.

9 Nuclear Medicine Europe. *What is nuclear medicine and how can it help Europe beat cancer?*; 2022. Available from: https://nuclearmedicineeurope.eu/wp-

content/uploads/2022/07/What-is-nuclear-medicine-and-how-can-it-help-Europe-beat-cancer.pdf.

10 *BiomedTracker: Pharma Intelligence*. 2023. Available from: https://www.biomedtracker.com/ [Accessed 10/10/2023].

11 Leiden University. *VOSviewer version 1..6.19*. 2023. Available from: https://www.vosviewer.com/ [Accessed 10/10/2023].

12 Novartis. *Novartis receives European Commission approval for Pluvicto® as the first targeted radioligand therapy for treatment of progressive PSMA–positive metastatic castration-resistant prostate cancer*. 2022. Available from: https://www.novartis.com/news/media-releases/novartis-receives-european-commission-approval-pluvicto-first-targeted-radioligand-therapy-treatment-progressive-psma-positive-metastatic-castration-resistant-prostate-cancer [Accessed 10/10/2023].

13 Telix Pharmaceuticals Limited. *Health Canada Approves Illuccix® for Prostate Cancer Imaging*. 2022. Available from: https://www.prnewswire.com/news-releases/health-canada-approves-illuccix-for-prostate-cancer-imaging-301649214.html [Accessed 10/10/2023].

14 Novartis Pharmaceuticals Canada. *PLUVICTO™ receives positive recommendations from CADTH and INESSS for progressive PSMA-positive metastatic castration-resistant prostate cancer*. 2023. Available from: https://www.newswire.ca/news-releases/pluvicto-tm-receives-positive-recommendations-from-cadth-and-inesss-for-progressive-psma-positive-metastatic-castration-resistant-prostate-cancer-864526183.html [Accessed 10/10/2023].

15 Blue Earth Diagnostics. *U.S. FDA Approves Blue Earth Diagnostics' POSLUMA® (Flotufolastat F 18) Injection, First Radiohybrid PSMA-targeted PET Imaging Agent for Prostate Cancer*. 2023. Available from: https://www.businesswire.com/news/home/20230530005180/en/U.S.-FDA-Approves-Blue-Earth-Diagnostics%E2%80%99-POSLUMA%C2%AE-Flotufolastat-F-18-Injection-First-Radiohybrid-PSMA-targeted-PET-Imaging-Agent-for-Prostate-Cancer [Accessed 10/10/2023].

16 Curium. *Curium Receives Marketing Authorization in the EU for PYLCLARI™, an Innovative 18F-PSMA PET Tracer Indicated in Adults With Prostate Cancer*. 2023. Available from: https://www.globenewswire.com/news-release/2023/07/28/2712980/0/en/Curium-Receives-Marketing-Authorization-in-the-EU-for-PYLCLARI-an-Innovative-18F-PSMA-PET-Tracer-Indicated-in-Adults-With-Prostate-Cancer.html [Accessed 10/10/2023].

17 Telix Pharmaceuticals Limited. *FDA Approves Expanded Indication for Telix's Illuccix® to Include Patient Selection for PSMA-Directed Radioligand Therapy*. 2023. Available from: https://www.prnewswire.com/news-releases/fda-approves-expanded-indication-for-telixs-illuccix-to-include-patient-selection-for-psma-directed-radioligand-therapy-301774122.html [Accessed 10/10/2023].

18 Actinium Pharmaceuticals I. *Actinium Highlights First-In-Class HER3 Targeted Radiotherapy Data Demonstrating Potent Anti-Cancer Activity of in Ovarian and Colorectal Cancer Models at the AACR Annual Meeting*. 2023. Available from: https://www.prnewswire.com/news-releases/actinium-highlights-first-in-class-her3-targeted-radiotherapy-data-demonstrating-potent-anti-cancer-activity-of-in-ovarian-and-colorectal-cancer-models-at-the-aacr-annual-meeting-301801356.html [Accessed 10/10/2023].

19 Telix Pharmaceuticals Limited. *Olaratumab Antibody Licensed from Lilly Demonstrates Proof of Concept as a Theranostic Radiopharmaceutical*. 2023. Available from: https://www.prnewswire.com/news-releases/olaratumab-antibody-licensed-from-lilly-demonstrates-proof-of-concept-as-a-theranostic-radiopharmaceutical-301798405.html [Accessed 10/10/2023].

20 Fusion Pharmaceuticals Inc. *Fusion Pharmaceuticals Announces Presentation of Preclinical Data Supporting FPI-2059 and Leading Targeted Alpha Therapy Platform at AACR Annual Meeting*. 2023. Available from: https://www.newswire.ca/news-releases/fusion-pharmaceuticals-announces-presentation-of-preclinical-data-supporting-fpi-2059-and-leading-targeted-alpha-therapy-platform-at-aacr-annual-meeting-870144630.html [Accessed 10/10/2023].

21 Lantheus. *41st Annual JP Morgan Healthcare Conference*. 2023. Available from: https://investor.lantheus.com/static-files/e8903e6a-93d6-4ef8-a58b-d0492b284564.

22 RayzeBio I. *RayzeBio nominates Glypican-3 (GPC3) targeted radiopharmaceutical therapy drug candidate for treatment of liver cancer*. 2023. Available from: https://rayzebio.com/rayzebio-nominates-glypican-3-gpc3-targeted-radiopharmaceutical-therapy-drug-candidate-for-treatment-of-liver-cancer/ [Accessed 10/10/2023].

23 Hu W, Pan D, Wang Y, Bao W, Zuo C, Guan Y, et al. PET Imaging for Dynamically Monitoring Neuroinflammation in APP/PS1 Mouse Model Using [18F]DPA714. *Frontiers in Neuroscience*. 2020;14:810. Available from: https://doi.org/https://dx.doi.org/10.3389/fnins.2020.00810.

24 Kim K, Kim H, Bae SH, Lee SY, Kim YH, Na J, et al. [18F]CB251 PET/MR imaging probe targeting translocator protein (TSPO) independent of its Polymorphism in a Neuroinflammation Model. *Theranostics*. 2020;10(20):9315-31. Available from: https://doi.org/https://dx.doi.org/10.7150/thno.46875.

25 Liu H, Luo Z, Gu J, Jiang H, Joshi S, Shoghi KI, et al. In vivo Characterization of Four 18F-Labeled S1PR1 Tracers for Neuroinflammation. *Molecular Imaging and Biology*. 2020;22(5):1362-9. Available from: https://doi.org/https://dx.doi.org/10.1007/s11307-020-01514-8.

26 Van Camp N, Balbastre Y, Herard AS, Lavisse S, Tauber C, Wimberley C, et al. Assessment of simplified methods for quantification of [18F]-DPA-714 using 3D whole-brain TSPO immunohistochemistry in a non-human primate. *Journal of Cerebral Blood Flow and Metabolism*. 2020;40(5):1103-16. Available from: https://doi.org/https://dx.doi.org/10.1177/0271678X19859034.

27 Chen X, Yang T, Guo F, Wu C, Liang YK, Wang D. Astudy of 68Ga-FAPIin the imaging of atherosclerosis inNew Zealand rabbits. *Journal of Nuclear Medicine*. 2021;62(SUPPL 1)https://jnm.snmjournals.org/content/62/supplement_1/1233

http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed22&NEWS=N&AN=635439906.

28 Song W, Song Y, Qin C, Gai Y, Zhang X, Lan X. Early monitoring of the atherosclerosis plaque formationby 68Ga-DOTA-TATE, 68Ga-LLP2A and F-FDG: Apreliminary study by head-to-head comparation. *Journal of Nuclear Medicine*. 2021;62(SUPPL 1)https://jnm.snmjournals.org/content/62/supplement_1/1230

http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed22&NEWS=N&AN=635439895.

29 Stahle M, Hellberg S, Virta J, Liljenback H, Metsala O, Li XG, et al. Evaluation of glucagon-like peptide-1 receptor expression in nondiabetic and diabetic atherosclerotic mice using PET tracer 68Ga-NODAGA-exendin-4. *American Journal of Physiology - Endocrinology and Metabolism*. 2021;320(5):E989-E98. Available from: https://doi.org/https://dx.doi.org/10.1152/AJPENDO.00465.2020.

30 Wang D, Chen X, Yang T, Guo F, Wu C, Liang YK. The availability of the fibroblast activation protein receptor in early identification of vulnerable atherosclerotic plaques: A preclinical study using a 68Ga- FAPIPET. *Journal of Nuclear Medicine*. 2021;62(SUPPL 1)https://jnm.snmjournals.org/content/62/supplement_1/1395

http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed22&NEWS=N&AN=635438305.

31 Sivapackiam J, Muthukumar K, Zhou D, Gropler R, Gelman A, Sharma V. 68Ga-Galuminox: A PET Tracer for Imaging Mitochondrial ROS Activity. *Molecular Imaging and Biology*. 2022;24(Supplement 2):S455. Available from: https://doi.org/https://dx.doi.org/10.1007/s11307-022-01794-2.

32 Darwesh A, Wellman R, Abbate V, Cooper MS, Hider R, Morais M, et al. Simple radiosynthesis of 68Ga-desferrioxamine B (68Ga DFO) for infection imaging. *European Journal of Nuclear Medicine and Molecular Imaging*. 2020;47(SUPPL 1):S298. Available from: https://doi.org/https://dx.doi.org/10.1007/s00259-020-04988-4.

33 Petrik M, Umlaufova E, Raclavsky V, Palyzova A, Havlicek V, Pfister J, et al. Preclinical evaluation of 68Ga-Desferal for bacterial infection imaging. *European Journal of Nuclear Medicine and Molecular Imaging*. 2020;47(SUPPL 1):S267-S8. Available from: https://doi.org/https://dx.doi.org/10.1007/s00259-020-04988-4.

34 Hubmann I, Mular A, Gumienna-Kontecka E, Misslinger M, Pfister J, Haas H, et al. Preclinical evaluation of 68ga-labelled artificial siderophores of the ferrioxamine type. *European Journal of Nuclear Medicine and Molecular Imaging*. 2021;48(SUPPL 1):S254-S5. Available from: https://doi.org/https://dx.doi.org/10.1007/s00259-021-05547-1.

35 Petrik M, Umlaufova E, Raclavsky V, Palyzova A, Havlicek V, Pfister J, et al. 68Ga-labelled desferrioxamine-B for bacterial infection imaging. *European Journal of Nuclear Medicine and Molecular Imaging*. 2021;48(2):372-82. Available from: https://doi.org/https://dx.doi.org/10.1007/s00259-020-04948-y.

36 Peukert C, Langer LNB, Wegener SM, Tutov A, Bankstahl JP, Karge B, et al. Optimization of Artificial Siderophores as 68Ga-Complexed PET Tracers for in Vivo Imaging of Bacterial Infections. *Journal of Medicinal Chemistry*. 2021;64(16):12359-78. Available from: https://doi.org/https://dx.doi.org/10.1021/acs.jmedchem.1c01054.

37 Darwesh A, Cooper M, Gibson V, Barrington S, Sallam M, Patel A, et al. Targeting microbial siderophore receptors: first GMP formulation of [68Ga]Ga-DFO for PET imaging of microbial infection. *Nuclear Medicine Communications*. 2022;43(5):578. Available from: https://doi.org/https://dx.doi.org/10.1097/MNM.0000000000001555.

38 Petrik M, Palyzova A, Novy Z, Houst J, Havlicek V, Khoylou M, et al. Monitoring Aspergillus fumigatus infection in rats using 68Ga-siderophores. *European Journal of Nuclear Medicine and Molecular Imaging*. 2022;49(Supplement 1):S18. Available from: https://doi.org/https://dx.doi.org/10.1007/s00259-022-05924-4.

39 Petrik M, Bendova K, Palyzova A, Novy Z, Havlicek V, Popper M, et al. 68Ga-siderophores for imaging Escherichia coli infection: selection of suitable candidates. *EJNMMI Radiopharmacy and Chemistry*. 2023;8(Supplement 1). Available from: https://doi.org/https://dx.doi.org/10.1186/s41181-023-00193-4.

40 Pan X, Zhu J, Xu Z, Xiao Q, Zhou X, Xu K, et al. 68Ga-WRWWWW Is a Potential Positron Emission Tomography Probe for Imaging Inflammatory Diseases by Targeting Formyl Peptide Receptor 2. *Molecular Pharmaceutics*. 2022;19(5):1368-77. Available from: https://doi.org/https://dx.doi.org/10.1021/acs.molpharmaceut.1c00922.

41 Puuvuori E, Liggieri F, Velikyan I, Chiodaroli E, Sigfridsson J, Romelin H, et al. PET-CT imaging of pulmonary inflammation using [68Ga]Ga-DOTA-TATE. *EJNMMI Research*. 2022;12(1):19. Available from: https://doi.org/https://dx.doi.org/10.1186/s13550-022-00892-0.

42 Ku A, Kondo M, Cai Z, Meens J, Li MR, Ailles L, et al. Dose predictions for [177Lu]Lu-DOTA-panitumumab F(ab')2 in NRG mice with HNSCC patient-derived tumour xenografts based on [64Cu]Cu-DOTA-panitumumab F(ab')2 - implications for a PET theranostic strategy. *EJNMMI Radiopharmacy and Chemistry*. 2021;6(1):25. Available from: https://doi.org/https://dx.doi.org/10.1186/s41181-021-00140-1.

43 Zhou R, Shen Y, Jin H, Wang Y. Preclinical Evaluation of [64Cu]NOTA-HFn as a PET Imaging Agent for Radioiodine Refractory Differentiated Thyroid Cancer. *European Journal of Nuclear Medicine and Molecular Imaging*. 2022;49(Supplement 1):S423. Available from: https://doi.org/https://dx.doi.org/10.1007/s00259-022-05924-4.

44 Zhou R, Shen Y, Wang Y, Jin H, Bi L. Preclinical Evaluation of [64Cu/67Cu]NOTA-HFn as a Theranostic Agent for Radioiodine Refractory Differentiated Thyroid Cancer. *Molecular Imaging and Biology*. 2022;24(Supplement 2):S465. Available from: https://doi.org/https://dx.doi.org/10.1007/s11307-022-01794-2.

45 Floberg JM, Wang L, Bandara N, Rashmi R, Mpoy C, Garbow JR, et al. Alteration of Cellular Reduction Potential Will Change 64Cu-ATSM Signal With or Without Hypoxia. *Journal of Nuclear Medicine*. 2020;61(3):427-32. Available from: https://doi.org/https://dx.doi.org/10.2967/jnumed.119.230805.

46 Liu T, Redalen KR, Karlsen M. Development of an automated production process of [64Cu][Cu (ATSM)] for positron emission tomography imaging and theranostic applications. *Journal of Labelled Compounds and Radiopharmaceuticals*. 2022;65(7):191-202. Available from: https://doi.org/https://dx.doi.org/10.1002/jlcr.3973.

47 Cantiello F, Crocerossa F, Cascini GL, Russo GI, Ferro M, Cimino S, et al. 64CuCl2 PET/CT as a potential new imaging method in prostate cancer: illusion or reality? *Minerva urologica e nefrologica = The Italian journal of urology and nephrology*. 2020. Available from: https://doi.org/https://dx.doi.org/10.23736/S0393-2249.20.03615-2.

48 Jiang L. PET Imaging of Lung Cancer with 64CuCl2: A Pilot Study. *European Journal of Nuclear Medicine and Molecular Imaging*. 2020;47(SUPPL 1):S643-S4. Available from: https://doi.org/https://dx.doi.org/10.1007/s00259-020-04988-4.

49 Wang Q, Song D, Ma X, Wu X, Jiang L. Preclinical PET imaging study of lung cancer with 64CuCl2. *Annals of Nuclear Medicine*. 2020;34(9):653-62. Available from: https://doi.org/https://dx.doi.org/10.1007/s12149-020-01491-6.

50 Aljammaz I. Synthesis and in vitro and in vivo evaluation of a new 64Cu-semicarbazone complex: potential theranostic radiopharmaceutical for hypoxic tumor. *Nuclear Medicine and Biology*. 2022;108-109(Supplement):S52. Available from: https://doi.org/https://dx.doi.org/10.1016/S0969-8051%2822%2900138-X.

51 Capriotti G, Piccardo A, Giovannelli E, Signore A. Targeting Copper in Cancer Imaging and Therapy: A New Theragnostic Agent. *Journal of Clinical Medicine*. 2023;12(1):223. Available from: https://doi.org/https://dx.doi.org/10.3390/jcm12010223.

52 Kirk FT, Munk DE, Swenson ES, Quicquaro A, Vendelbo MH, Schilsky M, et al. Effects of tetrathiomolybdate on copper distribution and biliary excretion: a controlled 64CuCl2 PET/MRI. *Journal of Hepatology*. 2023;78(Supplement 1):S985. Available from: https://doi.org/https://dx.doi.org/10.1016/S0168-8278%2823%2903042-8.

53 Watabe T, Liu Y, Kaneda-Nakashima K, Shirakami Y, Lindner T, Ooe K, et al. Theranostics targeting fibroblast activation protein in the tumor stroma: 64Cu- And 225Ac-labeled FAPI-04 in pancreatic cancer xenograft mouse models. *Journal of Nuclear Medicine*. 2020;61(4):563-9. Available from: https://doi.org/https://dx.doi.org/10.2967/jnumed.119.233122.

54 Belissant O, Dumulon-Perreault V, Milot M, Ben-Salem I, Croteau E, Ait-Mohand S, et al. Use of the fibroblast activation protein inhibitor [64Cu] Cu-DOTHA2-FAPI-04 to overcome heterogeneity in prostate cancer. *European Journal of Nuclear Medicine and Molecular Imaging*. 2021;48(SUPPL 1):S15-S6. Available from: https://doi.org/https://dx.doi.org/10.1007/s00259-021-05547-1.

55 Ghai A. Immuno PET imaging of CS1/SLAMF7 in multiple myeloma using Zr DFO elotuzumab. *Journal of Nuclear Medicine*. 2020;61(Supplement 1)http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed21&NEWS=N&AN=633250958.

56 Novy Z, Janousek J, Barta P, Petrik M, Hajduch M, Trejtnar F. Preclinical evaluation of anti-VEGFR2 monoclonal antibody ramucirumab labelled with zirconium-89 for tumour imaging. *Journal of Labelled Compounds and Radiopharmaceuticals*. 2021;64(7):262-70. Available from: https://doi.org/https://dx.doi.org/10.1002/jlcr.3909.

57 Jagoda EM, Basuli F, Olkowski C, Weiss I, Phelps TE, Wong K, et al. Immuno-PET Imaging of Siglec-15 Using the Zirconium-89-Labeled Therapeutic Antibody, NC318. *Molecular Imaging*. 2023;2023:3499655. Available from: https://doi.org/https://dx.doi.org/10.1155/2023/3499655.

58 Yang Y, Wang J, Liu W, Deng H, Zhao P, Liao W, et al. 89Zr and 177Lu labeling of anti-DR5 monoclonal antibody for colorectal cancer targeting PET-imaging and radiotherapy. *Journal of Radioanalytical and Nuclear Chemistry*. 2021;330(3):997-1005. Available from: https://doi.org/https://dx.doi.org/10.1007/s10967-021-07979-3.

59 Lau WL, Liang C, Liu H, Singh K, Mukherjee J. Development of zirconium-89 PET for in vivo imaging of alpha-klotho. *American Journal of Nuclear Medicine and Molecular Imaging*. 2020;10(2):95-105http://www.ajnmmi.us/files/ajnmmi0110442.pdf

http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed21&NEWS=N&AN=2004292965.

60 Zhang Y, Cheng D. Preclinical ImmunoPET Imaging of Gastric cancer- Infiltrating Myeloid Cells Using Zirconium-89 Labeled Anti-CDiib Antibody. *Journal of Nuclear Medicine*. 2021;62(SUPPL 1)https://jnm.snmjournals.org/content/62/supplement_1/1512

http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed22&NEWS=N&AN=635438243.

61 Krache A, Fontan C, Pestourie C, Bardies M, Bouvet Y, Payoux P, et al. Preclinical Pharmacokinetics and Dosimetry of an 89Zr Labelled Anti-PDL1 in an Orthotopic Lung

Cancer Murine Model. *Frontiers in Medicine*. 2022;8:741855. Available from: https://doi.org/https://dx.doi.org/10.3389/fmed.2021.741855.

62 Medicines and Healthcare products Regulatory Agency (MHRA). *MetaTrace FDG Solution for Injection Summary of Product Characteristics*.

63 Giammarile F, Castellucci P, Dierckx R, Estrada Lobato E, Farsad M, Hustinx R, et al. Non-FDG PET/CT in Diagnostic Oncology: a pictorial review. *Eur J Hybrid Imaging*. 2019;3(1):20. Available from: https://doi.org/10.1186/s41824-019-0066-2.

64 Royal College of Radiologists. Evidence-based indications for the use of PET-CT in the United Kingdom 2022. London: 2022.

65 Medicines and Healthcare products Regulatory Agency (MHRA). *Cardiogen-82 3.3–5.6 GBq radionuclide generator: SUmmary of Product Characteristics*

66 Giesel FL, Adeberg S, Syed M, Lindner T, Jiménez-Franco LD, Mavriopoulou E, et al. FAPI-74 PET/CT using either 18F-AlF or cold-kit 68Ga labeling: biodistribution, radiation dosimetry, and tumor delineation in lung cancer patients. *Journal of Nuclear Medicine*. 2021;62(2):201-7.

67 Natarajan A. Copper-64-immunoPET imaging: bench to bedside. *The Quarterly Journal of Nuclear Medicine and Molecular Imaging: Official Publication of the Italian Association of Nuclear Medicine (AIMN)[and] the International Association of Radiopharmacology (IAR),[and] Section of the Society of*. 2020;64(4):356-63. Available from: https://doi.org/10.23736/S1824-4785.20.03310-5.

68 Parakh S, Lee ST, Gan HK, Scott AM. Radiolabeled Antibodies for Cancer Imaging and Therapy. *Cancers*. 2022;14(6):1454. Available from: https://doi.org/10.3390/cancers14061454.

Appendix 1. Preclinical studies search strategy

Database: Embase (Ovid) <1974 to 2023 August 28>

Date of search: 29th August 2023

Records retrieved: 2,620

Search strategy:

1	positron emission tomography/ or whole body pet/	171713
2	(((PET or positron*) and (tracer* or tomograph* or imaging)) or positron emi*).mp.	288154
3	copper 62/ or copper 64/ or copper 67/ or fluorine 18/ or gallium 68/ or gallium 68 plus germanium 68/ or nitrogen 13/ or oxygen 15/ or rubidium 82/ or scandium 46/ or zirconium 89/	48943
4	(Cu or Copper* or 62Cu* or 62-Cu* or Cu62 or Cu-62 or 62Copper* or 64Cu* or 64-Cu* or Cu64 or Cu-64 or 64Copper* or 67Cu* or 67-Cu* or Cu67 or Cu-67 or 67Copper*).ti,hw,kf.	217940
5	(Fluori* or 18F* or 18-F* or F18 or F-18 or 18fluori*).ti,hw,kf.	209787
6	(Gallium* or 68Ga* or 68-Ga* or Ga688 or Ga-68 or 68gallium*).ti,hw,kf.	34154
7	(Nitro* or 13N* or 13-N* or N13 or N-13 or 13nitro*).ti,hw,kf.	609272
8	(Oxygen* or 15O* or 15-O* or O15 or O-15 or 15Oxygen*).ti,hw,kf.	962288
9	(Rubidi* or 82Rb* or 82-Rb* or Rb82 or Rb-82 or 82Rubidi*).ti,hw,kf.	11313
10	(Sc or Scandium* or 46Sc* or 46-Sc* or Sc46 or Sc-46 or 46Scandium*).ti,hw,kf.	10970

11	(Zr* or Zircon* or 89Zr* or 89-Zr* or Zr89 or Zr-89 or 89zircon*).ti,hw,kf.	28344
12	(or/3-11) and (1 or 2)	125902
13	limit 12 to yr="2020 -Current"	32539
14	exp *element/	1114812
15	exp *radiopharmaceutical agent/	133138
16	exp *"imaging and display"/	600763
17	exp *isotope labeling/	12542
18	*isotope analysis/	1758
19	exp *radioisotope/	128814
20	or/14-19	1904058
21	20 and 13	16365
22	preclinical study/	56391
23	(preclinical or pre-clinical).ti,hw,kf.	87345
24	"proof of concept"/	21820
25	exploratory research/	34351
26	(developing or development or develop or novel*).ti.	1251979
27	(exp animal/ not (exp human/ or exp human experiment/)) or (exp animal experiment/ or exp animal model/ or nonhuman/)	9506540
28	or/22-27	10347479
29	21 and 28	3199
30	29 not exp clinical study/	2620

Appendix 2. Clinical trials search strategy

Source: Clinicaltrials.gov, ScanMedicine

Date: 19th June 2023

Records retrieved: 5,816

Source	Search terms	Results
Clinicaltrials.gov	18F, Fluorine-18, N-13, O-15, Ga-68, Rb-82, Zr, Cu, Sc	5,214
ScanMedicine	18F, Fluorine-18, N-13, O-15, Ga-68, Rb-82, Zr, Cu, Sc	660
58 behavioural studies were removed from the total 5874 downloaded clinical trials prior to sifting.		

Appendix 3. Non-industry sponsors

Sponsors	Radionuclides	Location	EU or UK
Aarhus University Hospital	Cu	UK/EU	EU
AHS Cancer Control Alberta	F	US/Canada	
AHS Cancer Control Alberta|Cross Cancer Institute	F	US/Canada	
Alan Nichol|British Columbia Cancer Agency	F	US/Canada	
Amsterdam UMC - location VUmc	F	UK/EU	EU
Amsterdam UMC, location VUmc|ZonMw: The Netherlands Organisation for Health Research and Development	F	UK/EU	EU
Amsterdam UMC, VU University Medical Center	F	UK/EU	EU
Amsterdam University Medical Center - location VUmc	F	UK/EU	EU
Andrei Iagaru|Canary Foundation|Boston University|Stanford University	F	US/Canada	
Andrei Iagaru|National Cancer Institute (NCI)|Stanford University	F	US/Canada	
Andrei Iagaru|Stanford University	Zr	US/Canada	
Anna Raciborska|Maria Sklodowska-Curie National Research Institute of Oncology|Åukasiewicz Research Network|WrocÅ‚aw University of Environmental and Life Sciences|Institute of Mother and Child, Warsaw, Poland	F	UK/EU	EU

Antoni van Leeuwenhoek Hospital-Nuclear Medicine department	Zr	UK/EU	EU
Aou Di Bologna Policlinico S.Orsola-Malpighi	Ga	UK/EU	EU
Asan Foundation	F	ROW	
Asan Medical Center	F	ROW	
Assistance Publique - HÃ´pitaux de Paris|Pierre and Marie Curie University	F	UK/EU	EU
Assistance Publique - Hopitaux De PARIS (AP-HP)	F	UK/EU	EU
Assistance Publique Hopitaux De Marseille	F	UK/EU	EU
Azienda Ospedaliera Arcispedale S. Maria Nuova	F	UK/EU	EU
Azienda Ospedaliera Di Bologna Policlinico S. Orsola M. Malpighi	F	UK/EU	EU
Azienda Ospedaliera Ospedali Galliera	F	UK/EU	EU
Azienda Ospedaliera Sant'Andrea	Ga	UK/EU	EU
Azienda Ospedaliera Universitaria Careggi	F	UK/EU	EU
Azienda Ospedaliera Universitaria Integrata Verona	F	UK/EU	EU
Azienda Ospedaliero -Universitaria Pisana	F	UK/EU	EU
Azienda USL Di Forli'	F	UK/EU	EU
Barts Health NHS Trust	F	UK/EU	UK
Brigham and Women's Hospital	Zr	US/Canada	
Brigham and Women's Hospital|U.S. Army Medical Research Acquisition Activity	F	US/Canada	
Brigham and Women's Hospital|U.S. Army Medical Research and Development Command|Boston University	F	US/Canada	
British Columbia Cancer Agency|Canadian Institutes of Health Research (CIHR)	F	US/Canada	
Bundeswehr	F	UK/EU	EU
Cancer Institute and Hospital, Chinese Academy of Medical Sciences	F	ROW	
Canisius Wilhelmina Hospital	F	UK/EU	EU
Catharina Hospital Eindhoven	F	UK/EU	EU
CEA	F	UK/EU	EU
Cedars-Sinai Medical Center	F	US/Canada	
Central Hospital, Nancy, France	Ga	Location Unknown	

Centre de recherche du Centre hospitalier universitaire de Sherbrooke|Canadian Cancer Society (CCS)|UniversitÃ© de Sherbrooke	F	US/Canada	
Centre de recherche du Centre hospitalier universitaire de Sherbrooke|UniversitÃ© de Sherbrooke	F	US/Canada	
Centre Franois Baclesse	F	UK/EU	EU
Centre Francois Baclesse	F	UK/EU	EU
Centre Georges-Franois Leclerc	F	UK/EU	EU
Centre hospitalier de l'UniversitÃ© de MontrÃ©al (CHUM)	F	US/Canada	
Centre Hospitalier Universitaire de Caen Normandie	O	UK/EU	EU
Centre Hospitalier Universitaire de la RÃ©union	F	UK/EU	EU
Chang Gung Memorial Hospital	Ga	ROW	
Chang Gung Memorial Hospital|National Science Council, Taiwan	F	ROW	
Charite University, Berlin, Germany	F	UK/EU	EU
Children's Hospital of Philadelphia|University of Pennsylvania	F	US/Canada	
CHRU de Brest	F	Worldwide	
CHU de Bordeaux	F	UK/EU	EU
CHU de Caen	F	UK/EU	EU
CHU de la R union	F	UK/EU	EU
CHU de N mes	F	UK/EU	EU
CHU Toulouse	F	UK/EU	EU
City of Hope Medical Center|National Cancer Institute (NCI)	Cu	US/Canada	
Cliniques Universitaires Saint Luc	F	UK/EU	EU
Columbia University	F	US/Canada	
Columbia University|Hebrew Home at Riverdale|National Institute on Aging (NIA)	F	US/Canada	
Columbia University|National Institute of Neurological Disorders and Stroke (NINDS)	F	US/Canada	
Consorci Mar Parc de Salut de Barcelona (Parc de Salut MAR)	F	UK/EU	EU
Dae Hyuk Moon|Asan Medical Center	F	ROW	
David M. Schuster, MD|Emory University	F	US/Canada	
Department of Endocrinology, Sahlgrenska University Hospital	Ga	UK/EU	EU

Department of Neurology, Medical University of Vienna	F	UK/EU	EU
Department of Nuclear Medicine and Endocrinology, Paracelsus Medical University Salzburg	F	UK/EU	EU
Department of Nuclear Medicine, Aalborg University Hospital	Ga	UK/EU	EU
Deutsches Krebsforschungszentrum (DKFZ), Stiftung des ffentlichen Rechts	Ga	UK/EU	EU
Dr. Markus Hartenbach|German Federal Armed Forces	F	UK/EU	EU
Eastern Health, Canada	F	Location Unknown	
ECOG-ACRIN Cancer Research Group|Eastern Cooperative Oncology Group	F	US/Canada	
ECOG-ACRIN Cancer Research Group|National Cancer Institute (NCI)|Eastern Cooperative Oncology Group	F	US/Canada	
Edward D Huey, MD|National Institute on Aging (NIA)|Columbia University	F	US/Canada	
Emory University	Ga	US/Canada	
Emory University|National Cancer Institute (NCI)	F	US/Canada	
Ente Ospedaliero Ospedali Galliera	F, Cu	UK/EU	EU
Erasmus Medical Center	F	UK/EU	EU
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)|National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)|National Institutes of Health Clinical Center (CC)	F, Ga	US/Canada	
First Affiliated Hospital of Fujian Medical University	F	ROW	
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico Di Milano	F	UK/EU	EU
Fondazione Toscana Gabriele Monasterio	F	UK/EU	EU
Frederick Daniel Grant|Dana-Farber Cancer Institute|Boston Children's Hospital	F	US/Canada	
Fundaci ACE-Institut Catal de Neuroci ncies Aplicades	F	UK/EU	EU
Fundaci Cl nic per a la Recerca Biom dica	F	UK/EU	EU

Fundaci n P blica Andaluza para la Gesti n de la Investigaci n en Salud de Sevilla	F	UK/EU	EU
Fundacion Clinic per a la Recerca BiomÃ©dica	F	Location Unknown	
G.A.P. Hospers|University Medical Center Groningen	F	UK/EU	EU
Geriatric Centre, Ume University hospital	F	UK/EU	EU
German Cancer Research Center|ABX CRO|Friedrich-Alexander-UniversitÃ¤t Erlangen-NÃrnberg|University Hospital Freiburg	Ga	UK/EU	EU
German Oncology Center	F	UK/EU	EU
Ghent University Hospital	F	UK/EU	EU
Glenn Bauman|Western University, Canada|United States Department of Defense|Centre for Probe Development and Commercialization|Lawson Health Research Institute	F	US/Canada	
Gustave Roussy, Cancer Campus, Grand Paris	F	UK/EU	EU
Heike E Daldrup-Link|Stanford University	F	US/Canada	
Hoag Memorial Hospital Presbyterian	F	US/Canada	
Hospices Civils de Lyon	F	UK/EU	EU
Hospital Universitario Dr. Negrin	F	UK/EU	EU
Institut Cancerologie de l'Ouest|Fondation ARC	Cu	UK/EU	EU
Institut Cancerologie de l'Ouest|Siric Iliad	F	UK/EU	EU
Institut Curie	F	UK/EU	EU
Institut de cancerologie Strasbourg Europe	F	Location Unknown	
Institut De Cancerologie De L'ouest	F	UK/EU	EU
Institut de Recerca HSCSP	F	UK/EU	EU
Institute for Neurodegenerative Disorders	F	UK/EU	EU
Institute of Nuclear Energy Research, Taiwan	Ga	ROW	
Istituti Fisioterapici Ospitalieri	F	UK/EU	EU
Istituto Europeo Di Oncologia	F	UK/EU	EU
Istituto Neurologico Mediterraneo Neuromed	F	UK/EU	EU
Istituto Scientifico Romagnolo per lo Studio e la cura dei Tumori	F	UK/EU	EU
Istituto Scientifico Romagnolo Per Lo Studio E La Cura Dei Tumori (IRST) S.R.L. IRCCS	F	UK/EU	EU
Jae Seung Kim|Asan Medical Center	F	ROW	

Jae Seung Kim|Korea Health Industry Development Institute|Samsung Medical Center|Asan Medical Center	F	ROW	
James Brugarolas|University of Texas Southwestern Medical Center	Zr	US/Canada	
James M Noble, MD, MS, CPH, FAAN|National Institute on Aging (NIA)|Columbia University	F	US/Canada	
Joan Albert Barbera Mir|Hospital Clinic of Barcelona	F	Location Unknown	
Jonsson Comprehensive Cancer Center	Ga	US/Canada	
Jonsson Comprehensive Cancer Center|National Cancer Institute (NCI)	Ga	US/Canada	
Jules Bordet Institute	Ga	UK/EU	EU
Karolinska University Hospital	Ga	UK/EU	EU
King's College London	F	UK/EU	UK
KU Leuven	F	UK/EU	EU
Leiden Universitair Medisch Centrum	F	UK/EU	EU
Leiden University Medical Center	Zr	UK/EU	EU
Lek rska fakulta Univerzity Komensk ho v Bratislave	Ga	UK/EU	EU
Lida Jafari|University of California, Los Angeles|VA Greater Los Angeles Healthcare System	F	US/Canada	
M.D. Anderson Cancer Center|National Cancer Institute (NCI)|Trevarx Biomedical, Inc	F	US/Canada	
Maastricht University Medical Center	F	UK/EU	EU
MAASTRO Clinic	F	UK/EU	EU
Marcelo F. Di Carli, MD, FACC|Brigham and Women's Hospital	F	US/Canada	
Masaryk v onkologick stav	F	UK/EU	EU
Massachusetts General Hospital	F	US/Canada	
Massachusetts General Hospital|National Heart, Lung, and Blood Institute (NHLBI)	Cu	US/Canada	
Mayo Clinic	Ga	US/Canada	
Mayo Clinic|National Cancer Institute (NCI)	Ga	US/Canada	
Mayo Clinic|National Cancer Institute (NCI)|United States Department of Defense	Ga	US/Canada	
Medical University Innsbruck	Ga	UK/EU	EU
Medical University of Vienna, Department of Biomedical Imaging and Image-guided Therapy	F	UK/EU	EU

Medizinische Universit t Innsbruck	Ga	UK/EU	EU
Medizinische Universit t Wien, Univ.Klinik f.Radiodiagnostik	F	UK/EU	EU
Memorial Sloan Kettering Cancer Center	F	US/Canada	
Memorial Sloan Kettering Cancer Center|National Cancer Institute (NCI)	F	US/Canada	
Memorial Sloan Kettering Cancer Center|Weill Medical College of Cornell University|Broad Institute	Zr	US/Canada	
Michael Graham PhD, MD|University of Iowa	Ga	US/Canada	
Michael Graham PhD, MD|University of Iowa|Holden Comprehensive Cancer Center	Ga	US/Canada	
Michael Graham|Holden Comprehensive Cancer Center|University of Iowa	Ga	US/Canada	
Michael J. Fox Foundation for Parkinson's Research|Institute for Neurodegenerative Disorders	F	US/Canada	
Miguel Pampaloni|University of California, San Francisco	F	US/Canada	
Mikkel Holm Vendelbo	F	UK/EU	EU
MUW-Medical University of Vienna,Medizinische Universit t Wien	F	UK/EU	EU
Nanjing Medical University	F	ROW	
Nantes University Hospital	F	UK/EU	EU
National Cancer Institute (NCI)	F	US/Canada	
National Cancer Institute (NCI)|National Institutes of Health Clinical Center (CC)	F	US/Canada	
National Cancer Institute (NCI)|NRG Oncology	F	US/Canada	
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)|National Institutes of Health Clinical Center (CC)	Ga	US/Canada	
National Institute of Mental Health (NIMH)|National Institutes of Health Clinical Center (CC)	F	US/Canada	
National Institutes of Health Clinical Center (CC)	F	US/Canada	
National Taiwan University Hospital	F	ROW	
Neil M Rofsky, MD, MHA|University of Texas Southwestern Medical Center	F	US/Canada	

Norbert Avril, M.D.|Case Comprehensive Cancer Center	Ga	US/Canada	
Northwestern University|National Cancer Institute (NCI)	F	US/Canada	
Nottingham University Hospitals NHS Trust	F	UK/EU	UK
Odense University Hospital	F	UK/EU	EU
OHSU Knight Cancer Institute|National Cancer Institute (NCI)|Oregon Health and Science University|Weill Cornell University	F	US/Canada	
Ontario Clinical Oncology Group (OCOG)|Ontario Ministry of Health and Long Term Care	F	US/Canada	
Ospedale Classificato Equiparato Sacro Cuore Don Calabria - Presidio Ospedaliero Accreditato	F	UK/EU	EU
Ospedale San Raffaele	F	UK/EU	EU
Oxford University Hospitals NHS Trust	F	UK/EU	UK
Peking Union Medical College Hospital	Ga	ROW	
Peter MacCallum Cancer Centre, Australia	F	ROW	
Policlinico Universitario Agostino Gemelli	F	UK/EU	EU
Princess M xima Center for pediatric oncology	F	UK/EU	EU
Queen's Medical Center|National Cancer Institute (NCI)	F	US/Canada	
Radboud University Medical Center	F	UK/EU	EU
Radboud University Medical Center|Amsterdam UMC, location VUmc|University Medical Center Groningen|MMC Hopsital Veldvoven (Department of Surgery)	F	UK/EU	EU
Radboudumc	F	UK/EU	EU
Rahul Aggarwal|National Cancer Institute (NCI)|U.S. Army Medical Research Acquisition Activity|University of California, San Francisco	Cu	US/Canada	
Region Sk ne	F	UK/EU	EU
Rigshospitalet	Cu	UK/EU	EU
Rigshospitalet, Denmark	F, Cu	UK/EU	EU
Sanjiv Sam Gambhir|National Cancer Institute (NCI)|Stanford University	F	US/Canada	
Shanghai Chest Hospital	F	Location Unknown	
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins	F	US/Canada	

Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins|National Cancer Institute (NCI)	F	US/Canada	
Sir Mortimer B. Davis - Jewish General Hospital	F	US/Canada	
St. Antonius Hospital	Ga	UK/EU	EU
St. Jude Children's Research Hospital	N	US/Canada	
Stanford University	F	US/Canada	
Stanford University School of Medicine	F	Worldwide	
Stanford University|National Cancer Institute (NCI)	Ga	US/Canada	
Stanford University|National Institutes of Health (NIH)	F	US/Canada	
Stockholm County Council	F	UK/EU	EU
Sue O'Dorisio|National Cancer Institute (NCI)|University of Iowa	Ga	US/Canada	
Sue O'Dorisio|University of Iowa	Ga	US/Canada	
The European Uro-Oncology Group|Centre for Human Drug Research, Netherlands	F	UK/EU	EU
Thomas Hope|Conquer Cancer Foundation|Gateway for Cancer Research|Prostate Cancer Foundation|University of California, San Francisco	Ga	US/Canada	
Thomas Hope|University of California, San Francisco	F	US/Canada	
Tianjin Medical University Cancer Institute and Hospital	F	Location Unknown	
tichting Het Nederlands Kanker Instituut_Antoni van Leeuwenhoek	F	UK/EU	EU
Tim Lau|McGill University|The Royal Ottawa Mental Health Centre	F	Location Unknown	
Turku PET Centre	F	UK/EU	EU
Turku University Hospital	F	UK/EU	EU
UMC Utrecht	F	UK/EU	EU
UMCG	F	UK/EU	EU
Ume University Hospital	F	UK/EU	EU
UNC Lineberger Comprehensive Cancer Center	Ga	US/Canada	
Univ.-Kl.f.Nuklearmedizin Wien	F	UK/EU	EU
Universit del Piemonte Orientale	F	UK/EU	EU

Universit t Heidelberg, Medizinische Fakult t Mannheim	F	UK/EU	EU
Universitair Ziekenhuis Brussel|Kom Op Tegen Kanker|Agentschap voor Innovatie door Wetenschap en Technologie, Project Toegepast Biomedisch onderzoek met een primair Maatschappelijke finaliteit.	Ga	UK/EU	EU
Universitaire Ziekenhuizen KU Leuven|University Hospital, Antwerp|University Hospital, Ghent|Netwerk, Belgium	F	UK/EU	EU
University College, London|Cancer Research UK|Imperial College London|National Cancer Imaging Translational Accelerator	F	UK/EU	UK
University Cologne	F	UK/EU	EU
University Health Network, Toronto|Princess Margaret Hospital, Canada	F	US/Canada	
University Hospital Ghent	F	UK/EU	EU
University Hospital Maastricht	F	UK/EU	EU
University Hospital of Montpellier	F	UK/EU	EU
University Hospital Tuebingen	F	UK/EU	EU
University Hospital, Bordeaux	F	UK/EU	EU
University Hospital, Brest	F	UK/EU	EU
University Hospital, Caen	F	UK/EU	EU
University Hospital, Ghent	F	UK/EU	EU
University Hospital, Ghent|Kom Op Tegen Kanker	F	UK/EU	EU
University Hospital, Tours	F	UK/EU	EU
University Medical Center Groningen	Zr	UK/EU	EU
University Medical Center Groningen, Department of Rheumatology and Clinical Immunology	F	UK/EU	EU
University of Aarhus|Danish Cancer Society	F	UK/EU	EU
University of Aarhus|GCP-unit at Aarhus University Hospital, Aarhus, Denmark|REDCap	F	Location Unknown	
University of Alabama at Birmingham	F	US/Canada	
University of Alberta	F	US/Canada	
University of Alberta|Alberta Health services	F	US/Canada	
University of Alberta|Canadian Urological Association Scholarship Foundation	F	US/Canada	
University of British Columbia|British Columbia Cancer Agency	F	US/Canada	

University of Calgary	F	US/Canada	
University of California, San Francisco	Ga	US/Canada	
University of California, San Francisco|National Cancer Institute (NCI)	F	US/Canada	
University of Cologne	F	UK/EU	EU
University of Edinburgh	F	Worldwide	
University of Iowa|National Cancer Institute (NCI)|National Institutes of Health (NIH)	F	US/Canada	
University of Lausanne Hospitals|Swiss Heart Foundation	Ga	UK/EU	EU
University of Leipzig	F	UK/EU	EU
University of Leuven	F	UK/EU	EU
University of Manitoba|Winnipeg Regional Health Authority	F	US/Canada	
University of Michigan	Ga	US/Canada	
University of North Carolina, Chapel Hill|Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)	F	US/Canada	
University of North Carolina, Chapel Hill|North Carolina Translational and Clinical Sciences Institute	F	US/Canada	
University of Pennsylvania	F	US/Canada	
University of Pennsylvania|Brigham and Women's Hospital|University of Maryland|Yale University|Washington University School of Medicine|The Cardiovascular Medical Research and Education Fund	F	US/Canada	
University of Saskatchewan	Zr	US/Canada	
University of Texas Southwestern Medical Center	F	US/Canada	
University of Utah	F	US/Canada	
University of Washington	Ga	US/Canada	
University of Wisconsin, Madison	F	US/Canada	
University of Wisconsin, Madison|National Cancer Institute (NCI)	F	US/Canada	
VA Greater Los Angeles Healthcare System	F	US/Canada	

Vanderbilt University Medical Center|Vanderbilt Kennedy Center	F	US/Canada	
Vanderbilt-Ingram Cancer Center|National Cancer Institute (NCI)	F	US/Canada	
VU University Medical Center	F	UK/EU	EU
Washington University School of Medicine	F	US/Canada	
Washington University School of Medicine|National Cancer Institute (NCI)	F	US/Canada	
Washington University School of Medicine|St. Louis Children's Hospital	F	US/Canada	
Weill Medical College of Cornell University	Zr, Ga	US/Canada	
Weill Medical College of Cornell University|Cornell University	Ga	US/Canada	
West Virginia University	F, Ga	US/Canada	
Wuerzburg University Hospital|Charite University, Berlin, Germany|Heinrich-Heine University, Duesseldorf|University Hospital, Essen|Johannes Gutenberg University Mainz|Ludwig-Maximilians - University of Munich|Hannover Medical School|University of Leipzig|University of Florence|University of Padova|Cambridge University Hospitals NHS Foundation Trust|University Medical Center Nijmegen|Uppsala University Hospital|Assistance Publique - HÃ´pitaux de Paris|University of Vienna	F	UK/EU	EU
Xiangya Hospital of Central South University	F	ROW	
Xijing Hospital	F, Ga	Location Unknown	
	F	Location Unknown	

Appendix 4. Preclinical studies for Scandium, Rubidium, Oxygen and Nitrogen

The following list includes a total of 43 studies retrieved from Embase (Ovid) that included one of the relevant radionuclides (Sc, Rb, O or N) in title and that were not anaysed using visualisation of similarities.

1. Record no. 1 Ashworth, E. T., Ogawa, R., Vera, D. and Lindholm, P. (2023). **A novel method for tracking nitrogen kinetics in vivo and ex vivo using radioactive nitrogen-13 gas and Positron Emission Tomography.** bioRxiv https://doi.org/https://dx.doi.org/10.1101/2023.06.01.543280.

Rationale Decompression sickness (DCS) is caused by gaseous nitrogen dissolved in tissues forming bubbles during decompression. To date no method exists to identify nitrogen within tissues, but with advances in PET technology it may be possible to track gaseous radionuclides into tissues. We aimed to develop a method to track nitrogen movement in vivo that could then be used to further our understanding of DCS using nitrogen-13 (13N2) - a radioactive isotope of nitrogen that emits beta+ radiation. Methods A single anesthetized and ventilated Sprague Dawley rat lay supine inside a PET scanner for 30 min. The rat breathed oxygen for the first 2 min, then was switched to a bag containing 13N2 gas mixed with oxygen for 20 min, then breathed oxygen alone for the final 8 min. Gas samples were drawn from the inspiratory line at 5, 15 and 25 min. The PET scanner recorded 13N2 with energy windows of 250-750 keV. Following the scan, a mixed blood sample was taken from the heart, while the brain, liver, femur and thigh muscle were removed to determine organ radioactivity using a gamma counter. Results The gas samples at 5 (5.7 kbq.ml-1) and 15 min (5.3 kbq.ml-1) showed radioactivity in the inspired gas that was absent at 25 min (0.1 kbq.ml-1), when the 13N2 was stopped. The signal intensity in the PET scanner increased from baseline (0.03) to 2-12 min (0.68+/-0.31), and 12-22 min (0.88+/-0.06), before reducing slightly from 22-30 min (0.61+/-0.04). All organs had radioactivity when measured in the gamma counter, with the highest counts in the liver (12593 counts.min-1.g-1) and the lowest in the muscle (2687 counts.min-1.g-1). Principal Conclusions This study successfully demonstrated a quantitative 3D imaging method of tracking nitrogen gas through the body both in vivo and ex vivo using PET.Copyright The copyright holder for this preprint is the author/funder, who has granted bioRxiv a license to display the preprint in perpetuity. It is made available under a CC-BY-NC-ND 4.0 International license.

2. Record no. 507 Benabdallah, N., Zhang, H., Unnerstall, R., Fears, A., Summer, L., Fassbender, M., Rodgers, B. E., Abou, D., Radchenko, V. and Thorek, D. L. J. (2023). **Engineering a modular 44Ti/44Sc generator: eluate evaluation in preclinical models and estimation of human radiation dosimetry.** EJNMMI Research 13(1): 17 https://doi.org/https://dx.doi.org/10.1186/s13550-023-00968-5.

Background: 44Sc/47Sc is an attractive theranostic pair for targeted in vivo positron emission tomographic (PET) imaging and beta-particle treatment of cancer. The 44Ti/44Sc generator allows daily onsite production of this diagnostic isotope, which

may provide an attractive alternative for PET facilities that lack in-house irradiation capabilities. Early animal and patient studies have demonstrated the utility of 44Sc. In our current study, we built and evaluated a novel clinical-scale 44Ti/44Sc generator, explored the pharmacokinetic profiles of 44ScCl3, [44Sc]-citrate and [44Sc]-NODAGA (1,4,7-triazacyclononane,1-glutaric acid-4,7-acetic acid) in naive mice, and estimated the radiation burden of 44ScCl3 in humans. Method(s): 44Ti/44Sc (101.2 MBq) in 6 M HCl solution was utilized to assemble a modular ZR resin containing generator. After assembly, 44Sc was eluted with 0.05 M HCl for further PET imaging and biodistribution studies in female Swiss Webster mice. Based on the biodistribution data, absorbed doses of 44/47ScCl3 in human adults were calculated for 18 organs and tissues using the IDAC-Dose software. Result(s): 44Ti in 6 M HCl was loaded onto the organic resin generator with a yield of 99.97%. After loading and initial stabilization, 44ScCl3 was eluted with 0.05 M HCl in typical yields of 82.9 +/- 5.3% (N = 16), which was normalized to the estimated generator capacity. Estimated generator capacity was computed based on elution time interval and the total amount of 44Ti loaded on the generator. Run in forward and reverse directions, the 44Sc/44Ti ratio from a primary column was significantly improved from 1038 +/- 440 to 3557 +/- 680 (Bq/Bq) when a secondary, replaceable, ZR resin cartridge was employed at the flow outlet. In vivo imaging and ex vivo distribution studies of the reversible modular generator for 44ScCl3, [44Sc]-citrate and [44Sc]-NODAGA show that free 44Sc remained in the circulation significantly longer than the chelated 44Sc. The dose estimation of 44ScCl3 reveals that the radiation burden is 0.146 mSv/MBq for a 70 kg adult male and 0.179 mSv/MBq for a 57 kg adult female. Liver, spleen and heart wall will receive the highest absorbed dose: 0.524, 0.502, and 0.303 mGy/MBq, respectively, for the adult male. Conclusion(s): A clinical-scale 44Ti/44Sc generator system with a modular design was developed to supply 44ScCl3 in 0.05 M HCl, which is suitable for further radiolabeling and in vivo use. Our data demonstrated that free 44ScCl3 remained in the circulation for extended periods, which resulted in approximately 10 times greater radiation burden than stably chelated 44Sc. Stable 44Sc/47Sc-complexation will be more favorable for in vivo use and for clinical utility.Copyright © 2023, The Author(s).

3. Record no. 225 Biondetti, E., Cho, J. and Lee, H. (2023). **Cerebral oxygen metabolism from MRI susceptibility.** NeuroImage 276: 120189 https://doi.org/https://dx.doi.org/10.1016/j.neuroimage.2023.120189.

This article provides an overview of MRI methods exploiting magnetic susceptibility properties of blood to assess cerebral oxygen metabolism, including the tissue oxygen extraction fraction (OEF) and the cerebral metabolic rate of oxygen (CMRO2). The first section is devoted to describing blood magnetic susceptibility and its effect on the MRI signal. Blood circulating in the vasculature can have diamagnetic (oxyhemoglobin) or paramagnetic properties (deoxyhemoglobin). The overall balance between oxygenated and deoxygenated hemoglobin determines the induced magnetic field which, in turn, modulates the transverse relaxation decay of the MRI signal via additional phase accumulation. The following sections of this review then illustrate the principles underpinning susceptibility-based techniques for quantifying OEF and CMRO2. Here, it is detailed whether these techniques provide global (OxFlow) or local (Quantitative Susceptibility Mapping - QSM, calibrated BOLD - cBOLD, quantitative BOLD - qBOLD, QSM+qBOLD) measurements of OEF or CMRO2, and what signal components

(magnitude or phase) and tissue pools they consider (intravascular or extravascular). Validations studies and potential limitations of each method are also described. The latter include (but are not limited to) challenges in the experimental setup, the accuracy of signal modeling, and assumptions on the measured signal. The last section outlines the clinical uses of these techniques in healthy aging and neurodegenerative diseases and contextualizes these reports relative to results from gold-standard PET.Copyright © 2023

4. Record no. 722 Chen, S. X., Zhang, J., Xue, F., Liu, W., Kuang, Y., Gu, B., Song, S. and Chen, H. (2023). **In situ forming oxygen/ROS-responsive niche-like hydrogel enabling gelation-triggered chemotherapy and inhibition of metastasis.** Bioactive Materials 21: 86-96 https://doi.org/https://dx.doi.org/10.1016/j.bioactmat.2022.08.002.

Though the development of the diverse hypoxia-activated prodrugs (HAPs) has made great progresses in the last several decades, current cancer therapy based on HAPs still suffers many obstacles, e.g., poor therapeutic outcome owing to hard deep reaching to hypoxic region, and the occurrence of metastasis due to hypoxia. Inspired by engineered niches, a novel functional chitosan polymer (CS-FTP) is synthesized for construction of a hydrogel-based bio-niche (CS-FTP-gel) in aiming at remodeling tumor hypoxic microenvironment. The CS-FTP polymers are crosslinked to form a niche-like hydrogel via enzyme-mediated oxygen-consumable dimerization after injected into tumor, in which a HAP (i.e., AQ4N) could be physically encapsulated, resulting in enhanced tumor hypoxia to facilitate AQ4N-AQ4 toxic transformation for maximizing efficacy of chemotherapy. Furthermore, Pazopanib (PAZ) conjugated onto the CS backbone via ROS-sensitive linker undergoes a stimuli-responsive release behavior to promote antiangiogenesis for tumor starvation, eventually contributing to the inhibition of lung metastasis and synergistic action with AQ4N-based chemotherapy for an orthotopic 4T1 breast tumor model. This study provides a promising strategy for hypoxia-based chemotherapy and demonstrates an encouraging clinical potential for multifunctional hydrogel applicable for antitumor treatment.Copyright © 2022 The Authors

5. Record no. 117 Kvitastein, U. A., Kumarananthan, C. P., Fiskeseth, N. G. and Adamsen, T. C. H. (2023). **Production and separation of the PET-radionuclide Ti-45 from a liquid nat-Sc target for ligand complexation.** EJNMMI Radiopharmacy and Chemistry 8(Supplement 1) https://doi.org/https://dx.doi.org/10.1186/s41181-023-00193-4.

Aim: The most common PET-radionuclides are unsuitable for imaging of some physiological processes due to their short (e.g. C-11, Ga-68) or long half-lives (e.g. Zr-89, Cu-64). They either result in insufficient imaging or excessive radiation exposure. Titanium-45 is a promising PET-radionuclide with a half-life of 3.08 h. It has favorable decay characteristics for PET-imaging (85% positron decay) and has previously been produced in a cyclotron via the Sc-45(p,n)Ti-45 reaction by using a solid target [1, 2]. The aim of this study is to optimize the production of Ti-45 using a liquid target. Then isolate Ti-45 from the target material and other impurities formed during irradiation, using solid phase extraction (SPE) and liquid-liquid extraction (LLE) for further complexations with ligands. This to form a foundation for later development of radiopharmaceuticals labeled with Ti-45 for use in PET imaging. Material(s) and

Method(s): The liquid target was prepared by dissolving Sc(NO3)3 3H2O in HNO3. Using a PET Trace 860 cyclotron equipped with a PETtrace 800 68Ga Liquid target, different concentrations (1.0-2.5 M) Sc(NO3)3 were irradiated with a 14.3 MeV proton beam for 60-180 min with a beam-current of 20-30 muA. In the SPE approach the cyclotron product was loaded onto a ZR-resin, then the Sc-species were washed out with HCl, and finally Ti-45 was eluted using a ligand. This method was also automated using the FASTlabTM 2 synthesizer. In the LLE approach a mixture of guaiacol/anisole was used to extract Ti-45 from the aqueous phase into the organic phase. The phases were separated using a centrifuge and isolated. The organic phase was then mixed with different ligand solutions for complexation. The cyclotron product and the separation fractions were analyzed with gamma-ray spectrometry and the formation of the complexes was confirmed with radio-HPLC. A full factorial design was used to optimize the Ti-45 activity. Result(s): Gamma-ray spectrometry revealed EOB activities of Ti-45 ranging from 0.40 to 1.17 GBq in the cyclotron product. Co-production of radionuclidic impurities, i.e. Sc-44, Sc-44 and Mo-93m were found, and trace amounts of Ti-44 were also detected. The radionuclidic purity of the cyclotron product ranged from 85.5 to 99.3 %. Gammaray spectrometry of each separation fraction from the SPEs indicates impurities being washed out with HCl, and most of Ti-45 being eluted out by the ligand solution. For the LLEs the gamma-ray data show higher activity of Ti-45 in the organic phase, compared to the aqueous phase. Radio-HPLC of the [Ti-45]-ligand complexes shows peaks with retention times close to the retention times of cold reference Ti-ligand complexes. Conclusion(s): The productions resulted in Ti-45 activities ranging from 0.40 to 1.17 GBq (EOB) with a radionuclidic purity between 85.5% and 99.3%. Radionuclidic impurities, i.e, Sc-44, Sc-44m and Mo-93m were found, including trace amounts of Ti-44. Using lower currents and irradiation times yielded lower amounts of impurities. A model of the irradiation parameters and Ti-45 activities reveals that a combination of low current and irradiation time, and high concentration of both Sc(NO3)3 and HNO3 yields the highest Ti-45 activities. The complexation of Ti-45 with two different ligands was successfully achieved, utilizing both SPE and LLE for isolation of Ti-45. The SPE was also successfully automated by using the FASTlabTM 2 synthesizer. Further work includes isolating and refining the Ti-45 radiotracer from the complexation process through the use of semi-preparative HPLC. It is also necessary to study the biodistribution of the Ti-45 radionuclide. This is planned in two steps: (1) Ti-45 radiotracer distribution itself in healthy mice (2) biodistribution of a Ti-45 labeled biomolecule in a relevant cancer model.

6. Record no. 392 Pinchuk, A. N., Rampy, M. A., Longino, M. A., Durkee, B. Y., Counsell, R. E. and Weichert, J. P. (2023). **Effect of Polar Head Group Modifications on the Tumor Retention of Phospholipid Ether Analogs: Role of the Quaternary Nitrogen.** Pharmaceutics 15(1): 171 https://doi.org/https://dx.doi.org/10.3390/pharmaceutics15010171.

We have previously described the remarkable capacity of radioiodinated alkyl phospholipids to be sequestered and retained by a variety of tumors in vivo. We have already established the influence of certain structural parameters of iodinated alkyl phospholipids on tumor avidity, such as stereochemistry at the sn-2 carbon of alkylglycerol phosphocholines, meta-or para-position of iodine in the aromatic ring of phenylalkyl phosphocholines, and the length of the alkyl chain in alkyl phospholipids. In order to determine the additional structural requirements for tumor uptake and

retention, three new radioiodinated alkylphospholipid analogs, 2-4, were synthesized as potential tumor imaging agents. Polar head groups were modified to determine structure-tumor avidity relationships. The trimethylammonio group in 1 was substituted with a hydrogen atom in 2, an ammonio group in 3 and a tertiary butyl group in 4. All analogs were separately labeled with iodine-125 or iodine-124 and administered to Walker 256 tumor-bearing rats or human PC-3 tumor-bearing SCID mice, respectively. Tumor uptake was assessed by gamma-camera scintigraphy (for [I-125]-labeled compounds) and high-resolution micro-PET scanning (for [I-124]-labeled compounds). It was found that structural modifications in the polar head group of alkyl phospholipids strongly influenced the tumor uptake and tissue distribution of these compounds in tumor-bearing animals. Phosphoethanolamine analog 3 (NM401) displayed a very slight accumulation in tumor as compared with phosphocholine analog 1 (NM346). Analogs 2 (NM400) and 4 (NM402) lacking the positively charged nitrogen atom failed to display any tumor uptake and localized primarily in the liver. This study provided important insights regarding structural requirements for tumor uptake and retention. Replacement of the quaternary nitrogen in the alkyl phospholipid head group with non-polar substituents resulted in loss of tumor avidity.

7. Record no. 28 Trencsenyi, G. and Kepes, Z. (2023). **Scandium-44: Diagnostic Feasibility in Tumor-Related Angiogenesis.** International Journal of Molecular Sciences 24(8): 7400 https://doi.org/https://dx.doi.org/10.3390/ijms24087400.

Angiogenesis-related cell-surface molecules, including integrins, aminopeptidase N, vascular endothelial growth factor, and gastrin-releasing peptide receptor (GRPR), play a crucial role in tumour formation. Radiolabelled imaging probes targeting angiogenic biomarkers serve as valuable vectors in tumour identification. Nowadays, there is a growing interest in novel radionuclides other than gallium-68 (68Ga) or copper-64 (64Cu) to establish selective radiotracers for the imaging of tumour-associated neo-angiogenesis. Given its ideal decay characteristics (Ebeta + average: 632 KeV) and a half-life (T1/2 = 3.97 h) that is well matched to the pharmacokinetic profile of small molecules targeting angiogenesis, scandium-44 (44Sc) has gained meaningful attention as a promising radiometal for positron emission tomography (PET) imaging. More recently, intensive research has been centered around the investigation of 44Sc-labelled angiogenesis-directed radiopharmaceuticals. Previous studies dealt with the evaluation of 44Sc-appended avb3 integrin-affine Arg-Gly-Asp (RGD) tripeptides, GRPR-selective aminobenzoyl-bombesin analogue (AMBA), and hypoxia-associated nitroimidazole derivatives in the identification of various cancers using experimental tumour models. Given the tumour-related hypoxia- and angiogenesis-targeting capability of these PET probes, 44Sc seems to be a strong competitor of the currently used positron emitters in radiotracer development. In this review, we summarize the preliminary preclinical achievements with 44Sc-labelled angiogenesis-specific molecular probes.

8. Record no. 373 Unak, P., Yasakci, V., Tutun, E., Karatay, K. B., Walczak, R., Wawrowicz, K., Zelechowska-Matysiak, K., Majkowska-Pilip, A. and Bilewicz, A. (2023). **Multimodal Radiobioconjugates of Magnetic Nanoparticles Labeled with 44Sc and 47Sc for Theranostic Application.** Pharmaceutics 15(3): 850

https://doi.org/https://dx.doi.org/10.3390/pharmaceutics15030850.

This study was performed to synthesize multimodal radiopharmaceutical designed for the diagnosis and treatment of prostate cancer. To achieve this goal, superparamagnetic iron oxide (SPIO) nanoparticles were used as a platform for targeting molecule (PSMA-617) and for complexation of two scandium radionuclides, 44Sc for PET imaging and 47Sc for radionuclide therapy. TEM and XPS images showed that the Fe3O4 NPs have a uniform cubic shape and a size from 38 to 50 nm. The Fe3O4 core are surrounded by SiO2 and an organic layer. The saturation magnetization of the SPION core was 60 emu/g. However, coating the SPIONs with silica and polyglycerol reduces the magnetization significantly. The obtained bioconjugates were labeled with 44Sc and 47Sc, with a yield higher than 97%. The radiobioconjugate exhibited high affinity and cytotoxicity toward the human prostate cancer LNCaP (PSMA+) cell line, much higher than for PC-3 (PSMA-) cells. High cytotoxicity of the radiobioconjugate was confirmed by radiotoxicity studies on LNCaP 3D spheroids. In addition, the magnetic properties of the radiobioconjugate should allow for its use in guide drug delivery driven by magnetic field gradient.

9. Record no. 134 Waddle, S. L., Garza, M., Ying, C., Davis, L. T., Jordan, L. C., An, H. and Donahue, M. J. (2023). **Vascular space occupancy asymmetric spin echo (VASO-ASE) for non-invasive quantification of cerebral oxygen extraction fraction.** Magnetic Resonance in Medicine 90(1): 211-221 https://doi.org/https://dx.doi.org/10.1002/mrm.29618.

Purpose: Asymmetric spin echo (ASE) MRI is a method for measuring regional oxygen extraction fraction (OEF); however, extravascular tissue models have been shown to under-estimate OEF. The hypothesis investigated here is that the addition of a vascular-space-occupancy (VASO) pre-pulse will more fully suppress blood water signal and provide global OEF values more consistent with physiological expectation and 15O positron emission tomography (PET)-validated T2-relaxation-under-spin-tagging (TRUST) OEF measures. Method(s): Healthy adults (n = 14; age = 27.7 +/- 5.2 y; sex = 7/7 male/female) were scanned at 3.0T. Multi-echo ASE without inter-readout refocusing (ASERF-), multi-echo ASE with inter-readout refocusing (ASERF+), and single-echo VASO-ASE were acquired twice each with common spatial resolution = 3.44 x 3.44 x 3.0 mm and tau = 0-20 ms (interval = 0.5 ms). TRUST was acquired twice sequentially for independent global OEF assessment (tauCPMG = 10 ms; effective TEs = 0, 40, 80, and 160 ms; spatial resolution = 3.4 x 3.4 x 5 mm). OEF intraclass-correlation-coefficients (ICC), summary statistics, and group-wise differences were assessed (Wilcoxon rank-sum; significance: two-sided $p < 0.05$). Result(s): ASERF+ (OEF = 36.8 +/- 1.9%) and VASO-ASE (OEF = 34.4 +/- 2.3%) produced OEF values similar to TRUST (OEF = 36.5 +/- 4.6%, human calibration model; OEF = 32.7 +/- 4.9%, bovine calibration model); however, ASERF- yielded lower OEF (OEF = 26.1 +/- 1.0%; $p < 0.01$) relative to TRUST. VASO-ASE (ICC = 0.61) yielded lower ICC compared to other ASE variants (ICC >0.89). Conclusion(s): VASO-ASE and TRUST provide similar OEF values; however, VASO-ASE spatial coverage and repeatability improvements are required.

10. Record no. 671 Bentsen, S., Bang, L. E., Hasbak, P., Kjaer, A. and Ripa, R. S. (2022). **Amiodarone attenuates cardiac Rubidium-82 in consecutive PET/CT scans in a rodent model.**

Journal of Nuclear Cardiology 29(6): 2853-2862 https://doi.org/https://dx.doi.org/10.1007/s12350-021-02785-6.

Background: Risk stratification and diagnosis using Rubidium-82 (82Rb) positron emission tomography (PET) is a routine clinical approach in coronary artery disease (CAD). Various drugs are used to treat CAD; however, whether any of them change the uptake of 82Rb in the heart has not been investigated. The aim of this study is to determine whether drugs used in treatment of CAD affect the uptake of 82Rb in the heart in healthy rats. Method(s): Seventy-seven Sprague-Dawley rats were included in the cross-sectional study. All rats underwent baseline 82Rb PET/CT and divided into eleven groups treated with different drugs. One group was control group (no treatment), eight groups were treated with monotherapy (amiodarone, acetylsalicylic acid (ASA), clopidogrel, ticagrelor, atorvastatin, enalapril, amlodipine, metoprolol succinate), and two groups were treated with polypharmacy (ASA, ticagrelor, atorvastatin, amlodipine or ASA, clopidogrel, atorvastatin, amlodipine). Once a day, they were administered pharmacological therapy through oral gavage, and on day seven, follow-up scanned with 82Rb PET/CT. Result(s): In the control group without pharmacological treatment, no difference in the standard uptake value (SUV) ratio between heart and muscle from baseline to follow-up (5.8 vs 7.0, P = .3) was found. The group treated with amiodarone had a significantly reduced SUV ratio from baseline to follow-up (5.8 vs 5.1, P = .008). All other drugs investigated had no difference in SUV ratio from baseline to follow-up. Conclusion(s): In this study, we showed that drugs normally used to treat CAD do not affect the uptake of 82Rb. However, amiodarone result in a significantly lowered 82Rb uptake, compared to control. This information about amiodarone would probably not change the size assessment of a myocardial perfusion defect in a clinical setting. However, it could change the kinetic parameters when assessing absolute myocardial blood flow in patients treated with amiodarone.Copyright © 2021, American Society of Nuclear Cardiology.

11. Record no. 1238 Csupasz, T., Szucs, D., Kalman, F. K., Holloczki, O., Fekete, A., Szikra, D., Toth, E., Toth, I. and Tircso, G. (2022). **A New Oxygen Containing Pyclen-Type Ligand as a Manganese(II) Binder for MRI and 52Mn PET Applications: Equilibrium, Kinetic, Relaxometric, Structural and Radiochemical Studies.** Molecules (Basel, Switzerland) 27(2) https://doi.org/https://dx.doi.org/10.3390/molecules27020371.

A new pyclen-3,9-diacetate derivative ligand (H23,9-OPC2A) was synthesized possessing an etheric O-atom opposite to the pyridine ring, to improve the dissociation kinetics of its Mn(II) complex (pyclen = 3,6,9,15-tetraazabicyclo(9.3.1)pentadeca-1(15),11,13-triene). The new ligand is less basic than the N-containing analogue (H23,9-PC2A) due to the non-protonable O-atom. In spite of its lower basicity, the conditional stability of the [Mn(3,9-OPC2A)] (pMn = -log(Mn(II)), cL = cMn(II) = 0.01 mM. pH = 7.4) remains unaffected (pMn = 8.69), compared to the [Mn(3,9-PC2A)] (pMn = 8.64). The [Mn(3,9-OPC2A)] possesses one water molecule, having a lower exchange rate with bulk solvents (kex298 = 5.3 +/- 0.4 x 107 s-1) than [Mn(3,9-PC2A)] (kex298 = 1.26 x 108 s-1). These mild differences are rationalized by density-functional theory (DFT) calculations. The acid assisted dissociation of [Mn(3,9-OPC2A)] is considerably slower (k1 = 2.81 +/- 0.07 M-1 s-1) than that of the complexes of diacetates or bisamides of various 12-membered macrocycles and the parent H23,9-PC2A. The [Mn(3,9-OPC2A)]

is inert in rat/human serum as confirmed by 52Mn labeling (nM range), as well as by relaxometry (mM range). However, a 600-fold excess of EDTA (pH = 7.4) or a mixture of essential metal ions, propagated some transchelation/transmetalation in 7 days. The H23,9-OPC2A is labeled efficiently with 52Mn at elevated temperatures, yet at 37 degreeC the parent H23,9-PC2A performs slightly better. Ultimately, the H23,9-OPC2A shows advantageous features for further ligand designs for bifunctional chelators.

12. Record no. 919 Huang, L., Fang, J., Hong, S., Liu, H., Zhu, H., Feng, L., Zhuang, R., Zhao, X., Guo, Z. and Zhang, X. (2022). **MicroPET imaging of bacterial infection with nitroreductase-specific responsive 18F-labelled nitrogen mustard analogues.** European Journal of Nuclear Medicine and Molecular Imaging 49(8): 2645-2654 https://doi.org/https://dx.doi.org/10.1007/s00259-022-05710-2.

Purpose: Bacterial infection and antibiotic resistance are serious threats to human health. This study aimed to develop two novel radiotracers, 18F-NTRP and 18F-NCRP, that possess a specific nitroreductase (NTR) response to image deep-seated bacterial infections using positron emission tomography (PET). This method can distinguish infection from sterile inflammation. Method(s): 18F-NTRP and 18F-NCRP were synthesized via a one-step method; all the steps usually involved in tracer radiosynthesis were successfully adapted in the All-In-One automated module. After the physiochemical properties of 18F-NTRP and 18F-NCRP were characterized, their specificity and selectivity for NTR were verified in E. coli and S. aureus. The ex vivo biodistribution of the tracers was evaluated in normal mice. MicroPET-CT imaging was performed in mouse models of bacterial infection and inflammation after the administration of 18F-NTRP or 18F-NCRP. Result(s): Fully automated radiosynthesis of 18F-NTRP and 18F-NCRP was achieved within 90-110 min with overall decay-uncorrected, isolated radiochemical yields of 21.24 +/- 4.25% and 11.3 +/- 3.78%, respectively. The molar activities of 18F-NTRP and 18F-NCRP were 320 +/- 40 GBq/mumol and 275 +/- 33 GBq/micromol, respectively. In addition, 18F-NTRP and 18F-NCRP exhibited high selectivity and specificity for NTR response. PET-CT imaging in bacteria-infected mouse models with 18F-NTRP or 18F-NCRP showed significant radioactivity uptake in either E. coli- or S. aureus-infected muscles. The uptake for E. coli-infected muscles, 2.4 +/- 0.2%ID/g with 18F-NTRP and 4.05 +/- 0.49%ID/g with 18F-NCRP, was up to three times greater than that for uninfected control muscles. Furthermore, for both 18F-NTRP and 18F-NCRP, the uptake in bacterial infection was 2.6 times higher than that in sterile inflammation, allowing an effective distinction of infection from inflammation. Conclusion(s): 18F-NTRP and 18F-NCRP are worth further investigation to verify their potential clinical application for distinguishing bacterial infection from sterile inflammation via their specific NTR responsiveness.

13. Record no. 950 Jensen, M., Bentsen, S., Clemmensen, A., Jensen, J. K., Madsen, J., Rossing, J., Laier, A., Hasbak, P., Kjaer, A. and Ripa, R. S. (2022). **Feasibility of positron range correction in 82-Rubidium cardiac PET/CT.** EJNMMI Physics 9(1): 51 https://doi.org/https://dx.doi.org/10.1186/s40658-022-00480-0.

Background: Myocardial perfusion imaging (MPI) using positron emission tomography (PET) tracers is an essential tool in investigating diseases and treatment responses in cardiology. 82Rubidium (82Rb)-PET imaging is advantageous for MPI due to its short half-life, but cannot be used for small animal research due to the long positron range. We aimed to correct for this, enabling MPI with 82Rb-PET in rats. Method(s): The effect of positron range correction (PRC) on 82Rb-PET was examined using two phantoms and in vivo on rats. A NEMA NU-4-inspired phantom was used for image quality evaluation (%standard deviation (%SD), spillover ratio (SOR) and recovery coefficient (RC)). A cardiac phantom was used for assessing spatial resolution. Two rats underwent rest 82Rb-PET to optimize number of iterations, type of PRC and respiratory gating. Result(s): NEMA NU-4 metrics (no PRC vs PRC): %SD 0.087 versus 0.103; SOR (air) 0.022 versus 0.002, SOR (water) 0.059 versus 0.019; RC (3 mm) 0.219 versus 0.584, RC (4 mm) 0.300 versus 0.874, RC (5 mm) 0.357 versus 1.197. Cardiac phantom full width at half maximum (FWHM) and full width at tenth maximum (FWTM) (no PRC vs. PRC): FWTM 6.73 mm versus 3.26 mm (true: 3 mm), FWTM 9.27 mm versus 7.01 mm. The in vivo scans with respiratory gating had a homogeneous myocardium clearly distinguishable from the blood pool. Conclusion(s): PRC improved the spatial resolution for the phantoms and in vivo at the expense of slightly more noise. Combined with respiratory gating, the spatial resolution achieved using PRC should allow for quantitative MPI in small animals.Copyright © 2022, The Author(s).

14. Record no. 918 Narciso, L., Ssali, T., Liu, L., Jesso, S., Hicks, J. W., Anazodo, U., Finger, E. and St Lawrence, K. (2022). **Noninvasive Quantification of Cerebral Blood Flow Using Hybrid PET/MR Imaging to Extract the [15O]H2O Image-Derived Input Function Free of Partial Volume Errors.** Journal of Magnetic Resonance Imaging 56(4): 1243-1255 https://doi.org/https://dx.doi.org/10.1002/jmri.28134.

Background: Quantification of cerebral blood flow (CBF) with [15O]H2O-positron emission tomography (PET) requires arterial sampling to measure the input function. This invasive procedure can be avoided by extracting an image-derived input function (IDIF); however, IDIFs are sensitive to partial volume errors due to the limited spatial resolution of PET. Purpose(s): To present an alternative hybrid PET/MR imaging of CBF (PMRFlowIDIF) that uses phase-contrast (PC) MRI measurements of whole-brain (WB) CBF to calibrate an IDIF extracted from a WB [15O]H2O time-activity curve. Study Type: Technical development and validation. Animal Model: Twelve juvenile Duroc pigs (83% female). Population: Thirteen healthy individuals (38% female). Field Strength/Sequences: 3 T; gradient-echo PC-MRI. Assessment: PMRFlowIDIF was validated against PET-only in a porcine model that included arterial sampling. CBF maps were generated by applying PMRFlowIDIF and two previous PMRFlow methods (PC-PET and double integration method [DIM]) to [15O]H2O-PET data acquired from healthy individuals. Statistical Tests: PMRFlow and PET CBF measurements were compared with regression and correlation analyses. Paired t-tests were performed to evaluate differences. Potential biases were assessed using one-sample t-tests. Reliability was assessed by intraclass correlation coefficients. Statistical significance: (Formula presented.) = 0.05. Result(s): In the animal study, strong agreement was observed between PMRFlowIDIF (average voxel-wise CBF, 58.0 +/- 16.9 mL/100 g/min) and PET (63.0 +/- 18.9 mL/100 g/min). In the human study, PMRFlowDIM (y = 1.11x - 5.16, R2 = 0.99 +/- 0.01) and PMRFlowPC-PET (y = 0.87x + 3.82, R2 = 0.97 +/-

0.02) performed similarly to PMRFlowIDIF, and CBF was within the expected range (eg, 49.7 +/- 7.2 mL/100 g/min for gray matter). Data Conclusion(s): Accuracy of PMRFlowIDIF was confirmed in the animal study with the primary source of error attributed to differences in WB CBF measured by PC MRI and PET. In the human study, differences in CBF from PMRFlowIDIF, PMRFlowDIM, and PMRFlowPC-PET were due to the latter two not accounting for blood-borne activity. Level of Evidence: 2. Technical Efficacy Stage: 1.Copyright © 2022 International Society for Magnetic Resonance in Medicine.

15. Record no. 1189 Phipps, M., Cingoranelli, S., Lewis, J., Lapi, S., Cutler, C., Francesconi, L. and Deri, M. (2022). **Evaluation of 3,4,3-LI(1,2-HOPO) as a chelator for radioscandium based radiopharmaceuticals.** Nuclear Medicine and Biology 108-109(Supplement): S155-S156 https://doi.org/https://dx.doi.org/10.1016/S0969-8051%2822%2900331-6.

Objectives: A few different radioscandium nuclides, including 43Sc (t1/2 = 3.89 h, beta+ max = 1.20 MeV, BRbeta+ = 70.9%), 44Sc (t1/2 = 3.97 h, beta+ max = 1.47 MeV, BRbeta+ = 94.3%), and 47Sc (t1/2 = 3.35 d, beta- max = 0.6 MeV, BRbeta- = 100%, gamma = 157 keV, BRgamma = 68%) have decay properties that are suitable for use in radiopharmaceuticals.1 Both 43Sc and 44Sc are suited for use in positron emission tomography (PET) imaging, and 47Sc has emissions suitable for single photon emission computed tomography (SPECT) imaging as well as targeted radiotherapy. In the pursuit of designing constructs for use with these nuclides, an optimized ligand is desired. 3,4,3-LI(1,2-HOPO) (referred to as HOPO) is an octadentate ligand with oxygen donor groups that has demonstrated high affinity and fast formation kinetics for hard positively charged (+3, +4) metal ions.2,3,4 Methods: HOPO was synthesized as previously reported with minor adjustments.4 Macroscopic Sc-HOPO was characterized by X-ray crystallography, mass spectrometry, 1H-NMR, and 45Sc-NMR. Radiolabeling of HOPO or DOTA was performed with either 43Sc, 44Sc, or 47Sc and verified by ITLC and HPLC. 47Sc-HOPO was evaluated with an in vitro EDTA challenge study and an in vivo biodistribution study in healthy Balb/c female mice. Biodistribution with free 47Sc was also performed. 43Sc-HOPO was used for PET imaging in healthy mice over 90 min p/i with biodistribution being performed immediately after the end of the PET scan. Result(s): Non-radioactive, macroscopic Sc-HOPO has been characterized thoroughly. All nuclides of radioscandium used here radiolabeled HOPO with > 95% radiochemical yield after 1 h at 37degreeC. Synthesis of the desired complex was verified by HPLC coinjection with a macroscopic standard. In vitro EDTA challenge against 47Sc-radiolabeled constructs showed comparable stability of 47Sc-HOPO and 47Sc-DOTA with both having > 90% stability at 7d. Biodistribution with either 47Sc-HOPO or 43Sc-HOPO showed high in vivo stability with rapid hepatobiliary excretion. In 47Sc-HOPO, < 1% ID/g remained in any organ at 24 h. Conclusion(s): Macroscopic Sc-HOPO has been thoroughly characterized. Radioscandium complexes of HOPO have been synthesized using 43Sc, 44ScSc, and 47Sc at 37degreeC. 43Sc-HOPO and 47Sc-HOPO exhibited high in vivo stability. Future work will expand to the use of bifunctional HOPO variants to evaluate radiolabeled bioconjugates of radioscandium and HOPO in diseased mouse models using an appropriate biological targeting molecule. Acknowledgements: Supported by the Tow Foundation Graduate Fellowship from the MSKCC Center for Molecular Imaging and Nanotechnology, DOE IP# ST5001020, DESC0020197, NSF-DGE

0965983, and the National Institute of General Medical Sciences of the National Institutes of Health under Award Number SC2GM130464

16. Record no. 647 Shimochi, S., Ihalainen, J., Parikka, V., Kokkomaki, E., Forsback, S., Tolvanen, T., Yatkin, E., Gronroos, T. J. and Iida, H. (2022). **Longitudinal Assessment of Cerebral Oxygen Metabolism in a Rat Model of Neonatal Hypoxic-Ischemic Encephalopathy using PET with Spontaneous Inhalation of 15O-Labeled Oxygen Gases.** European Journal of Nuclear Medicine and Molecular Imaging 49(Supplement 1): S429 https://doi.org/https://dx.doi.org/10.1007/s00259-022-05924-4.

Aim/Introduction: Perinatal hypoxic-ischemic encephalopathy (HIE) is the leading cause of irreversible brain damage resulting in serious neurological dysfunction with high interindividual variability. Hypothermia is well-established therapy but has limited clinical benefits. The present study aimed to evaluate the feasibility of the PET imaging methodology with spontaneous inhalation of 15O-labeled gases (15O-PET), which provides cerebral oxygen metabolic parameters, to assess the pathophysiological progression of cerebral tissue damage in a rat model of neonatal HIE. Material(s) and Method(s): HIE was induced in nine-day-old rats with permanent ligation of the left common carotid artery followed by hypoxia (8% oxygen) for 120min. PET imaging was carried out essentially as reported by Temma et al.[1], except for the sophisticated radio-gas scavenging system implemented in the animal holder. Sequential 15O-PET scans were performed on days 1, 2, 7, and 14 after the insult in HIE (n=5) and normal pups without any insult (n=4). In each scan, a series of 15O-labeled gases were inhaled spontaneously and cerebral oxygen metabolic parameters including cerebral blood flow (CBF) and cerebral metabolic rate for oxygen (CMRO2) were calculated from the functional parametric images. After the last PET scan, brains were removed and histologically examined with H&E and Iba1 staining. Result(s): The implemented system succeeded in the efficient supply of 15O-labeled gases mixed with isoflurane to the animals and allowed the evacuation of excess 15O-gas around the body. CBF and CMRO2 in the ipsilateral side brains of HIE pups decreased remarkably on day 2 after the insult to 72.7+/-7.4% and 51.1+/-9.1% respectively compared to the contralateral sides, and then gradually recovered over 14 days in line with the increasing trend of those values in normal pups according to their natural aging process, while microglial activation was present around the infarct tissues in histology. The increasing trend in CMRO2 after the insult could be attributed to the development of neuronal cells and the increased neurotransmitter function in growing infants. Conclusion(s): The present 15O-PET system enabled sequential evaluations of progressive cerebral tissue damage and the recovery process associated with an early developmental period of the immature brain after hypoxic-ischemic insult in rat neonates. This completely noninvasive imaging strategy without the need for tracheostomy or blood sampling could be of value for assessing new supportive therapeutics which could potentially enhance the neuroprotective effects of hypothermia in neonatal HIE with highly individualized in vivo follow-up.

17. Record no. 673 Werner, R. A., Rowe, S. P. and Higuchi, T. (2022). **No major impact of prescribed CAD drugs on myocardial perfusion uptake derived by [82]rubidium PET.** Journal of Nuclear Cardiology 29(6): 2863-2865 https://doi.org/https://dx.doi.org/10.1007/s12350-

021-02786-5.

18. Record no. 1478 Ding, D., Feng, Y., Qin, R., Li, S., Chen, L., Jing, J., Zhang, C., Sun, W., Li, Y., Chen, X. and Chen, H. (2021). **Mn3+-rich oxide/persistent luminescence nanoparticles achieve light-free generation of singlet oxygen and hydroxyl radicals for responsive imaging and tumor treatment.** Theranostics 11(15): 7439-7449 https://doi.org/https://dx.doi.org/10.7150/THNO.59056.

X-ray excited persistent luminescence (XEPL) imaging has attracted increasing attention in biomedical imaging due to elimination of autofluorescence, high signal-to-noise ratio and repeatable activation with high penetration. However, optical imaging still suffers from limited for high spatial resolution. Method(s): Herein, we report Mn3+-rich manganese oxide (MnOx)-coated chromium-doped zinc gallogermanate (ZGGO) nanoparticles (Mn-ZGGOs). Enhanced XEPL and magnetic resonance (MR) imaging were investigated by the decomposition of MnOxshell in the environment of tumors. We also evaluated the tumor cell-killing mechanism by detection of reactive oxygen (ROS), lipid peroxidation and mitochondrial membrane potential changes in vitro. Furthermore, the in vivo biodistribution, imaging and therapy were studied by U87MG tumor-bearing mice. Result(s): In the tumor region, the MnOxshell is quickly decomposed to produce Mn3+and oxygen (O2) to directly generate singlet oxygen (1O2). The resulting Mn2+transforms endogenous H2O2into highly toxic hydroxyl radical (OH) via a Fenton-like reaction. The Mn2+ions and ZGGOs also exhibit excellent T1-weighted magnetic resonance (MR) imaging and ultrasensitive XEPL imaging in tumors. Conclusion(s): Both the responsive dual-mode imaging and simultaneous self-supplied O2for the production of 1O2and oxygen-independent OH in tumors allow for more accurate diagnosis of deep tumors and more efficient inhibition of tumor growth without external activation energy.

19. Record no. 1443 Fang, H., Gai, Y., Wang, S., Liu, Q., Zhang, X., Ye, M., Tan, J., Long, Y., Wang, K., Zhang, Y. and Lan, X. (2021). **Biomimetic oxygen delivery nanoparticles for enhancing photodynamic therapy in triple-negative breast cancer.** Journal of Nanobiotechnology 19(1): 81 https://doi.org/https://dx.doi.org/10.1186/s12951-021-00827-2.

Background: Triple-negative breast cancer (TNBC) is a kind of aggressive breast cancer with a high rate of metastasis, poor overall survival time, and a low response to targeted therapies. To improve the therapeutic efficacy and overcome the drug resistance of TNBC treatments, here we developed the cancer cell membrane-coated oxygen delivery nanoprobe, CCm-HSA-ICG-PFTBA, which can improve the hypoxia at tumor sites and enhance the therapeutic efficacy of the photodynamic therapy (PDT), resulting in relieving the tumor growth in TNBC xenografts. Result(s): The size of the CCm-HSA-ICG-PFTBA was 131.3 +/- 1.08 nm. The in vitro 1O2 and ROS concentrations of the CCm-HSA-ICG-PFTBA group were both significantly higher than those of the other groups ($P < 0.001$). In vivo fluorescence imaging revealed that the best time window was at 24 h post-injection of the CCm-HSA-ICG-PFTBA. Both in vivo 18F-FMISO PET imaging and ex vivo immunofluorescence staining results exhibited

that the tumor hypoxia was significantly improved at 24 h post-injection of the CCm-HSA-ICG-PFTBA. For in vivo PDT treatment, the tumor volume and weight of the CCm-HSA-ICG-PFTBA with NIR group were both the smallest among all the groups and significantly decreased compared to the untreated group ($P < 0.01$). No obvious biotoxicity was observed by the injection of CCm-HSA-ICG-PFTBA till 14 days. Conclusion(s): By using the high oxygen solubility of perfluorocarbon (PFC) and the homologous targeting ability of cancer cell membranes, CCm-HSA-ICG-PFTBA can target tumor tissues, mitigate the hypoxia of the tumor microenvironment, and enhance the PDT efficacy in TNBC xenografts. Furthermore, the HSA, ICG, and PFC are all FDA-approved materials, which render the nanoparticles highly biocompatible and enhance the potential for clinical translation in the treatment of TNBC patients. [Figure not available: see fulltext.].Copyright © 2021, The Author(s).

20. Record no. 1641 Ferini, G., Valenti, V., Tripoli, A., Illari, S. I., Molino, L., Parisi, S., Cacciola, A., Lillo, S., Giuffrida, D. and Pergolizzi, S. (2021). **Lattice or oxygen-guided radiotherapy: What if they converge? possible future directions in the era of immunotherapy.** Cancers 13(13): 3290 https://doi.org/https://dx.doi.org/10.3390/cancers13133290.

Palliative radiotherapy has a great role in the treatment of large tumor masses. However, treating a bulky disease could be difficult, especially in critical anatomical areas. In daily clinical practice, short course hypofractionated radiotherapy is delivered in order to control the symptomatic disease. Radiation fields generally encompass the entire tumor mass, which is homogeneously irradiated. Recent technological advances enable delivering a higher radiation dose in small areas within a large mass. This goal, previously achieved thanks to the GRID approach, is now achievable using the newest concept of LATTICE radiotherapy (LT-RT). This kind of treatment allows exploiting various radiation effects, such as bystander and abscopal effects. These events may be enhanced by the concomitant use of immunotherapy, with the latter being ever more successfully delivered in cancer patients. Moreover, a critical issue in the treatment of large masses is the inhomogeneous intratumoral distribution of well-oxygenated and hypo-oxygenated areas. It is well known that hypoxic areas are more resistant to the killing effect of radiation, hence the need to target them with higher aggressive doses. This concept introduces the "oxygen-guided radiation therapy" (OGRT), which means looking for suitable hypoxic markers to implement in PET/CT and Magnetic Resonance Imaging. Future treatment strategies are likely to involve combinations of LT-RT, OGRT, and immunotherapy. In this paper, we review the radiobiological rationale behind a potential benefit of LT-RT and OGRT, and we summarize the results reported in the few clinical trials published so far regarding these issues. Lastly, we suggest what future perspectives may emerge by combining immunotherapy with LT-RT/OGRT.Copyright © 2021 by the authors. Licensee MDPI, Basel, Switzerland.

21. Record no. 1659 Gertsenshteyn, I., Giurcanu, M., Vaupel, P. and Halpern, H. (2021). **Biological validation of electron paramagnetic resonance (EPR) image oxygen thresholds in tissue.** Journal of Physiology 599(6): 1759-1767 https://doi.org/https://dx.doi.org/10.1113/JP278816.

Measuring molecular oxygen levels in vivo has been the cornerstone of understanding the effects of hypoxia in normal tissues and malignant tumors. Here we discuss the

advances in a variety of partial pressure of oxygen ((Formula presented.)) measurements and imaging techniques and relevant oxygen thresholds. A focus on electron paramagnetic resonance (EPR) imaging shows the validation of treating hypoxic tumours with a threshold of (Formula presented.) <= 10 Torr, and demonstrates utility for in vivo oxygen imaging, as well as its current and future role in cancer studies. (Figure presented.).Copyright © 2020 The Authors. The Journal of Physiology © 2020 The Physiological Society

22. Record no. 1399 Ghiani, S., Hawala, I., Szikra, D., Trencsenyi, G., Baranyai, Z., Nagy, G., Vagner, A., Stefania, R., Pandey, S. and Maiocchi, A. (2021). **Synthesis, radiolabeling, and pre-clinical evaluation of [44Sc]Sc-AAZTA conjugate PSMA inhibitor, a new tracer for high-efficiency imaging of prostate cancer.** European Journal of Nuclear Medicine and Molecular Imaging 48(8): 2351-2362 https://doi.org/https://dx.doi.org/10.1007/s00259-020-05130-0.

Purpose: The aim of this work was to demonstrate the suitability of AAZTA conjugated to PSMA inhibitor (B28110) labeled with scandium-44 as a new PET tracer for diagnostic imaging of prostate cancer. Background(s): Nowadays, scandium-44 has received significant attention as a potential radionuclide with favorable characteristics for PET applications. A polyaminopolycarboxylate heptadentate ligand based on a 1,4-diazepine scaffold (AAZTA) has been thoroughly studied as chelator for Gd3+ ions for MRI applications. The excellent results of the equilibrium, kinetic, and labeling studies led to a preliminary assessment of the in vitro and in vivo behavior of [44Sc][Sc-(AAZTA)]- and two derivatives, i.e., [44Sc][Sc (CNAAZTA-BSA)] and [44Sc][Sc (CNAAZTA-cRGDfK)]. Result(s): B28110 was synthesized by hybrid approach, combining solid-phase peptide synthesis (SPPS) and solution chemistry to obtain high purity (97%) product with an overall yield of 9%. Subsequently, the radioactive labeling was performed with scandium-44 produced from natural calcium target in cyclotron, in good radiochemical yields (RCY) under mild condition (pH 4, 298 K). Stability study in human plasma showed good RCP% of [44Sc]Sc-B28110 up to 24 h (94.32%). In vivo PET/MRI imaging on LNCaP tumor-bearing mice showed high tracer accumulation in the tumor regions as early as 20 min post-injection. Ex vivo biodistribution studies confirmed that the accumulation of 44Sc-PSMA-617 was two-fold lower than that of the radiolabeled B28110 probes. Conclusion(s): This work demonstrated the suitability of B28110 for the complexation with scandium-44 at room temperature and the high performance of the resulting new tracer based on AAZTA chelator for the diagnosis of prostate cancer using PET.Copyright © 2021, Springer-Verlag GmbH Germany, part of Springer Nature.

23. Record no. 1585 Gronman, M., Tarkia, M., Stark, C., Vahasilta, T., Kiviniemi, T., Lubberink, M., Halonen, P., Kuivanen, A., Saunavaara, V., Tolvanen, T., Teuho, J., Teras, M., Savunen, T., Pietila, M., Yla-Herttuala, S., Roivainen, A., Knuuti, J. and Saraste, A. (2021). **Assessment of myocardial viability with [15O]water PET: A validation study in experimental myocardial infarction.** Journal of Nuclear Cardiology 28(4): 1271-1280 https://doi.org/https://dx.doi.org/10.1007/s12350-019-01818-5.

Background: Assessment of myocardial viability is often needed in patients with chest pain and reduced ejection fraction. We evaluated the performance of reduced resting MBF, perfusable tissue fraction (PTF), and perfusable tissue index (PTI) in the

assessment of myocardial viability in a pig model of myocardial infarction (MI). Methods and Results: Pigs underwent resting [15O]water PET perfusion study 12 weeks after surgical (n = 16) or 2 weeks after catheter-based (n = 4) occlusion of the proximal left anterior descending coronary artery. MBF, PTF, and PTI were compared with volume fraction of MI in matched segments as assessed by triphenyl tetrazolium chloride staining of LV slices. MBF and PTF were lower in infarcted than non-infarcted segments. Segmental analysis of MBF showed similar area under the curve (AUC) of 0.85, 0.86, and 0.90 with relative MBF, PTF, and PTI for the detection of viable myocardium defined as infarct volume fraction of < 75%. Cut-off values of relative MBF of >= 67% and PTF of >= 66% resulted in accuracies of 90% and 81%, respectively. Conclusion(s): Our results indicate that resting MBF, PTF, and PTI based on [15O]water PET perfusion imaging are useful for the assessment of myocardial viability.Copyright © 2019, The Author(s).

24. Record no. 1868 Haberska, L., Paisey, S., Watkins, A. and Marshall, C. (2021). **Optimisation of Cyclotron Production of [13N] Ammonia.** Nuclear Medicine Communications 42(10): 1170 https://doi.org/https://dx.doi.org/10.1097/MNM.0000000000001479.

Purpose: Cardiff University PET Imaging Centre (PETIC) introduced routine [13N]Ammonia production for pre-clinical research in 2018. However, the process proved problematic due to low yields, radioactive gas releases and repeated target rinses to unload the product. The aim of this project was to optimise the IBA Cyclone 18/9 cyclotron production of [13N]Ammonia to minimise the release of radioactive gases and maximise the final yield of [13N]Ammonia in order to facilitate pre-clinical research at PETIC. Method(s): [13N]Ammonia is produced by proton irradiation of a natural water target by the 16O(p, alpha)13N nuclear reaction. In order to improve production yields, modification of several cyclotron operating parameters was investigated: target current (10- 38 microA), volume of target solution (1.2- 1.8 ml) and helium transfer pressure (1 - 5 mbar) were optimised. Result(s): In result of this project, optimal production parameters have been established: target current of 15-20 microA, target volume of 1.6 ml, and helium transfer pressure of 2.5 mbar. The final product yield has increased from 1 GBq to 6 GBq and gaseous stack emissions have been reduced to less than 50 MBq. In addition, it is no longer necessary to undertake a target rinse post-production to deliver the final product to the hot cells. Conclusion(s): The implementation of the optimised parameters has increased the final product yield, reduced gaseous emissions and removed the requirement for multiple target rinses.

25. Record no. 1584 Kamani, C. H. and Prior, J. O. (2021). **Assessment of myocardial viability using a [15O]-water perfusion PET: Towards a one-stop shop?** Journal of Nuclear Cardiology 28(4): 1281-1283 https://doi.org/https://dx.doi.org/10.1007/s12350-019-01838-1.

26. Record no. 1883 Liu, Z., Thorn, S., Wu, J., Guo, X., De Rubio Cruz, P. G., Carson, R., Sinusas, A. and Liu, C. (2021). **Assessment of lower extremities flow using dynamic Rb-82 PET: Acquisition protocols and quantification methods.** Journal of Nuclear Medicine 62(SUPPL 1).

Background: Quantitative assessment of lower extremity skeletal muscle flow is critical for managing patients withdiabetes and peripheral arterial disease (PAD). However,

reliable quantitative methods are not well established. Inthis study, we aim to investigate and optimize data acquisition protocols and quantitative data processing methods for dynamic Rb-82 PET imaging in an established porcine model of PAD through tracer kinetic modeling. Method(s): Dynamic Rb-82 PET imaging was performed in five pigs following acute unilateral femoral arteryocclusion using a 4-ring Siemens Biograph mCT scanner with continuous bed motion (CBM) and Jubilant Rb-82generator, with additional pig and human studies ongoing. Rb-82 (518+/-37 MBq) was delivered using a constantactivity delivery protocol over 45 seconds per injection. In each study, multiple sequential dynamic PET scans wereacquired using several acquisition protocols that employed both a single bed position and/or CBM. With ongoinganalysis for all protocols, we focus on reporting 3 protocols: 1) 7-min single bed position dynamic scan of the heart to derive input function from left ventricle (LV) blood pool (35 frames, 5s/frame for the first 90s, then 30s/frame); 2)7-min single bed position dynamic scan of the legs (the same as above); and 3) 1.5-min single position scan(5s/frame x 24 frames) of the lower abdominal aorta (AA) followed by 5.5-min CBM scans (30s/frame x11 frames)between AA and the legs, with input function derived from AA. Protocols 1 and 2 were performed under stableresting conditions, while acquisition protocol 3 was performed both at rest and during adenosine-inducedvasodilation. Arterial blood activity was continuously sampled using an automated blood counter, and these data were used as the gold standard input function for each scan. A one-tissue compartmental model with blood volumeterm was used to quantify K . Image derived arterial input functions from LV and AA were compared with thoseobtained through the continuous input function using IDL 8.0 and MatLAB 2020b. Result(s): High quality voxel-by-voxel parametric K images of the legs were generated. K values for skeletal musclederived from Protocol 2 data using LV input function from Protocol 1 and 2 scans across the five pigs are0.070+/-0.041 mL/min/cm and 0.030+/-0.012 mL/min/cm for the sample ROIs in the non-ischemic legs and ischemiclegs, respectively ($p<0.05$). The image-derived input functions (IDIF) from LV are consistent with those of arterialblood samples. The peak input function derived from AA was consistently 60.0+/-0.3 % of the LV for all pigs, withlower terminal activity from AA, likely due to partial volume effect. The AA input functions from stress scans havesimilar peaks compared to those of the rest scans, but with slightly higher residual terminal activity. Furtherinvestigation is ongoing to quantify K based on data acquired on other acquisition protocols. Conclusion(s): It is feasible to quantify skeletal muscle blood flow in the lower extremities using dynamic Rb-82 PET.Optimal data acquisition protocols that take advantage of CBM, constant activity infusion, and an image derivedinput function, and tracer kinetic modeling methods need to be established to ensure accurate and reproduciblequantification of lower extremities flows in setting of PAD.

27. Record no. 1894 Narciso, L., Ssali, T., Liu, L., Biernask, H., Butlen, J., Morrison, L., Hadway, J., Corsaut, J., Hicks, J., Langham, M., Wehrlis, F., Iida, H. and St Lawrence, K. (2021). **A non-invasive hybrid PET/MR method for imaging thecerebral metabolic rate of oxygen.** Journal of Nuclear Medicine 62(SUPPL 1).

Introduction: Positron emission tomography (PET) is the gold standard for imaging the cerebral metabolic rate ofoxygen (CMRO); however, the technique is invasive as it requires arterial sampling and complex due to the need tocorrect for recirculating

[15O]H2O and blood-borne activity [1]. We propose a non-invasive hybrid PET/ magneticresonance imaging (MRI) method (PMROx) that uses MRI measurements of whole-brain (WB) CMRO to calibrate[15O]O2-PET. With PMROx, cerebral blood flow (CBF) images are obtained with a similar non-invasive PET/MRIapproach combining [15O]H2O PET with phase-contrast MRI [2]. Alternatively, PET imaging can be reduced to just[15O]O2inhalation by incorporating the MRI-based perfusion method, arterial spin labeling (PMROx) [3]. Here wepresent a comparison between PMROx and PMROx in animal experiments that also incorporated an establishedPET-alone method for validation [4]. The sensitivity of PMROx to altered metabolism was investigated byincreasing the anesthetics. Method(s): [15O]H2O and [15O]O2PET data were acquired in a hybrid PET/MR scanner (3 T Siemens BiographmMR), together with simultaneous MRI oximetry (OxFlow [5]) and perfusion (ASL), from juvenile pigs (n = 8).Animals were anesthetized with 3% isoflurane and 6 mL/kg/h propofol. Arterial sampling was performed for PET-alone measurements. Cerebral metabolism was reduced by increasing the propofol infusion to 20 mL/kg/h. Result(s): Significant correlations were found between regional CMRO measurements from PET and each of thePMROx methods (i.e. using either [15O]water or ASL to image CBF) with no significant differences between averageCMRO from the three techniques: 1.89 +/- 0.16 (PMROx), 1.88 +/- 0.24 (PMROx) and 1.81 +/- 0.10 mLO /100g/min(PET). Moreover, PMROx and PMROx were sensitive to propofol-induced reduction in CMRO (Fig. 1). Conclusion(s): This study provides an initial validation of a non-invasive PET/MRI technique that circumvents manyof the complexities of PET-only CMRO imaging. PMROx not only avoids arterial sampling, but can reduce the PETimaging procedure to [15O]O2by incorporating ASL-CBF images. Future studies in humans are required to validatethis approach.

28. Record no. 526 Narciso, L., Ssali, T., Liu, L., Biernaski, H., Butler, J., Morrison, L., Hadway, J., Corsaut, J., Hicks, J. W., Langham, M. C., Wehrli, F. W., Iida, H. and Lawrence, K. S. (2021). **A Noninvasive Method for Quantifying Cerebral Metabolic Rate of Oxygen by Hybrid PET/MRI: Validation in a Porcine Model.** Journal of Nuclear Medicine 62(12): 1789-1796 https://doi.org/https://dx.doi.org/10.2967/JNUMED.120.260521.

The gold standard for imaging the cerebral metabolic rate of oxygen (CMRO2) is PET; however, it is an invasive and complex procedure that also requires correction for recirculating 15O-H2O and the blood-borne activity. We propose a noninvasive reference-based hybrid PET/MRI method that uses functional MRI techniques to calibrate 15O-O2 PET data. Here, PET/MRI of oxidative metabolism (PMROx) was validated in an animal model by comparison to PET-alone measurements. Additionally, we investigated if the MRI perfusion technique arterial spin labeling (ASL) could be used to further simplify PMROx by replacing 15O-H2O PET, and if the PMROx was sensitive to anesthetic-induced changes in metabolism. Method(s): 15O-H2O and 15O-O2 PET data were acquired using a hybrid PET/MR scanner, together with simultaneous functional MRI (OxFlow and ASL), from juvenile pigs (n 5 9). Animals were anesthetized with 3% isoflurane and 6 mL/kg/h propofol for the validation experiments, and arterial sampling was performed for PET-alone measurements. PMROx estimates were obtained using whole-brain (WB) CMRO2 from OxFlow and local cerebral blood flow (CBF) from either noninvasive 15O-H2O PET or ASL (PMROxASL). Changes in metabolism were investigated by increasing the propofol infusion to 20 mL/kg/h.

Result(s): Good agreement and correlation were observed between regional CMRO2 measurements from PMROx and PET alone. No significant differences were found between OxFlow and PET-only measurements of WB oxygen extraction fraction (0.30 6 0.09 and 0.31 6 0.09) and CBF (54.1 6 16.7 and 56.6 6 21.0 mL/100 g/min), or between PMROx and PET-only CMRO2 estimates (1.89 6 0.16 and 1.81 6 0.10 mLO2/100 g/min). Moreover, PMROx and PMROxASL were sensitive to propofol-induced reduction in CMRO2. Conclusion(s): This study provides initial validation of a noninvasive PET/MRI technique that circumvents many of the complexities of PET CMRO2 imaging. PMROx does not require arterial sampling and has the potential to reduce PET imaging to 15O-O2 only; however, future validation involving human participants are required.

29. Record no. 1793 Narciso, L., Ssali, T., Liu, L., Biernaski, H., Butler, J., Morrison, L., Hadway, J., Hicks, J. W., Langham, M. C., Wehrli, F. W., Iida, H. and St Lawrence, K. (2021). **Validation of a non-invasive hybrid PET/MRI method for imaging the cerebral metabolic rate of oxygen (#209).** Journal of Cerebral Blood Flow and Metabolism 41(1 Supplement): 249-250 https://doi.org/https://dx.doi.org/10.1177/0271678X211061050.

Introduction: PET is the gold standard for imaging the cerebral metabolic rate of oxygen (CMRO2) in humans; however, the procedure requires multiple 15O-tracers and arterial blood sampling. Hybrid PET/MR offers a means of simplifying the procedure by using MRI-based measurements of whole-brain (WB) CMRO2 as a reference to calibrate dynamic 15O-oxygen-PET data.1 This hybrid approach eliminates the need for invasive arterial sampling, only requires PET images of 15O-oxygen, and reduces the total duration to 5 min. It is also predicted to be insensitive to errors related to blood-borne activity and recirculating water because they do not affect MRI CMRO2 measurements.2 In this study, we present initial validation of the approach conducted in a large animal model that enabled arterial sampling for measurement of CMRO2 by a previously validated PET method. Method(s): PET and MRI data were obtained from juvenile pigs (n=9, 18.9+/-2.1 kg) under two metabolic conditions on a 3T Siemens Biograph mMR system. MR imaging included arterial spin labelling (ASL) and Oxflow to measure regional cerebral blood flow (CBF) and WB CMRO2, respectively.3 Concurrent PET imaging involved 5-min list-mode acquisitions after injecting 500 MBq of 15O-water, followed by inhaling 2200 MBq of 15O-oxygen. Arterial sampling was obtained using an MR-compatible system (Swisstrace). CT images were acquired post-mortem for attenuation correction. Dynamic PET images were reconstructed into 48 time-frames (30x3s, 6x5s, 6x10s and 6x20s). CMRO2 images were generated from the PET data alone4 and by the hybrid PET/MR procedure. Result(s): Results from the hybrid PET/MR approach (n=6, Figure 1) presented mean CMRO2 within the expected range, for both baseline (1.88+/-0.24mL/100 g/min) and lower metabolic conditions (1.20+/-0.33mL/100 g/min; 36% reduction, p<0.01). Conclusion(s): Initial WB CMRO2 results obtained with the hybrid PET/MR approach were within the expected range, further reinforcing our previous assessments.1 These results suggest that quantitative measurements of CMRO2 can be obtained without the need for arterial blood sampling. The complete analysis of our experiments can be found in Narciso et al.2.

30. Record no. 1809 Phipps, M., Cingoranelli, S., Ferdous, J., Bhupathiraju, N. V. S. D., Lapi,

S., Lewis, J., Francesconi, L. and Deri, M. (2021). **Evaluation of [47Sc]Sc-HOPO toward radioscandium based radiopharmaceuticals.** Nuclear Medicine and Biology 96-97(Supplement): S91-S92 https://doi.org/https://dx.doi.org/10.1016/S0969-8051%2821%2900416-9.

Objectives: Scandium-44 (44Sc) (t1/2 = 4 h, E x = 1.47 MeV, BR^ = 94.3%) and 47Sc (t1/2 = 3.3 d, E x = 0.6 MeV, BR = 100%) are a potential matched pair of radionuclides for developing theranostic agents for positron emission tomography (PET) imaging and targeted radio-immunotherapy. 47Sc has a gamma emission (Ey = 159 keV) suitable for use in single photon emission computed tomography (SPECT) imaging. DOTA is a standard chelator for many radiometals and has been radiolabeled with 44Sc [1]. However, DOTA may not be the optimal chelator for radioscandium, so there is interest in developing better Sc chelators [2]. 3,4,3-LI(1,2-HOPO) (referred to as HOPO) can form octadentate constructs through its oxygen donors and demonstrates high affinity and fast kinetics with hard positive ions at the macroscopic and tracer scales [3-5]. (Figure Presented) Methods: Before radioactive work, stable 45Sc-HOPO was characterized by methods including IR, 1H-NMR, 45Sc-NMR, HPLC, mass spectrometry, and crystallography. 47Sc was produced via cyclotron at the University of Alabama at Birmingham. Radiochemically pure 47Sc was produced from an enriched 50TiO2 target by the 50Ti(p,a)47Sc reaction and separated adapting methods from Loveless et al. [6]. Targets were irradiated at 24 MeV on the UAB TR24 cyclotron. 47Sc was extracted using BDGA resin, isolated in 0.1 M HCl, and shipped to Memorial Sloan Kettering Cancer Center. The radiolabeling of HOPO and DOTA with 47Sc at 37degreeC was optimized and compared. Stability studies, including EDTA challenge at various pH values (5, 6, 7, 8), metal ion challenge (with Fe3+, Mg2+, Cu2+, Zn2+), and human serum stability were evaluated for 47Sc-DOTA and 47Sc-HOPO. Radiolabeling and stability studies were monitored by ITLC using 50 mM EDTA at pH 5. Biodistribution and SPECT imaging with free 47Sc and 47Sc constructs in healthy mice are underway. Result(s): Radiolabeling optimization resulted in 90% and >99% RCY at 37degreeC for 47Sc-DOTA and 47Sc-HOPO respectively. Formation of (Figure Presented) 47Sc-HOPO was verified by HPLC coinjection with a nonradioactive, well-characterized 45Sc-HOPO standard. 47Sc-DOTA and 47Sc-HOPO had comparable performance in stability studies. Conclusion(s): 47Sc-HOPO has been synthesized and has demonstrated high stability under various conditions. Its in vivo behavior is being investigated as well. This work will be followed by the evaluation of the bifunctional analogue p-SCN-Bn-HOPO as well as HOPO-antibody conjugates formed with the bifunctional ligand. In addition, analogous HOPO chelators such as 3,3,3-LI(1,2-HOPO) will be investigated.

31. Record no. 1804 Wyatt, N., Hogan, L., Pellegrini, P., Roberts, M., Hall, A., Smith, N., Hemzal, E., Hill, L., Howell, N., Middleton, R., Safavi-Naeini, M., Rendina, L. and Fraser, B. (2021). **Scandium-47 and lutetium-177 radiolabelling and stability studies of 1st and 2nd generation DOTA-triphenylphosphonium ligands - potential radionuclide theranostics for treatment of glioblastoma multi-forme.** Nuclear Medicine and Biology 96-97(Supplement): S93-S94 https://doi.org/https://dx.doi.org/10.1016/S0969-8051%2821%2900420-0.

Scandium-47 has emerged as a promising radioisotope for targeted radionuclide tumor therapy [1]. This is due, to a significant extent, from the combination of low energy /

short range p- emission, the availability of a "perfect theranostic pair" with Sc-44 for companion PET imaging, the potential to form highly stable radiometal complexes, and the availability of suitable y emissions for companion SPECT imaging [1,2]. Sc-47 also has a shorter half-life (3.35 d) than the chemically similar Lu-177 (6.7 d) which is significant given recent in vitro research that suggests longer lived isotopes require more intial radioactivity to have the same effect upon cell viability [3]. The shorter half-life of Sc-47 also suggests it may be more suitable for smaller biolgical vectors (with shorter biolgical half-lives) such as small molecules and low MW peptides. One area of clinical treatment where Sc-47 can have impact and where improvments in patient outcomes and survival rates remain stubbornly low is glioblastoma multiforme (GBM) [2]. GBM is the most common and aggressive form of malignant brain tumor and represents around 60% of all adult brain tumors with a global incidence of <10 per 100,000 persons [2,4]. The prognosis for GBM patients is poor with a -ear survival rate of 37%, 5 year rate of 5% and a median survival (Figure Presented) time of 10 months [5]. The current standard of treatment is resection of the tumor followed by radiation therapy and chemotherapy [6,7]. Given this poor prognosis there is a clear and unmet need for improved classes of treatment. Although significant progress has been made towards bringing GBM targeted radionuclide therapies to the clinic [8], the efforts to date have not included utilizing Sc-44/ Sc-47. Given this we are developing and evaluating Sc-44/Sc-47 and Lu-177/Ga-68 radiolabelled triphenylphosphonium (TPP) functional-ised DOTA ligands (1st and 2nd generation) as potential theranostics for GBM. Described herein is our work on comparing the radiolabel-ling efficiency (Sc-47 vs. Lu-177) and stability studies (PBS pH 7.4, rat plasma) for our 1st and 2nd generation DOTA-TPP ligands [9]. The presence of an additional carbonyl group in the 2nd generation DOTA-TPP ligand was anticipated to increase the number of donor atoms around the radiometal and affect radiolabelling reaction conditions and, more importantly, increase radiometal complex stability

32. Record no. 1472 Zhou, M., Liu, Y., Su, Y. and Su, Q. (2021). **Plasmonic Oxygen Defects in MO3- x (M = W or Mo) Nanomaterials: Synthesis, Modifications, and Biomedical Applications.** Advanced Healthcare Materials 10(23): 2101331 https://doi.org/https://dx.doi.org/10.1002/adhm.202101331.

Nanomedicine is a promising technology with many advantages and provides exciting opportunities for cancer diagnosis and therapy. During recent years, the newly developed oxygen-deficiency transition metal oxides MO3- x (M = W or Mo) have received significant attention due to the unique optical properties, such as strong localized surface plasmon resonance (LSPR), tunable and broad near-IR absorption, high photothermal conversion efficiency, and large X-ray attenuation coefficient. This review presents an overview of recent advances in the development of MO3- x nanomaterials for biomedical applications. First, the fundamentals of the LSPR effect are introduced. Then, the preparation and modification methods of MO3- x nanomaterials are summarized. In addition, the biological effects of MO3- x nanomaterials are highlighted and their applications in the biomedical field are outlined. This includes imaging modalities, cancer treatment, and antibacterial capability. Finally, the prospects and challenges of MO3- x and MO3- x-based nanomaterial for fundamental studies and clinical applications are also discussed.

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33. Record no. 2348 Almeida, A. G. (2020). **Myocardial oxygenation assessment at myocardial blood oxygen level-dependent MRI: A fresh look at an old promise.** Radiology 295(1): 94-95 https://doi.org/https://dx.doi.org/10.1148/radiol.2020200163.

34. Record no. 299 Guehl, N. J., Pelletier-Galarneau, M., Wooten, D. W., Guerrero, J. L., Kas, A., Normandin, M. D., Fakhri, G. E. and Alpert, N. M. (2020). **Preclinical Validation of a Single-Scan Rest/ Stress Imaging Technique for 13N-Ammonia Positron Emission Tomography Cardiac Perfusion Studies.** Circulation: Cardiovascular Imaging 13(1): E009407 https://doi.org/https://dx.doi.org/10.1161/CIRCIMAGING.119.009407.

BACKGROUND: We previously proposed a technique for quantitative measurement of rest and stress absolute myocardial blood flow (MBF) using a 2-injection single-scan imaging session. Recently, we validated the method in a pig model for the long-lived radiotracer 18F-Flurpiridaz with adenosine as a pharmacological stressor. The aim of the present work is to validate our technique for 13NH3. METHOD(S): Nine studies were performed in 6 pigs; 5 studies were done in the native state and 4 after infarction of the left anterior descending artery. Each study consisted of 3 dynamic scans: a 2-injection rest-rest single-scan acquisition (scan A), a 2-injection rest/stress single-scan acquisition (scan B), and a conventional 1-injection stress acquisition (scan C). Variable doses of adenosine combined with dobutamine were administered to induce a wide range of MBF. The 2-injection single-scan measurements were fitted with our nonstationary kinetic model (MGH2). In 4 studies, 13NH3 injections were paired with microsphere injections. MBF estimates obtained with our method were compared with those obtained with the standard method and with microspheres. We used a modelbased method to generate separate rest and stress perfusion images. RESULT(S): In the absence of stress (scan A), the MBF values estimated by MGH2 were nearly the same for the 2-radiotracer injections (mean difference: 0.067+/-0.070 mL.min-1.cc-1, limits of agreement: [-0.070 to 0.204] mL.min-1.cc-1), showing good repeatability. Bland-Altman analyses demonstrated very good agreement with the conventional method for.

35. Record no. 2467 Hashem, M., Zhang, Q., Wu, Y., Johnson, T. W. and Dunn, J. F. (2020). **Using a multimodal near-infrared spectroscopy and MRI to quantify gray matter metabolic rate for oxygen: A hypothermia validation study.** NeuroImage 206: 116315 https://doi.org/https://dx.doi.org/10.1016/j.neuroimage.2019.116315.

Non-invasive quantitative imaging of cerebral oxygen metabolism (CMRO2) in small animal models is crucial to understand the role of oxidative metabolism in healthy and diseased brains. In this study, we developed a multimodal method combining near-infrared spectroscopy (NIRS) and MRI to non-invasively study oxygen delivery and consumption in the cortex of mouse and rat models. The term CASNIRS is proposed to the technique that measures CMRO2 with ASL and NIRS. To determine the reliability of this method, CMRO2 values were compared with reported values measured with other techniques. Also, the sensitivity of the CASNIRS technique to detect changes in CMRO2 in the cortex of the animals was assessed by applying a reduction in core

temperature, which is known to reduce CMRO2. Cerebral blood flow (CBF) and CMRO2 were measured in five mice and five rats at a core temperature of 37 degreeC followed by another measurement at 33 degreeC. CMRO2 was 7.8 +/- 1.8 and 3.7 +/- 0.9 (ml/100 g/min, mean +/- SD) in mice and rats respectively. These values are in good agreement with reported values measured by 15O PET, 17O NMR, and BOLD fMRI. In hypothermia, we detected a significant decrease of 37% and 32% in CMRO2 in the cortex of mice and rats, respectively. Q10 was calculated to be 3.2 in mice and 2.7 in rats. In this study we showed that it is possible to assess absolute values of metabolic correlates such as CMRO2, CBF and oxygen extraction fraction (OEF) noninvasively in living brain of mice and rats by combining NIRS with MRI. This will open new possibilities for studying brain metabolism in patients as well as the many mouse/rat models of brain disorders.Copyright © 2019 The Authors

36. Record no. 519 Toramatsu, C., Mohammadi, A., Wakizaka, H., Seki, C., Nishikido, F., Sato, S., Kanno, I., Takahashi, M., Karasawa, K., Hirano, Y. and Yamaya, T. (2020). **Biological washout modelling for in-beam PET: rabbit brain irradiation by 11C and 15O ion beams.** Physics in medicine and biology 65(10): 105011 https://doi.org/https://dx.doi.org/10.1088/1361-6560/ab8532.

Positron emission tomography (PET) has been used for dose verification in charged particle therapy. The causes of washout of positron emitters by physiological functions should be clarified for accurate dose verification. In this study, we visualized the distribution of irradiated radioactive beams, 11C and 15O beams, in the rabbit whole-body using our original depth-of-interaction (DOI)-PET prototype to add basic data for biological washout effect correction. Time activity curves of the irradiated field and organs were measured immediately after the irradiations. All data were corrected for physical decay before further analysis. We also collected expired gas of the rabbit during beam irradiation and the energy spectrum was measured with a germanium detector. Irradiated radioactive beams into the brain were distributed to the whole body due to the biological washout process, and the implanted 11C and 15O ions were concentrated in the regions which had high blood volume. The 11C-labelled 11CO2 was detected in expired gas under the 11C beam irradiation, while no significant signal was detected under the 15O beam irradiation as a form of C15O2. Results suggested that the implanted 11C ions form molecules that diffuse out to the whole body by undergoing perfusion, then, they are incorporated into the blood-gas exchange in the respiratory system. This study provides basic data for modelling of the biological washout effect.

37. Record no. 2512 Toyohara, J., Kakiuchi, T., Ohba, H., Kanazawa, M., Tago, T., Sakata, M. and Harada, N. (2020). **Head to head comparison of [15O]H2O and [11C]MMP in non-human primates; tracers for measuring regional cerebral blood flow.** European Journal of Nuclear Medicine and Molecular Imaging 47(SUPPL 1): S667-S668 https://doi.org/https://dx.doi.org/10.1007/s00259-020-04988-4.

Aim/Introduction: Increases in fasting plasma glucose (PG) levels lead to a decrease in [18F]FDG uptake, especially in the precuneus, resulting in an Alzheimer's disease (AD)-like pattern. Therefore, patients with higher PG levels, such as those with diabetes, can be erroneously diagnosed with AD when PET imaging is done using [18F]FDG, due to

reduced uptake of [18F]FDG in the precuneus. To help avoid an erroneous diagnosis of AD due to differences in glucose metabolism, evaluating cerebral blood flow (CBF) in the brain is useful. However, current techniques such as SPECT and 15O-water PET have limitations in early diagnosis of AD because the images of they produce are of low resolution. Recently, we developed N-isopropyl-p-[11C] methylamphetamine ([11C]MMP) as a carbon-11-labeled alternative of the standard CBF SPECT tracer N-isopropyl-p-[123I]iodoamphetamine. In this study, we evaluated the brain kinetics of [11C]MMP in the non-human primate. Head-tohead comparison with [15O]H2O was also evaluated. Material(s) and Method(s): Two successive PET measurements with [15O] H2O and [11C]MMP under vehicle and acetazolamide (AZM: 10 mg/kg or 20 mg/kg) loading conditions were performed in 3 conscious state male monkeys (Macaca mulatta) with arterial blood sampling. Metabolite-corrected plasma and whole-blood time-activity curves were used as an input function for pharmacokinetic modeling of [11C]MMP. The preferred model was chosen according to the Akaike Information Criterion (AIC) and were used to calculate the influx constant (K1). Moreover, standardized uptake values (SUV) were estimated using different time intervals. Result(s): The preliminary kinetic analysis of the comparison of AIC (paired t test, $P < 0.05$) in all regions investigated showed that 1-tisue-compartment model provided significantly better AIC scores than the 2-tissue-compartment model ($n = 3$). The regional K1 values of [11C]MMP in vehicle treated monkey were well correlated with that in rCBF (Pearson $r = 0.9230$, $p < 0.0001$). Furthermore, short duration scan (0-10 min) of SUV showed good correlation with rCBF ($r = 0.9042$, $p < 0.0001$), too. The data suggest that [11C]MMP probably detect changes of rCBF in the low to normal range of flows. However, this correlation was decreased at higher flow range under AZM-loading (10 mg/kg: $r = 0.6581$, $p = 0.0041$; 20 mg/kg: $r = 0.7510$, $p = 0.0005$), due to the underestimation of rCBF at higher flows. Conclusion(s): The K1 and early phase SUV (0-10 min) of [11C]MMP well reflect rCBF in vehicle treated non-human primate, but that in higher flow region after AZM-loading did not.

38. Record no. 2067 van der Meulen, N. P., Hasler, R., Talip, Z., Grundler, P. V., Favaretto, C., Umbricht, C. A., Muller, C., Dellepiane, G., Carzaniga, T. S. and Braccini, S. (2020). **Developments toward the Implementation of 44Sc Production at a Medical Cyclotron.** Molecules (Basel, Switzerland) 25(20) https://doi.org/https://dx.doi.org/10.3390/molecules25204706.

44Sc has favorable properties for cancer diagnosis using Positron Emission Tomography (PET) making it a promising candidate for application in nuclear medicine. The implementation of its production with existing compact medical cyclotrons would mean the next essential milestone in the development of this radionuclide. While the production and application of 44Sc has been comprehensively investigated, the development of specific targetry and irradiation methods is of paramount importance. As a result, the target was optimized for the 44Ca(p,n)44Sc nuclear reaction using CaO instead of CaCO3, ensuring decrease in target radioactive degassing during irradiation and increased radionuclidic yield. Irradiations were performed at the research cyclotron at the Paul Scherrer Institute (~11 MeV, 50 microA, 90 min) and the medical cyclotron at the University of Bern (~13 MeV, 10 microA, 240 min), with yields varying from 200 MBq to 16 GBq. The development of targetry, chemical separation as well as the practical issues and implications of irradiations, are analyzed and discussed. As a proof-

of-concept study, the 44Sc produced at the medical cyclotron was used for a preclinical study using a previously developed albumin-binding prostate-specific membrane antigen (PSMA) ligand. This work demonstrates the feasibility to produce 44Sc with high yields and radionuclidic purity using a medical cyclotron, equipped with a commercial solid target station.

39. Record no. 2265 Wang, J., Mpharm, S. L., Liu, T. W., Zhang, J. M., Chen, Y., Li, J. M. and Xu, W. G. (2020). **Preliminary and Comparative Experiment Study Between 18F-Flurpiridaz and 13N-NH3.H2O Myocardial Perfusion Imaging With PET/CT in Miniature Pigs.** Molecular Imaging 19 https://doi.org/https://dx.doi.org/10.1177/1536012120947506.

Objectves: To comparatively explore the differences between 18F-Flurpiridaz and 13N-NH3.H2O PET/CT myocardial perfusion imaging in miniature pigs. Method(s): Ten Bama minipigs were divided into normal group and myocardial infarction group. The changes of the ratio of left ventricular myocardium to main organs with time were calculated and the best imaging time was confirmed for 18F-Flurpiridaz imaging in normal group. The image quality score, summed rest score(SRS), Extend, total perfusion deficit(TPD) and left ventricle ejection fraction(LVEF) were respectively compared for 18F-Flurpiridaz and 13N-NH3.H2O in infarction group. Result(s): 18F-Flurpiridaz was rapid distributed in myocardium, and the background counts of cardiac cavity were very low, and no obvious interference extracardiac radioactivity was observed. The radioactive ratio of the left ventricular myocardium to cardiac blood pool and adjacent liver were high. Compared with 13N-NH3.H2O, there were no significant differences in functional parameters, including SRS, Extend, TPD and LVEF. Conclusion(s): The results preliminaryly show that 18F-Flurpiridaz is a promising positron MPI agent with good image quality, ability of accurately evaluating cardiac function, and also convenience for application.Copyright © The Author(s) 2020.

40. Record no. 2016 Yamamoto, K., Brender, J. R., Seki, T., Kishimoto, S., Oshima, N., Choudhuri, R., Adler, S. S., Jagoda, E. M., Saito, K., Devasahayam, N., Choyke, P. L., Mitchell, J. B. and Krishna, M. C. (2020). **Molecular imaging of the tumor microenvironment reveals the relationship between tumor oxygenation, glucose uptake, and glycolysis in pancreatic ductal adenocarcinoma.** Cancer Research 80(11): 2087-2093 https://doi.org/https://dx.doi.org/10.1158/0008-5472.CAN-19-0928.

Molecular imaging approaches for metabolic and physiologic imaging of tumors have become important for treatment planning and response monitoring. However, the relationship between the physiologic and metabolic aspects of tumors is not fully understood. Here, we developed new hyperpolarized MRI and electron paramagnetic resonance imaging procedures that allow more direct assessment of tumor glycolysis and oxygenation status quantitatively. We investigated the spatial relationship between hypoxia, glucose uptake, and glycolysis in three human pancreatic ductal adenocarcinoma tumor xenografts with differing physiologic and metabolic characteristics. At the bulk tumor level, there was a strong positive correlation between18F-FDG-PET and lactate production, while pO2 was inversely related to lactate production and18F-2-fluoro-2-deoxy-D-glucose (18F-FDG) uptake. However, metabolism was not uniform throughout the tumors, and the whole tumor results masked different localizations that became apparent while imaging.18F-FDG uptake

negatively correlated with pO2 in the center of the tumor and positively correlated with pO2 on the periphery. In contrast to pO2 and18F-FDG uptake, lactate dehydrogenase activity was distributed relatively evenly throughout the tumor. The heterogeneity revealed by each measure suggests a multimodal molecular imaging approach can improve tumor characterization, potentially leading to better prognostics in cancer treatment.Copyright © 2020 American Association for Cancer Research.

41. Record no. 2000 Yan, R., Li, X., Song, J., Guo, M., Cai, H., Wu, Z., Wu, P., Li, L., Yang, M., Wang, Y. and Li, S. (2020). **Metabolic changes precede radiation-induced cardiac remodeling in beagles: Using noninvasive18f-fdg (18f-fludeoxyglucose) and13n-ammonia positron emission tomography/computed tomography scans.** Journal of the American Heart Association 9(18): e016875 https://doi.org/https://dx.doi.org/10.1161/JAHA.120.016875.

BACKGROUND: This study was performed to characterize the metabolic, functional, and structural cardiac changes in a canine model of radiation-induced heart disease by serial in vivo imaging and ex vivo analyses. METHODS AND RESULTS: Thirty-six dogs were randomly assigned to control or irradiated groups at 3 time points (months 3, 6, and 12 after radiation; each group comprised 6 dogs). The left anterior myocardium of dogs in irradiated groups was irradiated locally with a single dose of 20-Gy X-ray. The irradiated myocardial regions showed increased myocardial uptake of18F-FDG (18F-fludeoxyglucose) in the irradiated beagles, but the increased uptake area decreased at months 6 and 12 compared with month 3 after radiation. Abnormality of myocardial perfusion and cardiac function were detected at month 6 after radiation. Compared with the control groups, the protein expression of GLUT4 (glucose transporter 4) was upregulated in the irradiated groups, correlating with significantly decreased CPT1 (carnitine acyltransferase 1) expression. Mitochondria degeneration, swelling, and count reduction in the irradiated groups were observed. The difference in CD68 of macrophage markers and the inflammatory cytokines (IL-6 [interleukin 6], TNF-alpha [tumor necrosis factor alpha]) between the irradiation and control groups was not significant. Furthermore, the progressive aggravation of apoptosis and fibrosis was displayed. CONCLUSION(S): Elevated18F-FDG uptake occurred after irradiation and subsequently led to ventricular perfusion defects and dysfunction. The process was associated with myocardial metabolic substrate remodeling, cardiac muscle cell apoptosis, and myocardial fibrosis rather than inflammation.Copyright © 2020 The Authors.

42. Record no. 1927 Yokell, D. L., Rice, P. A., Neelamegam, R. and El Fakhri, G. (2020). **Development, validation and regulatory acceptance of improved purification and simplified quality control of [13N] Ammonia.** EJNMMI Radiopharmacy and Chemistry 5(1): 11 https://doi.org/https://dx.doi.org/10.1186/s41181-020-00097-7.

Background: [13N]Ammonia is a cyclotron produced myocardial perfusion imaging agent. With the development of high-yielding [13N]ammonia cyclotron targets using a solution of 5 mM ethanol in water, there was a need to develop and validate an automated purification and formulation system for [13N]ammonia to be in a physiological compatible formulation of 0.9% sodium chloride since there is no widely available commercial system at this time. Due to its short half-life of 10 min, FDA and USP regulations allow [13N]ammonia to be tested in quality control (QC) sub-batches

with limited quality control testing performed on the sub-batches for patient use. The current EP and the original USP method for the determination of the radiochemical purity and identity of [13N]ammonia depended on an HPLC method using a conductivity detector and a solvent free of other salts. This HPLC method created issues in a modern cGMP high volume PET manufacturing facility where the HPLC is used with salt containing mobile phase buffers for quality control analysis of other PET radiopharmaceuticals. Flushing of the HPLC system of residual salt buffers which may interfere with the [13N]ammonia assay can take several hours of instrument time. Since there are no mass limits on [13N]ammonia, a simplified TLC assay to determine radiochemical identity and purity could be developed to simplify and streamline QC. Result(s): We have developed and validated a streamlined automated synthesis for [13N]ammonia which provides the drug product in 8 mL of 0.9% sodium chloride for injection. A novel radio-TLC method was developed and validated to demonstrate feasibility to quantitate [13N]ammonia and separate it from all known radiochemical impurities. Conclusion(s): The process for automated synthesis of [13N]ammonia simplifies and automates the purification and formulation of [13N]ammonia in a cGMP compliant manner needed for high-throughput manufacture of [13N]ammonia. The novel radio-TLC method has simplified [13N]ammonia quality control (QC) and now enables it to be tested using the same QC equipment as [18F]fludeoxyglucose (FDA/USP recognized name for 2-[18F]fluoro-2-deoxy-D-glucose). Both the streamlined automated synthesis of [13N]ammonia and the novel radio-TLC method have been accepted and approved by the US Food and Drug Administration (FDA) for the cGMP manufacture of [13N]ammonia.Copyright © 2020, The Author(s).

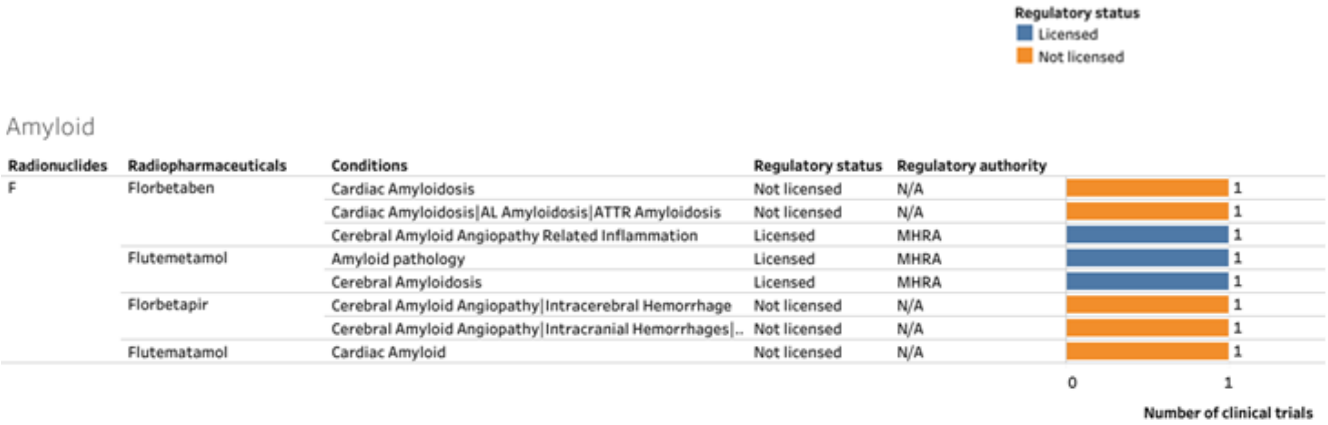
43. Record no. 2230 Yu, W., Su, X., Zhang, D., Qiao, F., Wang, H., Jiang, J. and Xu, H. (2020). **Dual-Tracer Assessment of Dynamic Changes in Reoxygenation and Proliferation Decrease During Fractionated Radiotherapy in Murine Tumors.** Frontiers in Oncology 10: 1046 https://doi.org/https://dx.doi.org/10.3389/fonc.2020.01046.

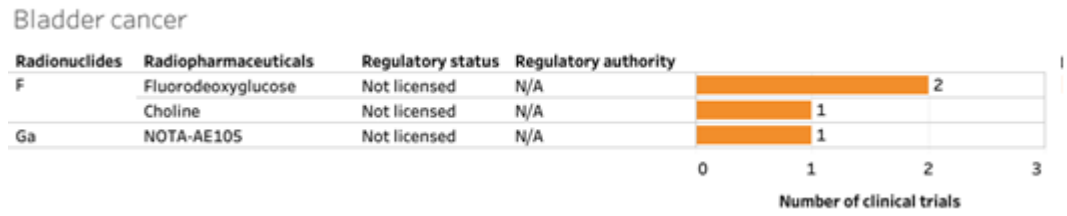
Objective: The present work aimed to assess reoxygenation and tumor inhibition during fractionated radiotherapy (FRT) in murine tumors using 18F-fluoromisonidazole (18F-FMISO) and 18F-fluorothymidine (18F-FLT) based micro positron emission tomography/computed tomography (PET/CT). Material(s) and Method(s): A nude mouse xenograft model was established with the head and neck squamous carcinoma cell (FaDu), followed by administration of FRT. Imaging was carried out with both 18F-FMISO and 18F-FLT PET/CT, prior to FRT (Pre-FRT, 0 Gy), during FRT (Inter-FRT, 21 Gy), and after FRT (Post-FRT, 40 Gy). The maximum standardized uptake (SUVmax) and tumor-to-normal muscle ratio (TNR) were determined in regions of interest (ROIs) in 18F-FMISO and 18F-FLT PET/CT images. Then, hypoxic (HV) and proliferative tumor (PTV) volumes obtained by PET/CT were analyzed. Immunohistochemistry was performed to analyze the changes of hypoxia-inducible factor- (HIF)-1alpha, carbonic anhydrase 9 (CAIX), Ki67 and proliferating cell nuclear antigen (PCNA). Associations of the levels of these biomarkers with PET/CT parameters were analyzed. Result(s): 18F-FMISO PET/CT demonstrated markedly elevated reduction rates of SUVmax (30.3 vs. 14.5%, p = 0.012), TNR (27.9 vs. 18.3%, p = 0.032) and HV (85.0 vs. 71.4%, p = 0.047) from Pre-FRT to Inter-FRT compared with values from Inter-FRT to Post-FRT. Meanwhile, PTV reduction rate in 18F-FLT PET/CT from Pre-FRT to Inter-FRT was significantly decreased compared with that from Inter-FRT to Post-FRT (21.2 vs. 82.7%,

p = 0.012). Tumor HIF-1alpha, CAIX, Ki67, and PCNA amounts were continuously down-regulated during radiotherapy. TNR (FMISO) showed significant correlations with HIF-1alpha (r = 0.692, p = 0.015) and CAIX (r = 0.801, p = 0.006) amounts in xenografts, while associations of SUVmax (FMISO) with hypoxia markers were weak (r = 0.418, p = 0.041 and r = 0.389, p = 0.037, respectively). SUVmax (FLT) was significantly correlated with Ki67 (r = 0.792, p = 0.003) and PCNA (r = 0.837, p = 0.004). Conclusion(s): Tumor reoxygenation occurs early during radiotherapy, while inhibition of cell proliferation by tumoricidal effects mainly takes place gradually with the course of radiotherapy. 18F-FMISO and 18F-FLT PET/CT are sensitive and non-invasive tools for the monitoring of tumor reoxygenation and proliferation during radiotherapy.

Appendix 5: Radiopharmaceutical pipelines for various therapeutic areas

During the meeting held on 16th November 2023, the WHSSC team requested additional analysis regarding specific indications in clinical development. A list of 28 categories was shared with the IO which included, adrenocortical, amyloid, anal, bladder, breast, cardiac conditions, cervical, choline, colorectal, cancer of unknown origin (cuo), endometrial cancer, euronet, gynaecological conditions, head & neck, lung, lymphoma, myeloma, neuroendocrine, oesophageal, other, ovary, pancreas, PSMA, PUO, SABR, sarcoma, thyroid, and vasculitis. An analysis of 17 of these categories was provided by the IO, which is presented below.





Cardiovascular conditions

Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority	
Cu	Thiosemicarbazone	Not licensed	N/A	1
	Fluorodeoxyglucose	Licensed	MHRA	1
	Dotatate	Licensed	MHRA	1
F	Flurpiridaz	Not licensed	N/A	4
	Sodium fluoride	Not licensed	N/A	3
	Fluorodeoxyglucose	Not licensed	N/A	3
	Florbetaben	Not licensed	N/A	2
	XTR004	Not licensed	N/A	1
	XTR003	Not licensed	N/A	1
	Water	Not licensed	N/A	1
	Triphenylphosphonium	Not licensed	N/A	1
	GP1	Not licensed	N/A	1
	FSPG	Not licensed	N/A	1
	Flutemetamol	Licensed	MHRA	1
	Flutematamol	Not licensed	N/A	1
	Fluorocholine	Not licensed	N/A	1
	FCPHA	Not licensed	N/A	1
	Choline	Not licensed	N/A	1
Ga	Edotreotide	Not licensed	N/A	1
O	Water	Not licensed	N/A	2
Ru	Chloride	Licensed	MHRA	1

0 1 2 3 4 5

Number of clinical trials

Choline

Radionuclides	Radiopharmaceuticals	Therapeutic area	Cancer/Non-cancer	Regulatory status	Regulatory authority	
F	Fluorocholine	Blood and bone marrow cancers	Yes	Not licensed	N/A	2
		Breast cancer	Yes	Not licensed	N/A	1
		Cardiovascular conditions	No	Not licensed	N/A	1
		Diabetes, other endocrinal, nutritional, metabolic conditions	No	Not licensed	N/A	5
		Liver cancer	Yes	Not licensed	N/A	2
		Metastases	Yes	Not licensed	N/A	2
		Multiple conditions	Both	Not licensed	N/A	2
		Prostate cancer	Yes	Not licensed	N/A	13
		Thyroid cancer	Yes	Not licensed	N/A	2
	Choline	Bladder cancer	Yes	Not licensed	N/A	1
		Brain cancer	Yes	Not licensed	N/A	1
		Cardiovascular conditions	No	Not licensed	N/A	1
		Diabetes, other endocrinal, nutritional, metabolic conditions	No	Not licensed	N/A	1
		Multiple cancers	Yes	Not licensed	N/A	1
		Prostate cancer	Yes	Not licensed	N/A	5
	Fluoroethylcholine	Prostate cancer	Yes	Not licensed	N/A	4

0 5 10 15

Number of clinical trials

Cervical cancers

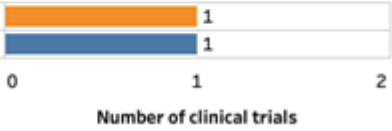
Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority	
F	Fluorodeoxyglucose	Not licensed	N/A	4
	HX4	Not licensed	N/A	1
	Fluoromisonidazole	Licensed	EMA	1
	Fluoroerytronitroimidazole	Not licensed	N/A	1

0 1 2 3 4 5

Number of clinical trials

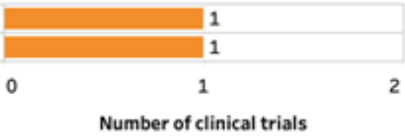
Colorectal cancers

Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority
Cu	ATSM	Not licensed	N/A
F	Fluorodeoxyglucose	Licensed	MHRA



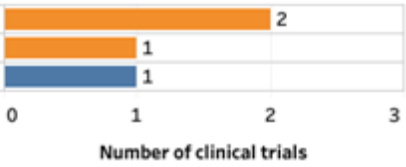
Endometrial cancer

Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority
F	Fluorodeoxyglucose	Not licensed	N/A
Ga	NOTA-Anti-HER2 VHH1	Not licensed	N/A



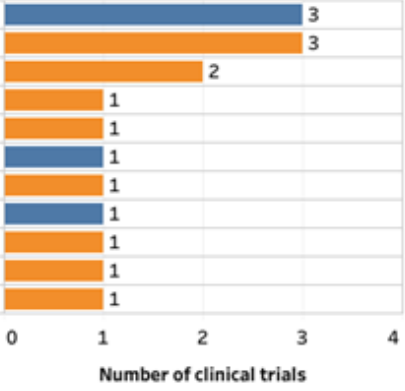
Gynaecological conditions

Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority
F	Fluorodeoxyglucose	Not licensed	N/A
	Fluorofuranylnorprogeste..	Not licensed	N/A
	Fluoroestradiol	Licensed	EMA



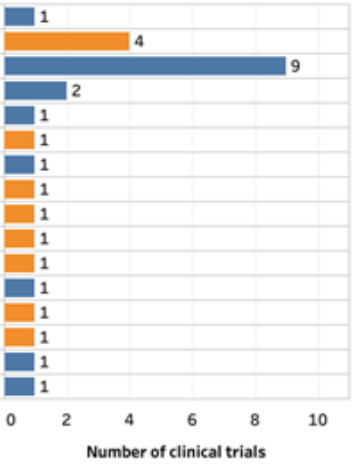
Head and neck cancers

Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority
F	Fluorodeoxyglucose	Licensed	MHRA
	Fluciclatide	Not licensed	N/A
	HX4	Not licensed	N/A
	ML-10	Not licensed	N/A
	Fluorothymidine	Not licensed	N/A
	Fluoromisonidazole	Licensed	EMA
	EF5	Not licensed	N/A
Ga	Dotatate	Licensed	MHRA
	Dota-E-(cRGDfK)2	Not licensed	N/A
Zr	Panitumumab	Not licensed	N/A
	Girentuximab	Not licensed	N/A



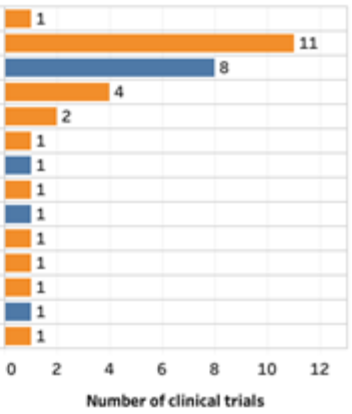
Lung cancer and other respiratory conditions

Radionuclides	Radiopharmaceuticals	Cancer/Non-cancer	Regulatory status	Regulatory authority
F	Fluorodeoxyglucose	No	Licensed	MHRA
			Not licensed	N/A
		Yes	Licensed	MHRA
	Fluoromisonidazole	Yes	Licensed	EMA
	FSPG	Yes	Licensed	MHRA
	Fluorothymidine	Yes	Not licensed	N/A
	Fludeoxyglucose	Yes	Licensed	EMA
	FAZA	Yes	Not licensed	N/A
	Dota-noc	No	Not licensed	N/A
	Arabinosyl guanine	Yes	Not licensed	N/A
Ga	MAA	Yes	Not licensed	N/A
	Gozetotide	Yes	Licensed	MHRA
	FAPI-46	Yes	Not licensed	N/A
N	Ammonia	No	Not licensed	N/A
Zr	Pembrolizumab	Yes	Licensed	MHRA
	Durvalumab	Yes	Licensed	MHRA



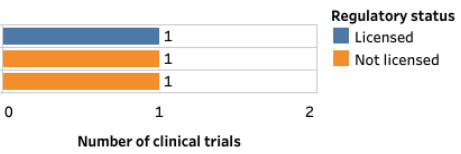
Breast cancer

Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority
Cu	Dota-trastuzumab	Not licensed	N/A
F	Fluoroestradiol	Not licensed	N/A
	Fluorodeoxyglucose	Licensed	MHRA
	Fluorothymidine	Not licensed	N/A
	DPA-714	Not licensed	N/A
	MFES	Not licensed	N/A
	Flutemetamol	Licensed	MHRA
	Fluorthanatrace	Not licensed	N/A
	Fluorofuranylnorprogeste..	Licensed	MHRA
	Fluorocholine	Not licensed	N/A
	FDHT	Not licensed	N/A
Ga	NeoB	Not licensed	N/A
Zr	Trastuzumab	Licensed	MHRA
	Girentuximab	Not licensed	N/A



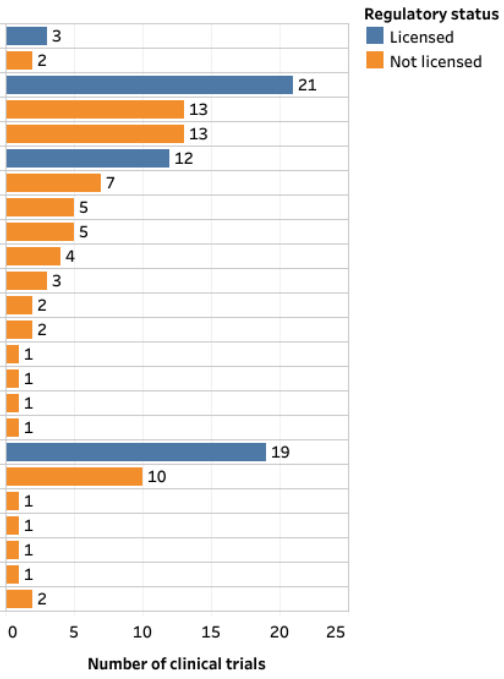
Oesophageal cancer

Radionuclides	Radiopharmaceuticals	Conditions	Regulatory status	Regulatory authority
F	Fluorodeoxyglucose	Esophageal Cancer|Lung Can..	Licensed	MHRA
Ga	ABY-025	Esophageal Neoplasms|Gast..	Not licensed	N/A
Zr	Girentuximab	Cervical Cancer|Colorectal C..	Not licensed	N/A



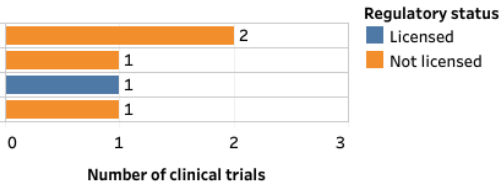
Prostate cancer

Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority	Number of clinical trials
Cu	Copper chloride	Licensed	MHRA	3
	SAR-Bombesin	Not licensed	N/A	2
F	Piflufolastat	Licensed	EMA	21
	PSMA-1007	Not licensed	N/A	13
	Fluorocholine	Not licensed	N/A	13
	Fluciclovine	Licensed	MHRA	12
	rhPSMA-7.3	Not licensed	N/A	7
	PSMA	Not licensed	N/A	5
	Choline	Not licensed	N/A	5
	Fluoroethylcholine	Not licensed	N/A	4
	Gozetotide	Not licensed	N/A	3
	Fluoromisonidazole	Not licensed	N/A	2
	CTT1057	Not licensed	N/A	2
	PSMA-617	Not licensed	N/A	1
	JK-PSMA-7	Not licensed	N/A	1
	Fluorochlorine	Not licensed	N/A	1
	Florastamin	Not licensed	N/A	1
Ga	Gozetotide	Licensed	MHRA	19
	HBED-CC PSMA	Not licensed	N/A	10
	RM2	Not licensed	N/A	1
	PSMA-617	Not licensed	N/A	1
	PSMA	Not licensed	N/A	1
	NeoB, PSMA-R2	Not licensed	N/A	1
Zr	DF-IAB2M	Not licensed	N/A	2



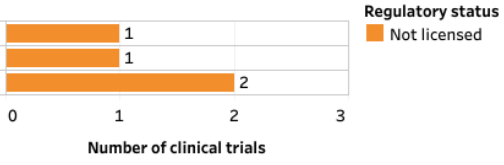
Ovarian cancer

Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority	Number of clinical trials
F	Fluoroestradiol	Not licensed	N/A	2
	PEG folate	Not licensed	N/A	1
	Fluorodeoxyglucose	Licensed	MHRA	1
Ga	FAPI-04	Not licensed	N/A	1



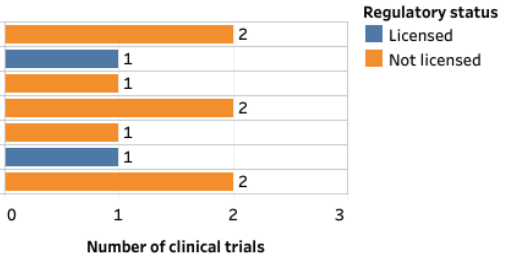
Pancreatic cancer

Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority	Number of clinical trials
F	Piflufolastat	Not licensed	N/A	1
	Fluorothymidine	Not licensed	N/A	1
Ga	FAPI-46	Not licensed	N/A	2



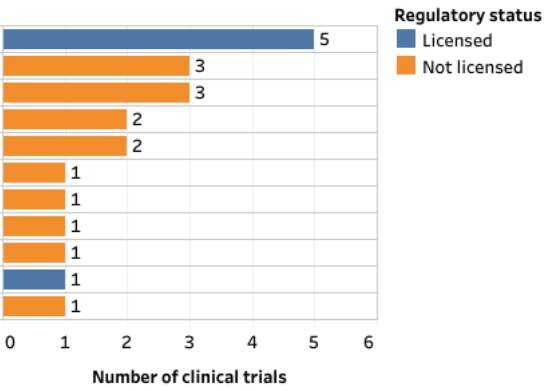
Thyroid cancer

Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority
F	Gozetotide	Not licensed	N/A
	Fluorodopa	Licensed	EMA
		Not licensed	N/A
	Fluorocholine	Not licensed	N/A
	HBED-CC PSMA	Not licensed	N/A
	Fluorodeoxyglucose	Licensed	MHRA
Ga	Dotatate	Not licensed	N/A



Blood and bone marrow cancers

Radionuclides	Radiopharmaceuticals	Regulatory status	Regulatory authority
F	Fluorodeoxyglucose	Licensed	MHRA
		Not licensed	N/A
	Fluorothymidine	Not licensed	N/A
	Sodium fluoride	Not licensed	N/A
	Fluorocholine	Not licensed	N/A
	FTC 146	Not licensed	N/A
Ga	Dota-SSTR	Not licensed	N/A
Zr	Rituximab	Not licensed	N/A
	Ofatumumab	Not licensed	N/A
	Daratumumab	Licensed	MHRA
	Atezolizumab	Not licensed	N/A



Acknowledgements and Disclaimers

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We would like to thank our project partners at All Wales PET Radiopharmaceutical Workstream who provided invaluable expertise, guidance, and input at various stages of this report

Report Title	**Business Continuity Risks Related to Establishment of the Joint Commissioning Committee**	**Agenda Item**	3.7
Meeting Title	**Joint Committee**	**Meeting Date**	30/01/2024
FOI Status	Open		
Author (Job title)	Managing Director		
Executive Lead (Job title)	Managing Director		

Purpose of the Report	The purpose of this report is to outline the business continuity risks for specialised services commissioning associated with the establishment of the new NHS Wales Joint Commissioning Committee on 1 April 2024.				
Specific Action Required	RATIFY ☐	APPROVE ☐	SUPPORT ☐	ASSURE ☐	INFORM ☒

Recommendation(s):

Members are asked to:

- **Note** the report; and
- **Note** the risks associated with the implementation of the new NHS Wales Joint Commissioning Committee, and **note** that the WHSSC Corporate Risk Assurance Framework (CRAF) will be updated to include the risks to specialised service business continuity.

BUSINESS CONTINUITY RISKS ASSOCIATED WITH THE ESTABLISHMENT OF THE NEW JOINT COMMISSIONING COMMITTEE

1.0 SITUATION

The purpose of this report is to outline the business continuity risks for specialised services commissioning associated with the establishment of the new NHS Wales Joint Commissioning Committee on 1 April 2024.

2.0 BACKGROUND

An independent review of national commissioning functions was conducted in May 2023, which reflected upon the experiences of the Welsh Health Specialised Services Committee (WHSSC) and the Emergency Ambulance Services Committee (EASC), which also includes the National Collaborative Commissioning Unit (NCCU), and to further build upon national commissioning arrangements. This included horizon scanning to explore other national commissioning functions and opportunities.

On the 12 July 2023 the Director General NHS Wales/NHS Wales Chief Executive wrote to WHSSC advising that the Minister for Health and Social Services (hereafter referred to as 'the Minister') accepted the recommendations arising from the review in full. The recommendations were as follows:

- WHSSC, EASC and NCCU should be combined to form a single Joint Committee. This would simplify and streamline the current arrangements. It would also create one central point of NHS commissioning expertise in Wales,
- This new Joint Committee should be given a new name to highlight that it is a new committee rather than just a merger of existing bodies,
- The term "specialist" [or "specialised"] should not be used in any new name, but the scope and responsibilities of the service should be defined,
- The new Joint Committee should take on an expert supportive role to Health Boards (HBs) in developing Regional and Inter HB commissioning. This would help build commissioning capacity across the health system in Wales,
- The new Joint Committee should be responsible for commissioning the 111 service. This could provide a model for managing other commissioned services within NHS Wales going forward,
- The current hosting agreement should be retained but would need to be reviewed after the new Joint Committee is established. (This single, new Joint Committee would be hosted by Cwm Taf Morgannwg UHB as the UHB is the current host and employer for the two existing Joint Committees),
- There is currently a lack of Public Health input around population needs assessment etc. and this should be remedied in line with the requirement in the Memorandum of Agreement,

- An organisational development programme should be put in place, including a behaviour framework. This would help ensure the new Joint Committee create its own identity; and
- The establishment of strengthened governance arrangements for the Joint Committee, as set out in further detail in the report.

A programme structure was established to implement the recommendations from the review. The Programme Initiation Document (PID) is attached at ***Appendix 1.***

3.0 ASSESSMENT

3.1 Process

The process is overseen by the National Commissioning Review Oversight Board established within Welsh Government (WG), which agrees recommendations to be put forward as Ministerial Advice. This is underpinned by 5 work-streams taking forward key elements of the programme:

1. Workforce (People)
   a. Management of the Organisational Process (OCP)
   b. Values and Behaviours
2. Communications and Engagement
   a. All communication and engagement with staff
3. Function and Form
   a. Functions and future structure of the new Joint Committee
4. Finance
   a. Merger of budgets, financial systems and supporting standing financial instructions
5. Governance
   a. Supporting legislation and governance framework for the new Joint Committee

To date the Oversight Board has agreed the new Joint Committee Structure, voting arrangements and the name (NHS Wales Joint Commissioning Committee) and the Minister has approved these recommendations. Also, the tier 1 and tier 2 organisational structures have been agreed by the Oversight Board, however at the time of writing there is ongoing discussion regarding the accountability of the tier 1 director and the titles and job descriptions of the tier 2 posts. There is ongoing work regarding the accountability framework and financial systems.

3.2 Risks

As with any organisational change there are risks to business continuity related to a range of different issues in the context of specialist services commissioning these are assessed as follows:

1. Make-up of the new Joint Commissioning Committee

The new Committee will be made up of a newly appointed Chair and 3 newly appointed Lay Members. It is possible that none of these appointees will have previous health service experience and lay members who have recent NHS Wales Health experience will not have commissioning experience specifically in the all Wales context of specialised services. In addition, the voting arrangements for the new JCC are different to the WHSSC Joint Committee. The Committee will need time to adjust to the new arrangements and fully understand their operation.

The risk is that during the first year of operation that the Committee will be unable to reach a decision on some of the more complex or contentious issues, that impact upon several HBs. This in turn could impact on the delivery of strategic projects within the WHSSC Integrated Commissioning Plan (ICP), such as neonatal strategic planning, the cardiac review and the change to the commissioning responsibility for plastic surgery.

To mitigate the risk advice has been given to the programme team on the Accountability Framework, and the WHSSC ICP has been reviewed and project timelines amended where required. It will be necessary for a robust and in depth induction be put in place for any new Chair and new lay members.

2. Workforce Retention

The organisational change process (OCP) for the programme, will ensure that all preparatory work and consultation with affected staff is undertaken, in line with the all Wales OCP process. However, as with any organisational change uncertainty can lead to increased workforce turn-over. There are some specific issues related to the current application of the change process. These relate to:

a. The inability to renew fixed term employment contracts beyond 1 April 2024,
b. The inability to recruit to vacant posts at any tier during the process. This currently includes directly funded WG Posts,
c. Advice from the host organisation that it is likely that applicants in the top tier posts will have restricted competition rights rather than slotting in or prior consideration in the OCP process. As explained in the FAQs this is because the scope of the posts will change from working for a specific commissioning body (WHSSC, EASC and NCCU) to a single joint commissioning body. There is ongoing discussion as to the type of recruitment process to be used,
d. The changes in portfolio of tier 2 director roles and proposed change to accountability of the tier 1 and 2 director roles, supported by the Oversight Board and on which the OCP will be consulted upon, increase organisational uncertainty.

The risk is that there will be a higher than expected turnover of staff within the specialised services team with a loss of specialised services commissioning expertise and high levels of vacancies leading to difficulties in delivering the WHSSC ICP and/or core business. This includes a specific **risk** to the delivery of

the WHSSC financial plan creating a potential cost pressure across the 7 HBs and applies across all portfolios. This risk is increased by potential new procurement legislation currently out to consultation.

There is a particularly high risk related to specialised mental health commissioning due to the current team arrangements and therefore delivery of:

- The WHSSC MH Specialist Services Strategy,
- The Single Commissioner Project; and
- The mental health contribution to the WHSSC financial plan for 2024/25. A key element of the strategy is to reduce reliance on the independent sector.

To mitigate the risk discussions have been held with the Programme Director and Senior Responsible Owner (SRO) regarding the process and communication with staff. There will be continuous review and prioritisation of the work-plan and feedback to the new Joint Committee on any impact on the ICP delivery in-year.

To mitigate the risk the Oversight Board has agreed that a transition plan will be developed and put in place to support transition from 1 April 2024. The transition plan will be developed by WG and signed off by the Director General of NHS Wales.

3. Financial Operating Model

For the new Committee to be operational from the 1st April 2024, it will require at a minimum, a working ledger, a working bank account and financial delegated authority to receive funding and make payment to Welsh HBs and Trusts.

1. Working ledger - The current operating working ledger as a continuation of the current arrangements will be sufficient for the new Committee,
2. Working bank account – EASC receives funds and transacts payments via the WHSSC, bank account and therefore one bank account already exists for the new Committee, however it will require a name change. There are no current signatories on the account within the Committee Team and therefore, the host is working to change the name on the account; and
3. Financial Delegated Authority – the Standing Orders (SO's), Standing Financial Instructions (SFI's), Scheme of Delegation and the Memorandum of Understanding are all expected to go to HB formal Board meetings in March for approval.

In addition, the authorised signatory for the Welsh HBs and WAST are at a level that currently can only be signed off by the Director of Finance and either the WHSSC Managing Director, or the EASC Managing Director on behalf of the relevant Committee.

The risk is that any delays to the bank account update will delay communication to HBs and WG in respect of updated details to provide funds to the Committee on 1st April.

The risk is that delays to the agreement of the SO's, SFI's, Scheme of Delegation and the Memorandum of Understanding with all HBs will result in Committee signatories with insufficient levels of delegated limits to pay Welsh HBs and Trusts on the 1st April.

The risk is that from 1st April, the current authorised signatory in respect of specialised services will not be in post and therefore there will be no-one with sufficient delegated authority to enter into contracts or make payments. For noting the authorisation of the 1st April payment will have to be made by 20th March for the payments to be processed in time.

To mitigate the risk the Director of Finance of the Committee will ensure the host Director of Finance is well informed of the updates and ensure risks are clearly articulated as known. The Committee may require the host to provide signatories if there are delays in delegated authorities ensuring the Committee and team act appropriately within its remit.

To mitigate the risk the Oversight Board has agreed that a transition plan will be developed and put in place to reduce the risks to business continuity. The transition plan will be developed by WG and then signed off by the Director General of NHS Wales.

4.0 BUSINESS OPERATING MODEL

Currently delivery of the WHSSC ICP is managed through the internal multidisciplinary arrangement known as Commissioning Teams and the Management Group sub-committee of WHSSC. Quality and patient safety issues are managed through Commissioning Teams with scrutiny by the WHSSC Quality and Patient Safety Committee, also a subcommittee of WHSSC. Maintaining normal business processes will require a continuation of the internal mechanisms and for a new sub-committee structure to be in place after 31st March 2024.

The risk is that normal business processes will be delayed if structures are not in place, affecting implementation of the WHSSC ICP and the appropriate escalation and de-escalation of clinical services.

To mitigate the risk a transition plan will be required (as above)

5.0 SUMMARY

There are risks to business continuity for specialised services commissioning business continuity related to:

- The make-up of the Joint Commissioning Committee,
- Workforce retention,
- The Financial operating model; and

- The Business operating model

These will be included in the next version of the WHSSC Corporate Risk Assurance Framework (CRAF) and the WHSSC legacy statement.

6.0 RECOMMENDATIONS

Members are asked to:

- **Note** the report; and
- **Note** the risks associated with the implementation of the new NHS Wales Joint Commissioning Committee, and **note** that the Corporate Risk Assurance Framework (CRAF) will be updated to include the risks to specialised service business continuity.

Governance and Assurance	
Link to Strategic Objectives	
Strategic Objective(s)	Governance and Assurance Implementation of the Plan Organisation Development
Link to Integrated Commissioning Plan	Yes: may affect delivery of the ICP
Health and Care Standards	Safe Care Effective Care Timely Care
Principles of Prudent Healthcare	Choose an item. Choose an item. Choose an item.
NHS Delivery Framework Quadruple Aim	The health and social care workforce is motivated and sustainable Choose an item. Choose an item. Choose an item.
Organisational Implications	
Quality, Safety & Patient Experience	Delivery of the duty of quality made be impaired by workforce gaps
Finance/Resource Implications	Direct effect may be to reduce the organisational running costs
Population Health	-
Legal Implications (including equality & diversity, socio economic duty etc)	-
Long Term Implications (incl WBFG Act 2015)	-
Report History (Meeting/Date/ Summary of Outcome	-
Appendices	Appendix 1 **-** National Commissioning Review PID

Llywodraeth Cymru
Welsh Government

PROGRAMME INITIATION DOCUMENT

Programme Name: National Commissioning Functions Implementation Programme
Programme: National Commissioning Functions Programme

Release Version:
Date:

Author:	Maxine Evans Programme Manager
Owner:	Samia Edmonds Senior Responsible Officer
Client:	Minister for Health and Social Services
Document Number:	Version 0.9

Document History

Revision History First Draft 21 June 2023

Revision Date	Previous Revision Date	Summary of Changes
22-6-23		KP additions
12-07-23	21-07-23	SE and Policy Leads comments and amendments
28-07-23		KP Additions NB Appendices not available in this draft
16-08-23	28-07.23	ME additions reflecting feedback from Oversight Board 09/08/23 and individual comments received
24-08.23	16-08-23	ME additions reflecting feedback from Implementation Board 22/08/23
06-09-23	24-08-23	ME amendments to all references of 'new body' within review recommendations (section 2) replaced with 'new (joint committee) Me amendments – added a high level summary of the workstreams main roles (made clear that legislation requirements fall under the Governance workstream) Me amendments to programme organogram moving programme support team to the side

Approvals This document has been approved by:

Name	Date of Issue	Version
Oversight Board subject to amendments agreed at its meeting on 06-09-23	13-09-2023	0.9

Distribution This document has been distributed to:

Name	Date of Issue	Version
Oversight Board	06-09-2023	0.9
Implementation Board	19-09.2023	0.9
Implementation Group	12-09.2023	0.9
Programme Support Team	19-09-2023	0.9
Health Boards x7	TBC	0.9

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1. Purpose

This Programme Initiation Document (PID) establishes oversight and programme arrangements to implement the recommendations made as an outcome of the independent review of national commissioning functions in Wales.

The PID addresses the following fundamental aspects of the programme:

- The stages and phasing of the programme.
- The aims and objectives of the programme.
- The expected benefits and outcomes of the programme.
- The roles and responsibilities of those involved in managing the programme.
- Delivery of the programme.

2. Background

An independent review was conducted in early 2023 to reflect upon the experiences of the Welsh Health Specialised Services Committee (WHSSC) and the Emergency Ambulance Services Committee (EASC), which also includes the National Collaborative Commissioning Unit (NCCU), and to further build upon national commissioning arrangements. This has included horizon scanning to explore other national commissioning functions and opportunities.

The review found that whilst there is good evidence of evolution and growing maturity in both WHSSC and EASC, there remain gaps and potentially lost opportunities in the current national commissioning arrangements in Wales. In particular, the review found scope to improve and strengthen decision making and accountability arrangements.

In summary, the independent review recommendations made are:

- WHSSC, EASC and NCCU should be combined to form a single Joint Committee. This would simplify and streamline the current arrangements. It would also create one central point of NHS commissioning expertise in Wales.
- This new Joint Committee should be given a new name to highlight that it is a new committee rather than just a merger of existing bodies.
- The term “specialist” [or “specialised”] should not be used in any new name, but the scope and responsibilities of the service should be defined.
- The new Joint Committee should take on an expert supportive role to health boards in developing Regional and Inter Health Board commissioning. This would help build commissioning capacity across the health system in Wales.
- The new Joint Committee should be responsible for commissioning the 111 service. This could provide a model for managing other commissioned services within NHS Wales going forward.
- The current hosting agreement should be retained but would need to be reviewed after the new Joint Committee is established. (This single, new joint committee would be hosted by Cwm Taf Morgannwg UHB as the UHB is the current host and employer for the two existing Joint Committees).
- There is currently a lack of Public Health input around population needs assessment etc. and this should be remedied in line with the requirement in the Memorandum of Agreement.

- An organisational development programme should be put in place, including a behaviour framework. This would help ensure the new Joint Committee create its own identity.
- The establishment of strengthened governance arrangements for the Joint Committee, as set out in further detail in the report.

Whilst the commissioning of 111 services was not explicitly included in the initial scope of the review, this falls under the opportunities that were explored as part of the horizon scanning. This was a strong view put forward by health boards. This recommendation will therefore be tested and explored further, alongside the proposed transition of the 6 Goals Urgent & Emergency Care Programme into the NHS Wales Executive.

The planned transfer of the Sexual Assault Referral Centres (SARC) commissioning service from the NHS Executive to the NCCU on 1 April 2024 will also be included within the remit of the project.

3. Programme Relationships

Key to the programme is the recognition of the relationship between the extant two Joint Committees and the seven Local Health Boards (LHBs).

Local health boards have a statutory responsibility for the commissioning and provision of services to meet the needs of their populations. Whilst they remain accountable, two Joint Committees were established as national, hosted bodies to support LHBs in discharging their commissioning function for an agreed portfolio of services. Health Boards provide the funding for these Joint Committees who have been given delegated responsibility for decision making via the seven Chief Executives on behalf of their individual Boards.

- **Welsh Health Specialised Services Committee (WHSSC)** - established in 2010 to ensure that the population of Wales has fair and equitable access to the full range of specialised services. WHSSC is responsible for the joint planning of specialised and tertiary services of the LHBs.
- **Emergency Ambulance Services Committee (EASC)** - established in 2015 with responsibility for planning and securing sufficient emergency and non-emergency ambulance services for the population. It includes the Welsh Ambulance Services NHS Trust (WAST) and Emergency Medical Retrieval and Transfer Service (EMRTS Cymru – Wales Air Ambulance).
- **The National Collaborative Commissioning Unit (NCCU)** - responsible for delivering national commissioning programmes for mental health and learning disability services. The NCCU is managed by the Chief Ambulance Services Commissioner (CASC).

4. Programme Definition

The Programme is defined as:

Implementation of the recommendations made as an outcome of the independent review of national commissioning functions in Wales.

5. Programme Scope

The Programme will include the following:

- WHSSC, EASC, NCCU commissioning bodies (the services that are currently commissioned by these bodies is included at appendix 4 – to be finalised in final draft)
- NHS 111 Wales Service – commissioning (not service delivery)
- Sexual Assault Referral Centres (SARC) commissioning (not service delivery)

6. Programme Aim and Objectives

The overall **aim** is:

To fully implement the Ministerial Directive following the independent review into national commissioning. Within this aim, the following principles from the original terms of reference will need to be considered:

- Improving outcomes and reducing inequalities
- Adding further value to the NHS system in Wales
- Strengthening and streamlining of commissioning functions, and associated decision making
- Building on evidence of good practice
- Supporting the development of commissioning expertise within the NHS in Wales
- Maximisation of national commissioning capacity and capabilities
- Minimal disruption to the system
- Minimal disruption to the existing workforce within WHSSC, EASC/ NCCU, the NHS 111 Wales programme and the SARC commissioning service
- Any changes to be implemented should be resource neutral as a minimum and will maximise the value and efficiencies delivered by current commissioning arrangements as the new Joint Committee matures (post April 2024)
- Exploit where possible, economies of scale through the establishment of a new Joint Committee by 1 April 2024.
- Enhanced improvement in transparency, rigour and accountability to the delivery of commissioned services through the new Joint Committee to health boards

The overall **objective** of the programme is to provide strategic direction and control to ensure all required preparatory work and engagement has been undertaken in order for the new Joint Committee to be operational and fit for purpose by 1 April 2024.

The arrangements and products to be put in place to facilitate ‘go-live’ on 1 April 2024 include:

- The appointment of a new single Joint Committee with a single Chair, for national commissioning
- A functional model and operational specifications
- Completion of the organisational change process
- Governance model and necessary supporting mechanisms
- Documented legacy statements to enable evaluation of the new Joint Committee overtime

- A clear identity
- Confirmed interim hosting agreement subject to review post implementation
- Delegation of functions by health boards
- Relationship with NHS Executive clarified

7. Programme Structure

See **Appendix 1** for organigram of the programme and workstream structure

7.1 Welsh Government Oversight Board

An Oversight Board will be established by Welsh Government, which will provide the strategic oversight, assurance and control of the overall strategic direction of the programme to create a new national commissioning Joint Committee, which will act on behalf of the seven health boards. It will champion the vision and objectives of the new Joint Committee at a senior level to oversee progress and to lead on the statutory, regulatory and legislative requirements for the establishent of the new committee by 1 April 2024. The Oversight Board will be accountable to the Minister for Health & Social Services and the Director General/ Chief Executive of NHS Wales. Its terms of reference (draft) can be found in **Appendix 2.**

7.2 NHS Implementation Board

The Joint Committees of WHSSC and EASC will form the basis of the programme's Implementation Board. It will lead on the execution of the programme providing assurance and advice to the Oversight Board. Within its responsibilities, it will ensure delivery of the programme of activities as set out in the PID, to facilitate the co-ordination, delivery and timescale for the development of a single commissioning joint committee for Wales in line with the review's recommendations and the decision of the Minister for Health and Social Services. Membership will be adapted to reflect and further explore other national commisisoning oportunities, including the commissioning of 111 services and SARC services. The Implementation Board will be provide assurance and make recommendations to the WG Oversight Board. It will retain some delegated decision making on minor matters to ensure the timely progression of certain milestones. Through its membership, the Chief Executive Officers will provide assurance to their individual Health Boards and CEO Leadership Board, on the direction and decisions of the programme. Its terms of reference (draft) can be found in **Appendix 3.**

7.3 Implementation Group

The Implementation Group will act as the sounding board between the Programme Support Team and the Implementation Board. It will be responsible for generating ideas and providing support and guidance to the workstream leads on an operational level, and for reviewing the outcome of activities and recommendations to be taken to the Implementation Board. Membership will be drawn from WHSSC, EASC, the NCCU, 111 and SARC services, and will meet monthly. Its terms of reference (draft) can be found in **Appendix 4.**

7.4 Programme Support Team

The Programme Support Team will be responsible for carrying out the programme activities through five dedicated workstreams, ensuring that timescales are met. Within its responsibilities, it will ensure all risks and issues are identified, logged and flagged

through the programme structure as appropriate. The Programme Support Team will undertake all administrative tasks associated with the programme including the production of workstream highlight reports, papers and action notes for the Implementation Group and Implementation Board. Membership will be drawn from WHSSC, EASC, the NCCU, 111 and SARC services.

7.5 Workstreams

1. Workforce (People) –
    a. Management of the Organisational Process (OCP)
    b. Values and Behaviours
2. Comms and Engagement
    a. All communication and engagement with staff
3. Function and Form
    a. Functions and future structure of the new Joint Committee
4. Finance
    a. Merger of budgets, financial systems and supporting standing financial instructions
5. Governance
    a. Supporting legislation and governance framework for the new Joint Committee

8. Product Breakdown and Deliverables

The following are the high-level deliverables within the programme:

- Programme approval.
- Development of programme infrastructure.
- Reporting of risks, mitigations and progress to the WG Oversight Board.
- Scoping the current commissioning Joint Committees.
- Communication and engagement with affected staff.
- Communication with external stakeholders.
- Completion of Organisational Change Process (OCP).
- Establishment of infrastructure for new single commissioning Joint Committee and its management structure including any required statutory or regulatory instruments.
- Establishment of governance arrangements.
- Recruitment of single Chair and independent members to the new Joint Committee.
- Development and agreement of Model Standing, Reservation and Delegation of Powers and Standing Financial Instructions for issue to new Joint Committee and Health Boards.
- Launch of the new Joint Committee

9. Programme Activities and Timeline

A summary of key milestones, by month and workstream, can be found in **Appendix 5.** Each workstream lead will develop its own detailed work plan to underpin the delivery of the programmes activities within the agreed timescales.

10. Constraints

- Capacity of programme implementation team.
- Timeframe for Ministerial decision.
- Timeliness and availability of information and documentation required from each organisation affected (WHSSC, EASC, NCCU, 111 and SARC).
- Capacity of workforce to focus on the establishment of the new Joint Committee whilst performing current roles and responsibilities.
- Availability of resources to deliver programme.

11. Assumptions

Assumptions made in the planning of this programme are:

- This is a priority for Welsh Government and the organisations affected.

12. Tolerances

To be agreed by the Oversight Board but deadline for go live of 1st April 2024 is a fixed point.

Shadow running period can be flexed.

13. Risk

A risk register for the programme will be developed and maintained as the programme progresses. This will assess and identify actions to mitigate the constraints highlighted above.

14. Reporting

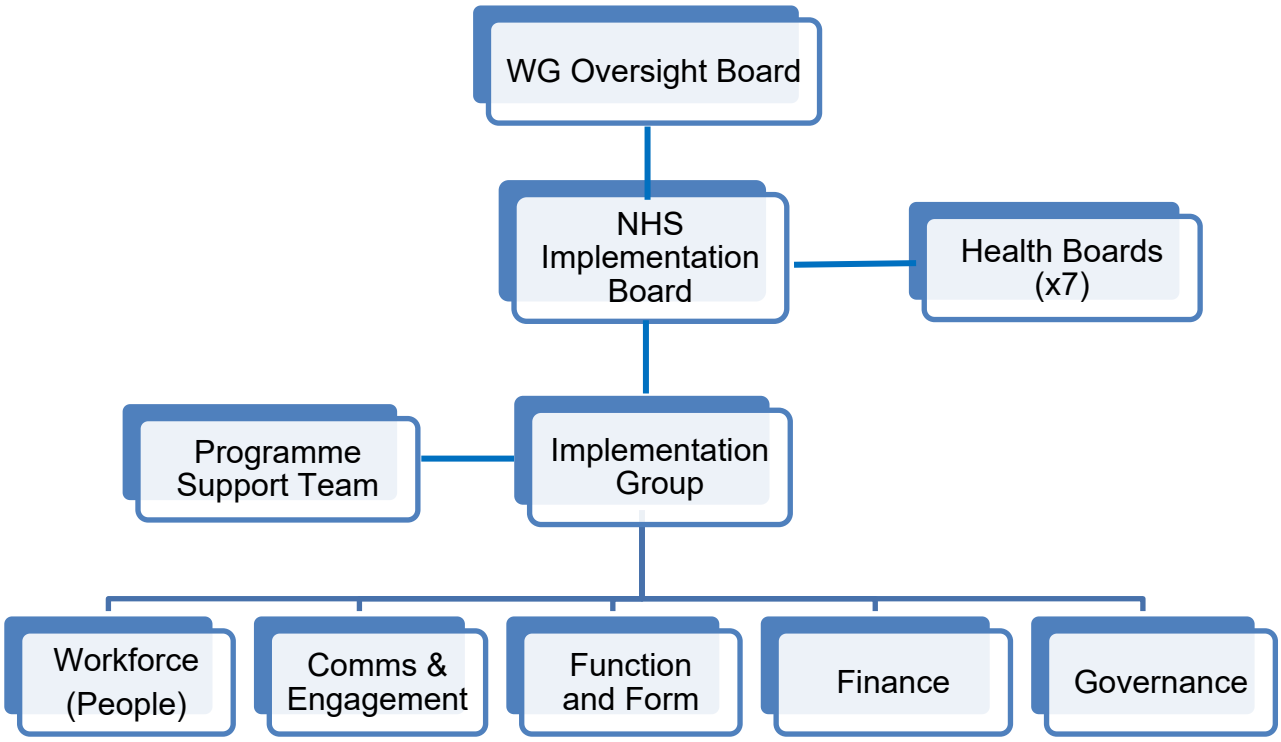
The programme will report to the Implementation Board, which will feed into the Oversight Board which has overall accountability for the delivery of the programme.

Update reports will be taken to both Boards on a monthly basis.

15. Footnote

This programme is separate to the Care and Support programme which is pending establishment. However, shared learning that can be brought into this programme will be considered.

Appendix 1 - National Commissioning Implementation Programme/Workstream Structure



Appendix 2 - Oversight Board Terms of Reference

National Commissioning Functions
Oversight Board

Terms of Reference v0.5

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1. Context

An independent review was conducted in early 2023 to reflect upon the experiences of the Welsh Health Specialised Services Committee (WHSSC) and the Emergency Ambulance Services Committee (EASC), which also includes the National Collaborative Commissioning Unit (NCCU), and to further build upon national commissioning arrangements. This has included horizon scanning to explore other national commissioning functions and opportunities.

The review found that whilst there is good evidence of evolution and growing maturity in both WHSSC and EASC, there remain gaps and potentially lost opportunities in the current national commissioning arrangements in Wales. In particular, the review found scope to improve and strengthen decision making and accountability arrangements.

In summary, the recommendations made are:

- WHSSC, EASC and NCCU should be combined into a single Joint Committee. This would simplify and streamline the current arrangements. It would also create one central point of NHS commissioning expertise in Wales.
- This new Joint Committee should be given a new name to highlight that it is a new committee rather than just a merger of existing bodies.
- The term “specialist” [or “specialised”] should not be used in any new name, but the scope and responsibilities of the service should be defined.
- The new Joint Committee should take on an expert supportive role to health boards in developing Regional and Inter Health Board commissioning. This would help build commissioning capacity across the health system in Wales.
- The new Joint Committee should be responsible for commissioning the 111 service. This could provide a model for managing other commissioned services within NHS Wales going forward.
- The current hosting agreement should be retained but would need to be reviewed after the new Joint Committee is established. (This single, new joint committee would be hosted by Cwm Taf Morgannwg UHB as the UHB is the current host and employer for the two existing Joint Committees).
- There is currently a lack of Public Health input around population needs assessment etc. and this should be remedied in line with the requirement in the Memorandum of Agreement.
- An organisational development programme should be put in place, including a behaviour framework. This would help ensure the new Joint Committee) creates its own identity.
- The establishment of strengthened governance arrangements for the Joint Committee, as set out in further detail in the report.

Whilst the commissioning of 111 services was not explicitly included in the initial scope of the review, this falls under the opportunities that were explored as part of the horizon scanning. This was a strong view put forward by health boards. This recommendation will therefore be tested and explored further, alongside the proposed transition of the 6 Goals Urgent & Emergency Care Programme into the NHS Wales Executive.

The planned transfer of the Sexual Assault Referral Centres (SARC) commissioning service from the NHS Executive to the NCCU on 1 April 2024 will also be included within the remit of the project.

2. Purpose of the Oversight Board

The overall objective of the programme is to provide strategic direction and control to ensure all required preparatory work and engagement has been undertaken in order for the new Joint Committee to be operational and fit for purpose by 1 April 2024.

The arrangements and products to be put in place to facilitate 'go-live' on 1 April 2024 include:

- The appointment of a new single Joint Committee for national commissioning
- A functional model and operational specifications
- Completion of the organisational change process
- Governance model and necessary supporting mechanisms
- A clear identity
- Confirmed hosting agreement
- Delegation of functions by health boards
- Clarify the alignment and interface with the NHS Executive, particularly in relation to the commissioning of 111 services and the relationship with national programmes more broadly

In this context, the Board will provide the strategic oversight, assurance and control of the overall strategic direction of the programme to create a new national commissioning Joint Committee, which will act on behalf of the seven health boards. It will champion the vision and objectives of the new Joint Committee at a senior level to oversee progress and to lead on the statutory, regulatory and legislative requirements for the establishment of the new Joint Committee by 1 April 2024.

The Oversight Board will be accountable to the Minister for Health & Social Services and the Director General/Chief Executive of NHS Wales.

Updates will also be provided to the Health & Social Services Group Executive Directors Team and the NHS Wales Leadership Board.

Specifically, the Board will:

- Provide assurance to the SRO about the deliverability of the programme, including the designated workstreams.
- Support the SRO with decision making.
- Enable the SRO to provide briefings to the Minister for Health & Social Services, the Director General/ CEO of NHS Wales and the Public Bodies Unit.

- Support the programme with the management of key stakeholders.

3. Remit of the Board

- The NHS Implementation Board will report to the Oversight Board which, in turn, will support the SRO with assurance and decision making.
- Ensure the resources required are regularly reviewed and considered against agreed programme deliverables.
- To provide scrutiny and seek assurance from the Implementation Board to enable the Oversight Board to support the SRO in decision making and provide assurance to the Minister for Health and Social Services and the Director General/Chief Executive for NHS Wales
- Provide a point of escalation and resolution for significant risks and issues which cannot be managed or mitigated within the implementation arrangements that may impact on delivery.
- Provide a point of escalation and resolution for areas of dispute which cannot be managed or agreed within the implementation arrangements that may impact on delivery.
- Provide the SRO with advice, guidance, and assurance on matters of governance to ensure the programme is managed in line with Welsh Government PPM requirements.
- Provide the assurance mechanism to the Minister for Health & Social Services and the Director General/ CEO of NHS Wales on the implementation of the recommendations from the independent review of national commissioning functions.

4. Membership

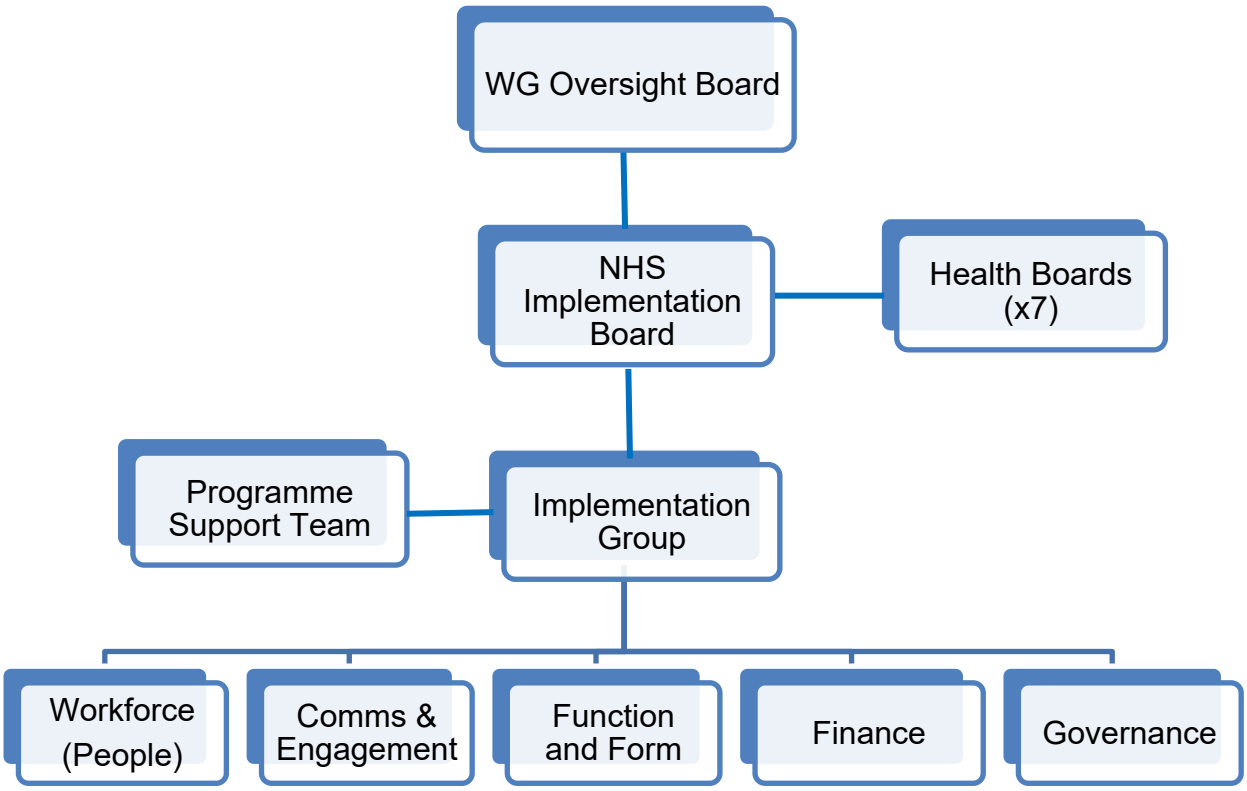
- **Chair/SRO:**
  - Samia Edmonds
- **Deputy Chair:**
  - Chris Jones, DCMO
- **Hosting body representatives and lead CEOs**:
  - Paul Mears
  - Nicola Prygodzicz
- **Chairs of the current national commissioning functions:**
  - Kate Eden
  - Chris Turner
- **Directors of the current national commissioning functions:**
  - Sian Lewis
  - Stephen Harrhy
  - Richard Bowen
- **Policy Leads:**
  - Melanie Westlake (NHS Wales Governance)
  - Aled Brown (Urgent & Emergency Care)
  - Pat Vernon (WHSSC)
  - Iain Hardcastle (Planning)
  - Finance (tbc)
  - Workforce?

- **Independent members**:
  - Mari Williams (Legal Services)
  - Christopher Griffiths (Legal Services)
- **Observers**:
  - Programme Director
  - Programme Lead

Audit Wales will act as an independent strategic advisor. Papers of all meetings will be shared routinely.

Additional members will be co-opted as necessary to ensure the Board fully meets its purpose and work plan.

5. Accountability/ Structures



6. Meetings

- The Oversight Board will meet monthly, and as required to meet the requirements of the programme.
- Members are permitted to send a deputy if unavailable to attend. Notification must be provided to the Chair in advance.
- It will be quorate with the following members present:
- Chair or Deputy Chair; at least two WG policy leads; at least two representatives from the national commissioning bodies; and one representative from a hosting body.

- Other WG & NHS directors / senior leaders to be invited to oversight board meetings as necessary, depending on subject matter to be discussed.
- Standing agenda items will include:
    - programme update;
    - highlight reports;
    - risks and issues;
    - programme decision log;
    - communications and engagement.
- Secretariat will be provided by the Health & Social Service Group Planning Team with a record maintained of actions and decisions, and progress monitored through the overall programme plan.

7. Agenda/Papers

- The agenda will be based on items agreed with the chair.
- Members may submit agenda items with notice as far in advance as possible.
- The agenda and papers will be circulated three days prior to the meeting.
- Programme overview and workstream highlight reports will be prepared in the prescribed format.

8. Close

The programme board will conclude upon completion of its business and as agreed by the SRO.

Appendix 3 - Implementation Board Terms of Reference

(To be added when signed off)

Appendix 4 - Implementation Group Terms of Reference

National Commissioning Functions
Implementation Group

Terms of Reference v0.4

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9. Context

An independent review was conducted in early 2023 to reflect upon the experiences of the Welsh Health Specialised Services Committee (WHSSC) and the Emergency Ambulance Services Committee (EASC), which also includes the National Collaborative Commissioning Unit (NCCU), and to further build upon national commissioning arrangements. This has included horizon scanning to explore other national commissioning functions and opportunities.

The review found that whilst there is good evidence of evolution and growing maturity in both WHSSC and EASC, there remain gaps and potentially lost opportunities in the current national commissioning arrangements in Wales. In particular, the review found scope to improve and strengthen decision making and accountability arrangements.

In summary, the recommendations made are:

- WHSSC, EASC and NCCU should be combined into a single Joint Committee. This would simplify and streamline the current arrangements. It would also create one central point of NHS commissioning expertise in Wales.
- This new Joint Committee should be given a new name to highlight that it is a new committee rather than just a merger of existing bodies.
- The term “specialist” [or “specialised”] should not be used in any new name, but the scope and responsibilities of the service should be defined.
- The new Joint Committee should take on an expert supportive role to health boards in developing Regional and Inter Health Board commissioning. This would help build commissioning capacity across the health system in Wales.
- The new Joint Committee should be responsible for commissioning the 111 service. This could provide a model for managing other commissioned services within NHS Wales going forward.
- The current hosting agreement should be retained but would need to be reviewed after the new Joint Committee is established. (This single, new joint committee would be hosted by Cwm Taf Morgannwg UHB as the UHB is the current host and employer for the two existing Joint Committees).
- There is currently a lack of Public Health input around population needs assessment etc. and this should be remedied in line with the requirement in the Memorandum of Agreement.
- An organisational development programme should be put in place, including a behaviour framework. This would help ensure the new Joint Committee creates its own identity.
- The establishment of strengthened governance arrangements for the Joint Committee, as set out in further detail in the report.

Whilst the commissioning of 111 services was not explicitly included in the initial scope of the review, this falls under the opportunities that were explored as part of the horizon scanning. This was a strong view put forward by health boards. This recommendation will therefore be tested and explored further, alongside the proposed transition of the 6 Goals Urgent & Emergency Care Programme into the NHS Wales Executive.

The planned transfer of the Sexual Assault Referral Centres (SARC) commissioning service from the NHS Executive to the NCCU on 1 April 2024 will also be included within the remit of the project.

10. Purpose of the Implementation Group

The overall objective of the programme is to provide strategic direction and control to ensure all required preparatory work and engagement has been undertaken in order for the new Joint Committee to be operational and fit for purpose by 1 April 2024.

The arrangements and products to be put in place to facilitate 'go-live' on 1 April 2024 include:

- The appointment of a new single Joint Committee with a single Chair, for national commissioning
- A functional model and operational specifications
- Completion of the organisational change process
- Governance model and necessary supporting mechanisms
- Documented legacy statements to enable evaluation of the new Joint Committee overtime
- A clear identity
- Confirmed interim hosting agreement subject to review post implementation
- Delegation of functions by health boards

In this context, the Implementation Group will act as the sounding board between the Programme Support Team and the Implementation Board. It will be responsible for generating ideas and providing support and guidance to the workstream leads on an operational level, and for reviewing the outcome of activities and recommendations to be taken to the Implementation Board.

Specifically the Implementation Group will:

- Provide a steer and direction to the Programme Support Team to ensure progression of the programme within the agreed timescales and provide operational advice to support activities where they are off-track
- Review the outcome of workstream activities to ensure they are fit for purpose prior to reporting to the Implementation Board
- Review all highlight reports and papers prior to sharing with the Implementation Board
- Ensure the programme is being managed and controlled effectively through the Programme Support Team.

- Ensure that the change is managed within best practice guidelines, including the NHS Wales Organisational Change Policy, and that staff affected by the change feel supported and valued.
- Ensure significant risks and issues are being tracked and managed effectively by workstream leads and support them in their risk management activities
- Escalate areas of dispute to the Implementation Board which cannot be managed or mitigated within the implementation arrangements that may impact on delivery.
- Identify interdependencies across the workstreams are identified, managed and optimised.
- Ensure the Programme Support Team is adequately resourced to deliver the programme

11. Membership

- **EASC/NCCU:**
  - Chief Ambulance Services Commissioner EASC/NCCU – Co-Chair
  - Deputy Chief Ambulance Service Committee
  - Clinical Director for NCCU
  - Deputy Director Communications and Engagement (EASC/NCCU)
  - Deputy Director and Head of Nursing (NCCU)
  - Committee Secretary

- **WHSSC:**
  - Managing Director WHSSC – Co-Chair
  - Director of Finance WHSSC and EASC/NCCU
  - Medical Director WHSSC
  - Director of Nursing WHSSC
  - Director of Planning WHSSC
  - Director for Mental Health & Vulnerable Adults WHSSC
  - Committee Secretary

- **111 and Six Goals Programme:**
  - Head of the National Programme for Urgent & Emergency Care 111 – Nicola
  - Workforce and Commissioning Lead for the 111 Programme Board

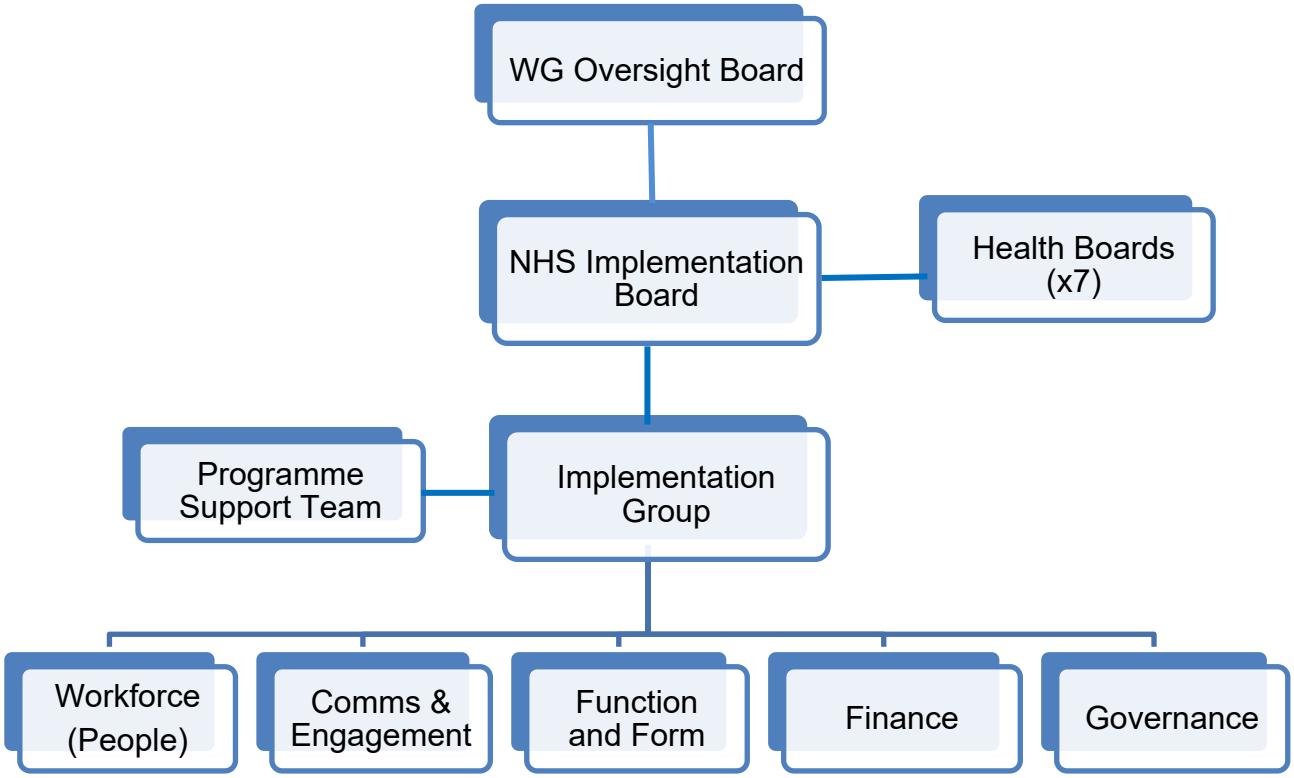
- **Health Boards:**
  - Director of Strategic Planning, or nominated deputy
  - Director of Finance, or nominated deputy
  - Board Secretary

- **Provider:**
  - Executive Director of Operations, WAST
  - Executive Director of Strategic Transformation, Planning and Digital, Velindre

- Programme Director for Project
- Programme Finance Director for Project
- Programme Manager for Project

Additional members will be co-opted as necessary to ensure the Group fully meets its purpose and work plan.

12. Accountability/ Structures



13. Meetings

- The Implementation Group will meet monthly, and as required to meet the requirements of the programme.
- Members are permitted to send a deputy if unavailable to attend. Notification must be provided to the Chair in advance.
- It will be quorate with the following members present:
  - 1 person representing WHSSC,
  - 1 person representing EASC and the NCCU
  - 1 person representing 111 Programme Board
  - 1 person representing Health Boards
  - At least one of the Programme Support Team will be expected to be present.
- Standing agenda items will include:
  - Programme update;
  - Highlight reports;
  - Risks and issues;

    - Programme decision log;
    - Communications and engagement.
- Secretariat will be provided by the programme support team with a record maintained of actions and decisions, and progress monitored through the overall programme plan.

14. Agenda/Papers

- The agenda will be based on items agreed with the chair.
- Members may submit agenda items with notice as far in advance as possible.
- The agenda and papers will be circulated three days prior to the meeting.
- Programme overview and workstream highlight reports will be prepared in the prescribed format.

15. Review

The Terms of Reference will be reviewed within 3 months of the start to ensure purpose remain extant for the duration of the project.

Appendix 5 - Key Programme Activities and Timeline

Month	Key Activities	Workstream
Aug – Sept 23	Sign off PID	
Aug – Sept 23	Establish and provide sign off to programme structure, sub-structure, and terms of reference	
Aug 23	Fully explore opportunities for national commissioning functions with health boards and key stakeholders	Function & Form
Aug 23	Scope 111 and SARC commissioning functions to determine inclusion within the new Joint Committee	Function & Form
Aug 23	Map committee structures, where appropriate, of WHSSC, EASC and NCCU	Workforce
Aug 23	Engage with Trade Unions on proposed new Joint Committee and planned OCP	Workforce
Aug 23	Develop Communication & Engagement Plan, including staff survey, FAQ sheet and staff bulletin to share with affected staff and wider key stakeholders	Comms' & Engagement
Aug 23 – Mar 24	Schedule joint staff meetings for the duration of the programme, to provide key updates and listen to feedback	Comms' & Engagement
Sept 23	Agree name for new Joint Committee (will require Ministerial approval)	Function & Form
Sept 23	Develop and agree commissioning functions for new Joint Committee	Function & Form
Sept 23	Produce legacy statements for WHSSC, EASC, NCCU, 111 and SARC commissioning to support future evaluation of new Joint Committee	Function & Form
Sept 23 – Oct 23	Develop structure for new Joint Committee	Function & Form
Sept 23 – Oct 23	Undertake financial assessment of WHSSC, EASC, NCCU, 111 and SARC commissioned services, and identify a budget for transfer to the new Joint Committee	Finance
Sept 23 – Oct 23	Map all fixed assets and lease arrangements	Finance
Sept 23	Map staffing structures of WHSSC, EASC, NCCU, 111 and SARC commissioning, and gather job descriptions in readiness for OCP process	Workforce
Sept 23 – Oct 23	Confirm structure for Tier 1 (Executive and Senior Management AfC 8c and above)	Workforce

Month	Key Activities	Workstream
Sept 23	Produce Staff Consultation paper for phased OCP process (Tiers 1, 2 and 3)	Workforce
Sept 23	Board secretaries advised of decision-making process and timelines for approval of delegation of functions to their individual Health Boards, and built in to Board agenda's	Governance
Sept 23 – Oct 23	Seek Ministerial approval to proceed with recruitment of a single Chair and Independent Members for the new Joint Committee	Governance
Oct – Nov 23	Develop branding for new Joint Committee in line with guidelines	Function & Form
Oct – Dec 23	Scope IT infrastructure and IG requirements, including transfer of documents, for new Joint Committee (NWSSP and DHCW support required)	Function & Form
Oct – Nov 23	Map all new sources of information re: 111 and SARC	Finance
Oct – Nov 23	Map all contracts for commissioning	Finance
Oct 23	Scope statutory instruments and legislation required for the establishment of the new Joint Committee	Governance
Oct – Nov 23	Scope Governance Framework and identify products for development (SO's, SFI's, Reservation and Delegation of Powers, MoU's, Policies and Procedures)	Governance
Oct 23 – Nov 23	Chief Executives to take agreed delegation of functions of the new Joint Committee to their individual Health Boards (supporting SO's and SFI's under development)	Governance
Oct 23	Carry out 4 week OCP consultation with affected staff and trade unions	Workforce
Oct 23 – Nov 23	Where required, produce and approve through HR process, job descriptions for Tier 1	Workforce
Oct 23 – Jan 24	Commence recruitment process for new Chair	Workforce
Nov – Dec 23	Undertake Tier 1 OCP process (job matching / slotting-in / prior consideration / TUPE)	Workforce
Nov 23	Confirm structure for Tier 2 (Snr/Middle Management AfC 8b - 7)	Workforce
Nov 23	Where required, produce and approve through HR process, job descriptions for Tier 2	Workforce
Nov – Dec 23	Prepare for transfer of documents to new website as appropriate (NWSSP and DHCW support required)	Function & Form
Nov 23 – Jan 24	Develop SO's, SFI's, Reservation and Delegation of Powers and MoU's for approval by committee and boards of Local Health Boards on establishment	Governance
Dec 23 – Jan 24	Undertake Tier 2 OCP process (job matching / slotting-in / prior consideration / TUPE)	Workforce

Month	Key Activities	Workstream
Dec 23	Commence recruitment process for Independent Members	Workforce
Jan 24	Confirm structure for Tier 3 (Officer AfC 6 - 3)	Workforce
Jan 24	Where required, produce and approve through HR process, job descriptions for Tier 3	Workforce
Jan 24	Commence process for securing Public Health involvement to support the commissioning functions of the new Joint Committee	Workforce
Jan 24	Develop OD Programme, including a Behaviour Framework, to support the principles and values of the new Joint Committee	Governance
Jan – Feb 24	Chief Executives to take Governance Framework including SO's, Reservation and Delegation of Powers and SFI's to the individual Heath Boards for approval	Governance
Feb – Mar 24	Undertake Tier 3 OCP process (job matching / slotting-in / prior consideration / TUPE)	Workforce
Feb 24	Interview process and appointment of Independent Members	Workforce
Mar 24	OCP process concluded	Workforce
Mar 24	Public Health support in place	Workforce
Mar 24	Chair and Independent Members in post	Workforce
Mar 24	Health Board approved delegation of functions in place	Governance
Mar 24	OD and Behavioural Framework in place	Governance
Mar 24	Website live	Function & Form
Mar 24	Go live of new Joint Committee	Function & Form

Report Title	**Corporate Risk Assurance Framework (CRAF)**	**Agenda Item**	3.8
Meeting Title	**Joint Committee**	**Meeting Date**	30/01/2024
FOI Status	Open/Public		
Author (Job title)	Head of Corporate Governance and Risk and Governance Officer		
Executive Lead (Job title)	Committee Secretary and Associate Director of Corporate Services		

Purpose of the Report	The purpose of this report is to present WHSSC's updated Corporate Risk Assurance Framework (CRAF) and outline the risks scoring 15 or above on the commissioning teams and directorate risk registers.				
Specific Action Required	RATIFY ☐	APPROVE ☒	SUPPORT ☐	ASSURE ☒	INFORM ☒

Recommendation(s)

Members are asked to:

- **Note** the updated Corporate Risk Assurance Framework (CRAF) and changes to the risks outlined in this report as at 31 December 2023,
- **Approve** the CRAF as at 31 December 2023; and
- **Note** that the CRAF is presented to each Integrated Governance Committee, Quality & Patient Safety Committee, CTMUHB Audit & Risk Committee and the Risk Scrutiny Group (RSG) meetings.

CORPORATE RISK ASSURANCE FRAMEWORK (CRAF)

1.0 SITUATION

The purpose of this report is to present WHSSC's updated Corporate Risk Assurance Framework (CRAF) and outline the risks scoring 15 or above on the commissioning teams and directorate risk registers.

2.0 BACKGROUND

WHSSC is committed to developing and implementing a Risk Management Strategy that will identify, analyse, evaluate and control the risks that threaten the delivery of its strategic objectives and delivering against its Integrated Commissioning Plan (ICP). The strategy is applied alongside other key management tools, such as performance, quality and financial reports, to provide the Joint Committee (JC) with a comprehensive picture of the organisation's risk profile.

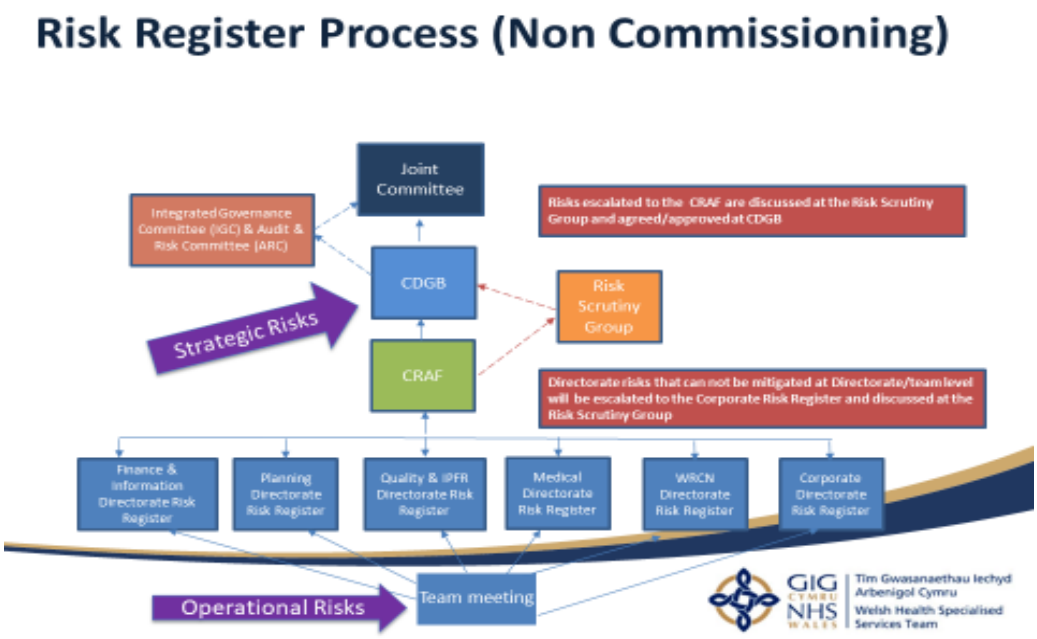
WHSSC revised its approach to assurance and risk management in April/May 2021 and developed the WHSSC risk management strategy, assessment and scoring to align with the approach undertaken in CTMUHB (our host). The JC agreed the approach, format and content of the Corporate Risk Assurance Framework (CRAF) at its meeting on the 11 May 2021 and receives the CRAF at least twice per year. The in-depth scrutiny and monitoring of corporate risks was delegated to sub-committees in order that they could provide assurance to the JC, through their Committee Update Reports, on the management of its principal risks.

The Executive Directors are responsible for reviewing and discussing their commissioning/corporate risks, and agreeing any new risks and the escalation/de-escalation of operational risks that are on directorate risk registers. It is the role of the Executive Directors to review controls and ensure appropriate action plans are in place, which might include the development of corporate risk management strategies to manage risk(s). Effective management of these risks enables the organisation to improve its chances of success and reduce the likelihood of failure.

Each directorate risk register is submitted to the Risk Scrutiny Group (RSG) on a bi-monthly basis. The membership of the RSG includes Directorate Managers who review and scrutinise the narrative, scores and mitigating actions for each risk. The risks are validated by the RSG and are subject to continuous review by the Executive Director lead for each risk. In addition to reviewing Directorate Risks, the RSG also receives a deep dive into a Commissioning Team Risk Register at each of its meetings.

Any risks identified as scoring 15 and above are captured on the CRAF and are presented to the Corporate Directors Group Board (CDGB) for scrutiny on a monthly basis. The Quality & Patient Safety Committee (QPSC), the Integrated Governance Committee (IGC) and the Cwm Taf Morgannwg Audit & Risk Committee (ARC) receive the CRAF at each meeting and the Joint Committee receive the CRAF on a six monthly basis for assurance. The infographic outlined in ***Figure 1*** below outlines the governance framework for risk management.

Figure 1 – WHSSC Risk Management Framework



3.0 ASSESSMENT

3.1 Risk Summary – December 2023

The December 2023 CRAF is presented at ***Appendix 1*** for information.

As at 31 December 2023, there are **25** risks on the CRAF. A summary of these risks is outlined below.

3.2 Commissioning Risks – December 2023

There are currently **20** commissioning risks open with a risk score of 15 and above, which are included on the CRAF.

Work continues with the commissioning teams to ensure the following:

- A structured statement describes the risk,
- Controls are in place that modify the risk and gaps are identified; and
- All actions that mitigate the risk are SMART and have action leads.

A summary of the changes that have taken place in December 2023 are outlined in ***table 1*** below.

Table 1 – Commissioning Risk Summary – December 2023

Commissioning Risk Activity	Update as at December 2023
New Commissioning Risks	3 new Commissioning Risks: • Risk 61 – CT050 Cardiac – Obesity Surgery Waiting Times • Risk 62 – CT051 Cardiac – TARN delays • Risk 63 – NCC063 Neuro – Neurosurgery Sustainability
Escalated Commissioning Risks	No risks were escalated.
De-escalated Commissioning Risks	1 risk was de-escalated: • Risk 44 – Paediatric Cardiac Surgery
Closed Risks	No risks were closed.

3.3 Organisational Directorate Risks – December 2023

There are currently **5** organisational risks open with a risk score of 15 and above, which are included on the CRAF.

A summary of the changes for December 2023 are outlined in the table below. The full CRAF and risk schedules are presented at ***Appendix 1*** for information.

Table 2 – Organisational Risk Summary – December 2023

Organisational Risk Activity	Update as at December 2023
New Organisational Risks	No new organisational risks.
Escalated Organisational Risks	No risks were escalated.
De-escalated Organisational Risks	No risks were de-escalated.
Closed Risks	No risks were closed

The risks scoring below 15 are being managed within the directorate/teams and all risks are monitored through the Risk Scrutiny Group (RSG).

4.0 RISK ACTIVITY - JULY 2023 – DECEMBER 2023

The Joint Committee last received the CRAF on 18 July 2023, an overview of the changes between July 2023 and December 2023 are presented at ***Appendix 2*** for completeness[1].

5.0 GOVERNANCE AND RISK

5.1 Internal Audit Progress

An internal audit on WHSSC's risk management process was undertaken on the 16 March 2022, and received an internal audit assessment rating of "reasonable assurance". Overall, the feedback was positive with some minor recommendations to strengthen and develop training, risk narrative and scrutiny. Progress against the recommendations is monitored by the CTMUHB ARC.

5.2 Risk Scrutiny Group

A Risk Scrutiny Group (RSG) Meeting took place on 22 November 2023. Directorate Risk registers were discussed and reviewed.

Risk owners have been requested to provide detailed narrative on any changes to risk scores. The corporate governance team will monitor this and will support to directorates with risk descriptions as required.

6.0 RECOMMENDATIONS

Members are asked to:

- **Note** the updated Corporate Risk Assurance Framework (CRAF) and changes to the risks outlined in this report as at 31 December 2023,
- **Approve** the CRAF as at 31 December 2023; and
- **Note** that the CRAF is presented to each Integrated Governance Committee, Quality & Patient Safety Committee, CTMUHB Audit & Risk Committee and the Risk Scrutiny Group meetings.

[1] The QPSC, the IGC and the CTMUHB ARC receive the CRAF at each meeting and the Joint Committee receive the CRAF on a six monthly basis for assurance.

Governance and Assurance	
Link to Strategic Objectives	
Strategic Objective(s)	Governance and Assurance
Link to Integrated Commissioning Plan	Implementation of agreed ICP
Health and Care Standards	Safe Care Effective Care Governance, Leadership and Accountability
Principles of Prudent Healthcare	Only do what is needed Reduce inappropriate variation Choose an item.
Institute for HealthCare Improvement Quadruple Aim	Improving Patient Experience (including quality and Satisfaction) Improving Health of Populations Choose an item.
Organisational Implications	
Quality, Safety & Patient Experience	Ensuring the organisation has robust risk management arrangements in place that ensure organisational risks are captured, assessed and mitigating actions are taken, is a key requisite to ensuring the quality, safety & experience of patients receiving care and staff working in WHSSC.
Finance/Resource Implications	The risks outlined within this report have resource implications, which are being addressed by each respective Executive Director lead and taken into consideration as part of the WHSSC Integrated Commissioning Plan (ICP) processes.
Population Health	There are no immediate adverse population health implications.
Legal Implications (including equality & diversity, socio economic duty etc)	It is essential that there are robust arrangements in place to identify, assess, mitigate and manage risks encountered by WHSSC. Failure to maintain such arrangements may have legal implications.
Long Term Implications (incl WBFG Act 2015)	The robust arrangements in place to identify, assess, mitigate and manage risks encountered by WHSSC consider the long-term impact of decisions, to work better with people, communities and each other, and to prevent persistent problems such as poverty, health inequalities and climate change.

Report History (Meeting/Date/ Summary of Outcome	-
Appendices	Appendix 1 – Corporate Risk Assurance Framework (CRAF) December 2023 Appendix 2 - Summary of Risk Activity from July - Dec 2023

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

Corporate Risk Assurance Framework (CRAF)

December 2023

Dashboard of Risk

Impact	5			**47** IF - Sustainability and Delivery of Service provided by Cardiff and Vale University Health Board **58** Goal methods and outcomes pressures **59** Calea Contract Renewal	**60** WFI treatment – temporary pause	**48** Wales Fertility Institute **63** Neurosurgery Sustainability - **NEW RISK**
	4			**44** Paediatric cardiac surgery – **DE-ESCALATED REDUCED RISK**	**06** Paediatric patients waiting for surgery **28** Workforce and Capacity **38** No neonatal cot availability in South Wales due to staffing shortages **40** Limited outpatient dialysis capacity in Swansea **50** Deep Brain Stimulation and delays in communication with gatekeeper/referring clinician **51** Deep Brain Stimulation – lack of awareness of eligibility criteria re unmet need **52** Additional Dialysis Sessions **53** C&VUHB Neurosciences Staffing issues/level **55** CVUHB Neo-natal workforce **56** CVUHB Neo-natal infection control **57** Delays in surgery due to insufficient theatre beds Neurosurgery **61** Obesity surgery waiting times – **NEW RISK** **62** TARN delays – **NEW RISK**	**26** Neuropsychiatry patients waiting times **29** WHSSC IPFR Governance **34** Lack of paediatric intensive care beds **54** NWAS
	3					**03** Plastic Surgery Delays **46** North Wales Outreach Plastic Surgery Clinic Management Arrangements
	2					
	1					
		1	2	3	4	5
CXL		**Likelihood**				

Risk Register/Summary of Risk

Risk Ref	Domain	Summary of Risk	Initial Score	Current Consecutive Monthly Score	Target Score	Trend since previous month	Last Review Date	Next Review Date	Scrutiny Committee	Lead Director
3 CB03 **Cancer & Blood**	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Plastic Surgery Delays** There is a risk of poor patient experience and poor outcome for plastic surgery patients in south Wales. This is caused by failure to achieve the maximum waiting times target with some patients waiting in excess of 52 weeks. This leads to a commissioned service that does not meet waiting times standards and therefore does not provide the required quality of service.	**15**	**15**	**6**	**Risk score remains the same** ↔	22/12/23	26/01/23	Joint Committee	Director of Planning & Performance
		Provider/s: SBUHB	**C3 x L5**	**C3 x L5**	**C2 x L3**					
6 P/21/10 **Women & Children**	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Paediatric patients waiting for surgery** There is a risk that paediatric patients waiting for surgery in the Children's Hospital of Wales are waiting in excess of 36 weeks due to COVID-19. The consequence is the condition of the patient could worsen and that the current infrastructure is insufficient to meet the backlog.	**16**	**16**	**4**	**Risk score remains the same** ↔	20/12/23	17/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: CVUHB	**C4 x C4**	**C4 x C4**	**C2 x C2**					
26 NCC046 **Mental Health & Vulnerable Groups**	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Neuropsychiatry patients waiting times** There is a risk that neuropsychiatry patients will not be able to be treated in a timely manner with the appropriate therapy support, due to staffing issues. The consequence patients will have long waiting times to access the service and the lack of availability of step down facilities to support the acute centre will also result in delays.	**20**	**20**	**4**	**Risk score remains the same** ↔	December 2023 - Cancelled	22/01/2024	Joint Committee	Director of Mental Health
		Provider/s: CVUHB	**C4 x L5**	**C4 x L5**	**C4 x L1**					
28 CS3 **Corporate Services**	Workforce and Capacity	**Workforce and Capacity** There is a risk that WHSSC is unable to keep up with the increasing work demand. Due to additional work related services currently commissioned through HB's or services which are new to Wales. As a consequence this could have an impact on teams to absorb the additional work	**20**	**16**	**9**	**Risk score remains the same** ↔	December 2023	January 2024	Joint Committee	Committee Secretary
		Provider/s: N/A	**C5 x L4**	**C4 x L4**	**C3 x L3**					
29 CS8 **Corporate Services / Quality and IPFR**	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**WHSSC IPFR ToR and Governance** There is a risk that WHSSC will be unable to meet the TOR for the All Wales IPFR panel due to the inability to achieve quoracy in the membership and consequently this may lead to delayed decision-making. In addition, there is also a risk that the current IPFR governance arrangements are not robust and as a consequence this may also lead to legal challenges in the form of judicial reviews.	**16**	**20**	**4**	**Risk score remains the same** ↔	December 2023	January 2024	Joint Committee	Director of Nursing/ Committee Secretary
		Provider/s: N/A	**C4 x L4**	**C4 x L5**	**C2 x L2**					
34 P/21/02 **Women & Children**	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Lack of Paediatric Intensive Care Beds** ***There is a risk*** that a paediatric intensive care bed, in the Children's Hospital for Wales, will not be available when required ***due to*** constraints within the service. ***There is a consequence*** that paediatric patients requiring intensive care will be cared for in, inappropriate areas where the necessary skills or equipment are not available or the patient being transferred out of Wales.	**12**	**20**	**4**	**Risk score remains the same** ↔	20/12/23	17/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: CVUHB	**C3 x L4**	**C4 x L5**	**C2 x L2**					

Risk Ref	Domain	Summary of Risk	Initial Score	Current Consecutive Monthly Score	Target Score	Trend since previous month	Last Review Date	Next Review Date	Scrutiny Committee	Lead Director
38 P/21/16 **Women & Children**	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Neonatal Cots** **There is a risk** that there will not be a Neonatal cot available across the south Wales region **due to** significant neonatal nursing shortages. **There is a consequence** that babies will need to travel to NHS England to receive their care or be cared for in an inappropriate setting whilst waiting for an available cot	**16**	**16**	**4**	**Risk score remains the same** ↔	20/12/23	17/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: CVUHB	**C4 x L4**	**C4 x L4**	**C2 x L2**					
40 WKN 08 **Welsh Kidney Network**	Impact on the safety of patients, staff or public (physical/psychological harm)	**Limited outpatient dialysis capacity in Swansea** **There is a risk** that the number of patients receiving outpatient haemodialysis in Morriston will exceed capacity. **As a consequence** there is need for expansion of outpatient service provision to include demand from the Neath Port Talbot area and Bridgend localities.	**12**	**16**	**2**	**Risk score remains the same** ↔	December 2023	January 2024	Joint Committee	Programme Director
		Provider/s: SBUHB	**C3 x L4**	**C4 x L4**	**C2 x L1**					
46 CB06 **Cancer & Blood**	Impact on the safety of patients, staff or public (physical/psychological harm)	**North Wales Outreach Plastic Surgery Clinic Management Arrangements** There is a risk that patients may come to harm due to a lack of clinical prioritisation and oversight of waiting lists for outreach plastic surgery clinics in YG and YGC. This is caused by lack of clarity in the governance and management arrangements for these clinics. This could lead to poor patient experience and outcomes.	**9**	**15**	**4**	**Risk score remains the same** ↔	22/12/23	26/01/23	Joint Committee	Director of Planning & Performance
		Provider/s: St Helens and Knowsley NHS Trust & BCUHB	**C3 x L3**	**C3 x L5**	**C2 x L2**					
47 IF14 **Intestinal Failure**	Impact on the safety of patients, staff or public (physical/psychological harm)	**CVUHB delivery of IF service** ***There is a risk*** that due to issues of provider sustainability and delivery, that Cardiff and Vale University Health Board will no longer be able to provide Intestinal Failure services to the welsh population and as a consequence resulting in no service available in Wales	**20**	**15**	**6**	**Risk score remains the same** ↔	27/12/23 Cancelled	24/01/24	Joint Committee	Director of Planning & Performance
		Provider: University Hospital of Wales	**C5 x L4**	**C5 x L3**	**C3 x L3**					
48 P/21/20 **Women and Children**	Impact on the safety of patients, staff or public (physical/psychological harm)	**Wales Fertility Institute** ***There is a risk*** the Wales Fertility Institute (WFI) in Neath & Port Talbot Hospital are not providing a safe and effective service ***due to*** 7 major concerns identified during a relicensing inspection by HFEA in January 2023. ***There is a consequence*** that families who have treatment at this centre are not receiving the quality of care expected from the service and in turn impacting outcomes.	**16**	**25**	**4**	**Risk score remains the same** ↔	20/12/23	17/01/24	Joint Committee	Director of Planning & Performance
		Provider: SBUHB	**C4 x L4**	**C5 x L5**	**C2 x L2**					
50 **NCC060** **Neurosciences**	Impact on the safety of patients, staff or public (physical/psychological harm)	**Deep Brain Stimulation and delays in communication with gatekeeper/referring clinician** There is a risk that patients with Parkinson's disease, tremor and dystonia who have undergone Deep Brain Stimulation at North Bristol NHS Trust do not receive the correct ongoing treatment including medication due to significant delays in communication with the gatekeeper and referring clinicians.	**16**	**16**	**4**	**Risk score remains the same** ↔	12/12/23	09/01/24	Joint Committee	Director of Planning & Performance
		Provider: North Bristol NHS Trust	**C4 x L4**	**C4 x L4**	**C2 x L2**					
51 **NCC061** **Neurosciences**	Impact on the safety of patients, staff or public (physical/psychological harm)	**Deep Brain Stimulation – lack of awareness of eligibility criteria re unmet need** There is a risk that patients with Parkinson's disease, tremor and dystonia who could benefit from Deep Brain Stimulation aren't being referred for assessment and treatment due to a lack of awareness of	**16**	**16**	**4**	**Risk score remains the same** ↔	12/12/23	09/01/24	Joint Committee	Director of Planning & Performance

Risk Ref	Domain	Summary of Risk	Initial Score	Current Consecutive Monthly Score	Target Score	Trend since previous month	Last Review Date	Next Review Date	Scrutiny Committee	Lead Director
		eligibility criteria and potential to benefit amongst referring clinicians.								
		Provider: North Bristol NHS Trust	**C4 x L4**	**C4 x L4**	**C2 x L2**					
52 WKN12 Welsh Kidney Network	Impact on the safety of patients, staff or public (physical/psychological harm)	**Renal Dialysis capacity at BCU: There is a risk** that due to the current physical environment of the unit at YGC that additional dialysis sessions will not be able to be accommodated. Mold satellite unit was commissioned to act as the contingency for growth for Wrexham for the next 10 years as well as being able to accept patients from the east of the YGC catchment. BCU has already has to utilise additional capacity at Mold (May/June 23). The financial model at BCUHB creates issues with utilising resources across BCUHB. **As a consequence** patients may not be able to dialyse in the unit closest to home.	**25**	**16**	**2**	**Risk score remains the same** ↔	December 2023	January 2024	Joint Committee	Programme Director & Performance
		Provider: BCUHB	**C4 x L4**	**C4 x L4**	**C3 x L2**					
53 NCC062 Neurosciences	Impact on the safety of patients, staff or public (physical/psychological harm)	**CVUHB Neurosciences Staffing issues/level** There is a risk that patients requiring admission to the Inpatient Neuro-rehabilitation Unit (C&VUHB) are unable to access specialist rehabilitation due to considerable staffing pressures as the service has a number of current vacancies which the service are unable to recruit to the posts. The gap in the number of posts that has been commissioned is not meeting the national standards.	**16**	**16**	**2**	**Risk score remains the same** ↔	12/12/23	09/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: CVUHB	**C4 x L4**	**C4 x L4**	**C2 x L2**					
54 MH/23/16 Mental Health & Vulnerable Groups	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**NWAS** There is a risk that tier 4 providers for CAMHS cannot meet the service specification due to environmental and workforce issues, with a consequence that children could abscond/come to harm.	**20**	**20**	**8**	**Risk score remains the same** ↔	December 2023 - Cancelled	December 2023 - Cancelled	Joint Committee	Director of Mental Health
		Provider/s: BCUHB	**C4 x L5**	**C4 x L5**	**C4 x L2**					
55 P/21/22 Women & Children	Impact on the safety of Patient / Staff /Public Safety (Physical/Psychological harm) Population health	**CVUHB NICU – workforce** There is a risk that neonates who require tertiary regional neonatal support in South Wales may be inappropriately cared for, due to the impact of the available workforce within UHW, to support the current intensive care demand. There is a consequence that a neonate may be cared for in an inappropriate care setting, where the necessary skills and/or equipment are not available.	**16**	**16**	**4**	**Risk score remains the same** ↔	20/12/23	17/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: CVUHB	**C4 x L4**	**C4 x L4**	**C2 x L2**					
56 P/21/23 Women & Children	Impact on the safety of Patient / Staff /Public Safety (Physical/Psychological harm) Population health	**CVUHB NICU– infection control** There is a risk that neonates within the Neonatal Intensive Care Unit environment within UHW, are at greater risk of exposure to IP&C issues, whilst safer practice monitoring is being embedded. This is following a recent MRSA outbreak and identification of other organisms within the clinical area. There is a consequence of increased neonatal morbidity, if processes to address these issues are not effectively implemented.	**16**	**16**	**4**	**Risk score remains the same** ↔	20/12/23	17/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: CVUHB	**C4 x L4**	**C4 x L4**	**C2 x L2**					
57 NCC049 Neurosciences	Impact on the safety of Patient / Staff /Public Safety (Physical/Psychological harm)	**Delays in surgery due to insufficient theatre beds** **There is a risk** that patients in south Wales will have their surgery delayed **due to** insufficient theatre and inpatient bed capacity to deliver the required commissioned activity that meet the needs of the population **with a consequence** of deteriorating condition and disease progression. Theatre and bed capacity was reinstated from	**16**	**16**	**4**	**Risk score remains the same** ↔	12/12/23	09/01/24	Joint Committee	Director of Planning & Performance

Risk Ref	Domain	Summary of Risk	Initial Score	Current Consecutive Monthly Score	Target Score	Trend since previous month	Last Review Date	Next Review Date	Scrutiny Committee	Lead Director
	Population health	Sept 2022 close to pre-COVID levels, the service will move towards having a footprint pre-COVID levels.								
		Provider/s: CVUHB	**C4 x L4**	**C4 x L4**	**C4 x L1**					
58 PT/13 Planning	Impact on the safety of Patient / Staff /Public Safety (Physical/Psychological harm) Population health	**Goal methods and outcomes pressures** **There is a risk** not all goal methods and outcomes will be achieved from the 2023/24 plan **due to** the financial pressures and request of savings **as a consequence** there is uncertainty on how these will be taken forward.	**15**	**15**	**4**	**Risk score remains the same** ↔	December 2023	January 2024	Joint Committee	Director of Planning & Performance
		Provider/s: All Health Boards	**C5 x L3**	**C5 x L3**	**C2 x L2**					
59 IF15 Intestinal Failure	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Calea Contract Renewal** **There is a risk** that HPN supply to patients could be impacted **due to** the current homecare provider contracts ending March 24 with no current arrangement to extend **which as a result** could leave patients without a service	**15**	**15**	**12**	**Risk score remains the same** ↔	27/12/23 Cancelled	24/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: Calea and Baxter	**C5 x L4**	**C5 x L3**	**C4 x L3**					
60 P/21/24 Women & Children	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	***There is a risk*** all licensed HFEA activity at WFI will urgently and temporarily need to cease due to the fact that the Person Responsible (PR) has stood down from the role and there has been a failure to appoint a new PR to fulfil their duties. ***There is a consequence*** that patients in active treatment will need to have their treatment plan temporarily paused and the centre would not be able to accept new patients on a temporary basis.	**20**	**20**	**4**	**Risk score remains the same** ↔	20/12/23	17/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: SBUHB	**C5 x L4**	**C5 x L4**	**C2 x L2**					
61 CT050 Cardiac	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Obesity surgery waiting times** There is a risk that patients from Betsi Cadwaladar University Health Board and North Powys awaiting obesity surgery produces in Salford Royal Hospital will have their treatment delayed due to long waiting times, which the hospital have advised will be unlikely to reduce significantly in the short to medium-term.	**16**	**16**	**4**	**NEW RISK**	01/12/23	12/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: Salford Royal Hospital, Northern Care Alliance NHS Trust	**C4 x L4**	**C4 x L4**	**C2 x L1**					
62 CT051 Cardiac	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**TARN delays** As a result of the TARN database being taken offline in June 2023, and owing to delays in the instituting of both interim arrangements and a sustainable long-term solution, the South Wales Major Trauma Network will be subject to risks relating to: • A large and growing TARN submission backlog • The unknown status of historical TARN data • Delays to the availability of reporting – including quarterly dashboards, clinical reports and TARN analytics – impeding the ability of the Network to monitor the implementation of the PBC and benchmark performance	**16**	**16**	**4**	**NEW RISK**	01/12/23	12/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: South Wales Trauma Network, Swansea Bay University Health Board (data collected from all South Wales Health Boards)	**C4 x L4**	**C4 x L4**	**C4 x L1**					

Risk Ref	Domain	Summary of Risk	Initial Score	Current Consecutive Monthly Score	Target Score	Trend since previous month	Last Review Date	Next Review Date	Scrutiny Committee	Lead Director
63 NCC063 Neurosciences	Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Neurosurgery Sustainability** There is a risk that the delay in progressing the Neurosurgery Sustainability and Standards CIAG scheme for the ICP 22/23 and not investing in key high risk posts (Intra operative Monitoring (IOM), CNS Skull Base and Neuromodulation) due to the financial pressures of NHS Wales would as a consequence result in the loss of the sub speciality services of Neurosurgery (Skull Base, Facial Pain, Complex Spine and elements of tumour surgery). The IOM post is recommended by NICE guidelines and the lack of ability to recruit to this post substantively, would mean that these subspecialty surgeries would have to cease in Wales with patients then being required to receive treatment in North Bristol Trust (NBT). Additionally there is no commissioned CNS posts for skull base and Neuromodulation services, the service is managed by single handed consultants resulting in consultant time being used inappropriately to deliver nurse led services – this does not meet national standards and patients would be denied timely access to neurosurgical advice and treatment.	25	25	4	**NEW RISK**	12/12/23	09/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: BCUHB)	C5 x L5	C5 x L5	C2 x L2					

Reduced Risk

44 P/21/19 **Women and Children**	Impact on the safety of patients, staff or public (physical/psychological harm)	**Paediatric cardiac surgery** ***There is a risk*** that paediatric cardiac surgery patients referred to Bristol Children's Hospital, will have longer waits than is clinically appropriate ***due to*** lack of availability of a PIC bed within the Bristol Hospital. ***There is a consequence*** that the condition of the patient could deteriorate whilst waiting.	16	12	4	**Risk score lowered from 16 to 12** ⬇	20/12/23	17/01/24	Joint Committee	Director of Planning & Performance
		Provider/s: University Hospital Bristol	C4 x L4	C4 x L3	C2 x L2					

Risk Ref: 3 Plastic Surgery Delays (CB03)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)

Director Lead: Director of Planning & Performance
Assuring Committee: Joint Committee Reviewed Assurance

Risk: There is a risk of poor patient experience and poor outcome for plastic surgery patients in south Wales. This is caused by failure to achieve the maximum waiting times target with some patients waiting >104 weeks.
This leads to a commissioned service that does not meet waiting times standards and therefore does not provide the required quality of service.

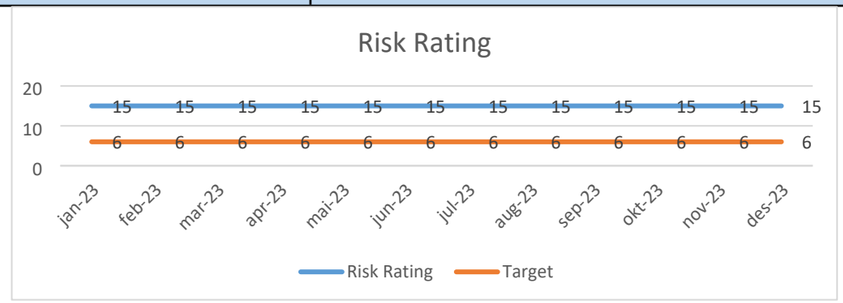
Date Added to Register: 26/02/21 (first identified 17/03/14)

Provider/s: SBUHB

Date Last Reviewed by:
Joint Committee –18 July 2023
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	3x5	**15**
Current	**3x5**	**15**
Target	2x3	**6**



Groups discussed risk during period

Commissioning Team 30/01/23
Commissioning Team 02/03/23
Commissioning Team 27/03/23
Commissioning Team 17/04/23
Commissioning Team 18/05/23
Commissioning Team 30/06/23
Commissioning Team 28/07/23
Commissioning Team 29/09/23
Commissioning Team 23/10/23
Commissioning Team 01/12/23
Commissioning Team 22/12/23

What controls have we put in place for the risk:

- Recovery plan requested from SBUHB
- Continue to monitor progress against the recovery plan
- Request waiting list data
- This risk is included within the C&B register for monitoring purposes, it is included within the overarching risk for waiting times (Risk 33(CS/10 CD03) Welsh Government Priority Delivery Measures)
- Work to change the commissioning model has progressed and approved by Joint Committee
- The outcome from these workshops i.e. a recommendation that WHSSC establish a project to re-align commissioning responsibilities between WHSSC and Health Boards was approved by Joint Committee in January 2023.
- A Project initiation Document (PID) is due to go to MG in April 2023 outlining timescales for this project.
- Monthly escalation level 2 meetings are in place. At the meeting on 28th July, a delivery plan was not provided as core theatre sessions were still being balanced internally with other specialties in the prioritisation of capacity. However an action plan for additional activity was presented which included 3 sessions of theatre time per week for hand surgery in the day surgery unit at Singleton starting in Sept 2023. It was subsequently confirmed in a letter to Sian Lewis that SBUHB will not be able to clear the 104 week waiting list within the WG target.
- Data received from the service which suggests a significant improvement in performance. To be cross-validated with DHCW data. Current delivery plan will still mean there will be >200 breaches of those waiting >104 weeks.

What actions should we take:

Action	Lead	Date
To monitor progress against the plastic surgery recovery plan via monthly commissioner assurance meetings with SBUHB**.** Next meeting arranged for Dec 22	LA-Senior Planner	Monthly
To report on progress against the recovery plan at the Cancer & Blood commissioning team meeting and to CDGB as appropriate.	LA – Senior Planner	Monthly
Plastic surgery service to complete the assurance template developed to evidence that the service has maximised performance given current resource constraints: treat in turn rate, outsource/insource, list validation.	LA – Senior Planner	Completed
To recommend to CDG that consideration should be given to placing the service into escalation further to Joint Committee's agreement to return to normal performance management arrangements (subject to outcome of meeting with SBUHB on recovery trajectories to be held on 30.11.22). Escalation Level 1 agreed by CDGB in December 2022 and weekly submission of activity and waiting list data is required.	LA – Senior Planner	Completed
To request further detail on the recently received delivery plan and to review the recently received quality report. To re-assess the escalation level in June.	LA – Senior Planner VDJ – Quality Lead	Complete
Escalation increased to level 2 (letter to SBU on 7th July). SBU action plan and revised delivery plan requested. Level 2 escalation meeting scheduled 28th July.	LA – Senior Planner	Complete. Next escalation meeting: January

Additional comments:
Aug 23 – At the meeting on 28th July, a delivery plan was not provided as core theatre sessions were still being balanced internally with other specialties in the prioritisation of capacity. However an action plan for additional activity was presented which included 3 sessions of theatre time per week for hand surgery in the day surgery unit at Singleton starting in Sept. It was subsequently confirmed in a letter to Sian Lewis that SBUHB will not be able to clear the 104 week waiting list within the WG target.
Oct 23: Cross validation completed. WHSSC's head of information satisfied with reconciliation of DHCW and SBUHB data. Escalation meeting on 23.10.23: SBU is currently achieving the trajectory set out in the delivery plan for treating patients waiting > 104 wks. The action plan for additional activity is being achieved. WHSSC-SBUHB SLA meeting on 24.20.23: SBU confirmed there will be breaches of 104 weeks at March 2024 as forecast in the delivery plan and that plastics is in the 1% tolerance agreed by SBU with Welsh Government.
Nov 23: The C&B commissioning team noted that the number of long waiting patients is reducing. The service is performing well with overspend forecast. The service had been invited to propose further options for the very longest waiters since circa 100 are forecast to be waiting in excess of 156 wks by March 2024. However, no further local options have been identified.
Dec 23: The C&B commissioning team noted that the service is over-performing compared to contract.

Risk Ref: 6 - Paediatric patients waiting for surgery (P/21/10)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)

Director Lead: Director of Planning & Performance
Assuring Committee: Joint Committee Reviewed Assurance

Risk: There is a risk that paediatric patients waiting for surgery in the Children's Hospital of Wales are waiting in excess of 36 weeks due to COVID-19. The consequence is the condition of the patient could worsen and that the current infrastructure is insufficient to meet the backlog.

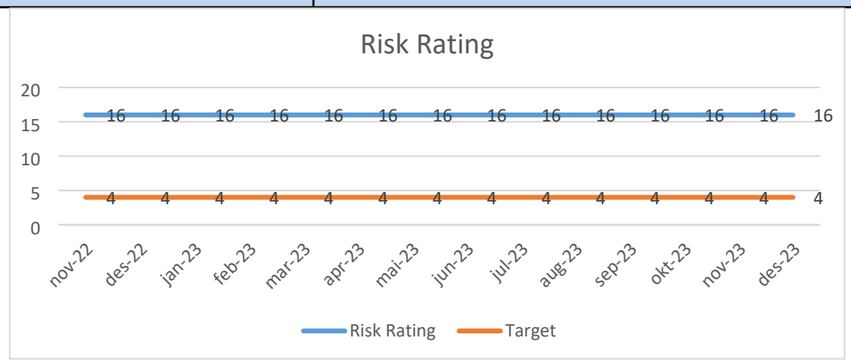
Date Added to Register:24/02/21

Provider/s: CVUHB

Date last reviewed by:
Joint Committee –18 July 2023
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	**4x4**	**16**
Target	2x2	**4**



Groups discussed risk during period

Commissioning Team - 24/01/23
Commissioning Team - 21/02/23
Commissioning Team - 21/03/23
Commissioning Team - 20/04/23
Commissioning Team - 16/05/23
Commissioning Team – 20/06/23
Commissioning Team – 18/07/23
Commissioning Team – 15/08/23
Commissioning Team – 19/09/23
Commissioning Team - 18/10/23
Commissioning Team - 15/11/23
Commissioning Team – 20/12/23

What controls have we put in place for the risk:

- Ongoing monitoring at Quarterly Commissioner Assurance Meeting with provider
- This risk is included within the W&C register for monitoring purposes, it is included within the overarching risk for waiting times (Risk 33(CS/10 CD03) Welsh Government Priority Delivery Measures).
- Plan in place for a number of children to be outsourced to NHS England and the Private Sector.
- Performance Management arrangements to be re-instigated which will allow WHSSC to identify and monitor where the issues are that need addressing.
- Monthly escalation meetings have been established – first meeting scheduled 26/04.
- Action plan received against escalation objectives
- Continue with outsourcing to NHS England and the Private Sector.

What actions should we take:

Action	Lead	Date
• Request information from Health Board in advance of Quarterly Commissioner Assurance Meeting to seek update on current capacity including: • Staffing establishment • Bed and theatre capacity • Assurance on clinical management of patients on WL • Recovery trajectory	W&C Planner	Quarterly
• Requested information on long waiting patients from provider to support potential outsourcing arrangements.	W&C Planner	Complete
• Meetings being scheduled with NHS England providers to discuss outsourcing capacity	W&C Planner	Complete
• Requested plan from C&V to manage long waiting patients, with clear trajectories and timeframes.	W&C Planner	Complete
• Requested revised recovery plan further to Joint Committee	W&C Planner	Complete
• Discussing with local Health Boards scope for mutual aid.	W&C Planner	Complete
• Place service in escalation Level 3	W&C Planner	Complete
• Performance Management arrangements to be re-instigated	Director of Planning	Monthly
• Requested revised trajectories that reach contract baseline as a minimum	Director of Planning	Complete
• Performance reporting to JC & MG via performance report	Director of Planning	Monthly
• Executive to Executive meeting scheduled with C&VUHB	Director of Planning	Complete
• WHSSC JC Workshop - Paediatrics	Director of Planning	Complete
• Triple Escalation meeting to discuss detail and progress against action plan	W&C planner	17/01/24

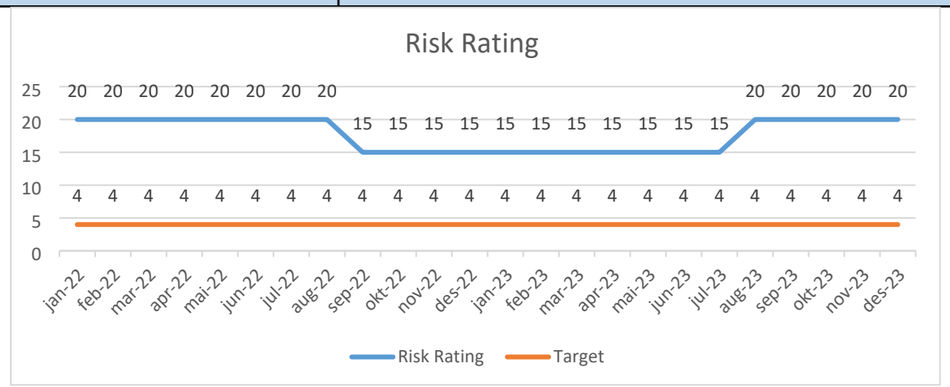
Additional comments:
July 2022 – W&C Commissioning team discussed and reviewed the risk. Quarterly Assurance meeting took place provider confirmed 109 patients waiting between 52 and 104 weeks and 25 patients waiting over 105 weeks. Therefore, risk cannot be reduced.
Nov 23 - W&C Commissioning team reviewed the risk which remains unchanged
Dec 23 - W&C Commissioning team reviewed the risk which remains unchanged

Risk Ref: 26 - Neuropsychiatry patients waiting times (NCC046) **Risk Domain:** Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Director Lead:** Director of Mental Health **Assuring Committee:** Joint Committee
Risk: There is a risk that neuropsychiatry patients will not be able to be treated in a timely manner with the appropriate therapy support ***due to*** staffing issues. ***The consequence*** *patients will have* long waiting times to access the service and the lack of availability of step down facilities to support the acute centre will also result in delays.	**Date Added to Register: 12/02/2020** **Moved to MH& VG register July 2021** **Provider/s**: CVUHB

Date last reviewed by:
Joint Committee –18 July 2023
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x5	**20**
Current	**4x5**	**20**
Target	4x1	**4**



Groups discussed risk during period

Commissioning Team 19/12/22
Commissioning Team 23/01/23
Commissioning Team 27/02/23 – Cancelled
Commissioning Team 27/03/23
Commissioning Team 24/04/23
Commissioning Team 22/05/23
Commissioning Team 26/06/23
Commissioning Team 27/07/23
Commissioning Team 29/08/23
Commissioning Team 25/09/23
Commissioning Team 23/10/2023– Cancelled – Not quorate
Commissioning Team 27/11/23
Commissioning Team December 23 - Cancelled

What controls have we put in place for the risk:

- Business case received
- Developed ICP scheme
- Service transferred to the Mental Health portfolio
- Planned six monthly review meetings with the service to ensure staff have the specific training, skill and expertise to meet the needs of the existing service and provide an equitable service across Wales
- Funding release was submitted to the March 2023 MG meeting for Phase 2A of the All-Wales Neuropsychiatry Scheme. The funding release was not approved and it is going back to the April 2023 MG meeting.
- Funding paused

What actions should we take:

Action	Lead	Date
NCCCT to monitor the recovery plan through the six monthly Risk, Assurance and Recovery meeting.	Planning Manager	Six monthly
The scheme was scored 2nd highest risk and has been included in the WHSSC ICP funding 21/22. Business Case received from the service in May 2021. Planning Manager to develop ICP scheme in collaboration with the Service.	Planning Manager	Completed
Funding releases paper being prepared for submission to July CDGB and monitoring group	Planning Manager	Completed
Funding release paper submitted to July Management group.	Planning Manager	Completed
Phase 2b to be considered within the mental health strategy	Senior Planning Manager	Completed
Neuropsychiatry data to be analysed to inform future mitigation actions	Senior Planning Manager	Completed

Additional comments:
CIAG approved phase 2a of Neuropsychiatry scheme phase 2b to be considered within mental health strategy.
June 22 – Second consultant appointed within service, therefore, risk to be discussed at July commissioning meeting with a view to lowering the risk. Phase 2a to be implemented during this financial year and CIAG bid for phase 2b should provide a basis to close this risk.
Sept 22 – Risk Score Lowered to 15 at commissioning team meeting 28/09/22. Further monitoring to continue following the implementation of further service development during 2022/23 and 2023/24.
March 23 – Risk score remains the same
April 23 – Risks reviewed agreed it is appropriate for risk score to remain the same and to be reviewed May 22nd
August 23 – Risk score increased due to delays of funding release for Neuro to be revised following discussions around risk assessment verses financial plans
September 23 - Risk remains the same – Risk discussed at Commissioning Team 25/9/23 and agreed this risk remains high due to the impact of the Neuropsychiatry CIAG scheme being paused, and the impact on the service as a result. Lack of funding and investment in the service is impacting particularly on staffing with staff turnover and vacancies increasing with the possibility that the current service may have to close due to these staffing issues.
October 23 - Risk remains the same meeting cancelled as not quorate
November 23 – Risk score remains the same
December 23 – Meeting cancelled, risk remains the same.

Risk Ref: 28 Workforce and Capacity (CS3 / CD01)
Risk Domain: Workforce and Capacity

Director Lead: Committee Secretary
Assuring Committee: CDGB

Risk: There is a risk that WHSSC is unable to keep up with the increasing work demand. Due to additional work related services currently commissioned through HB's or services which are new to Wales. As a consequence this could have an impact on teams to absorb the additional work.

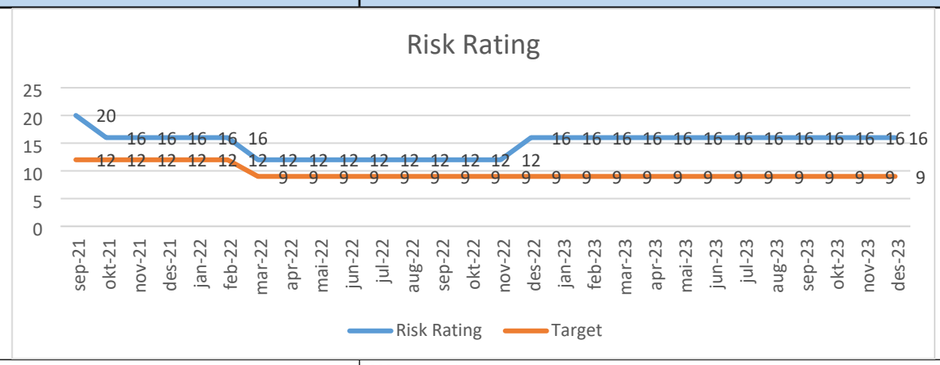
Date Added to Register: 16.09.21

Provider/s: N/A

Date Last Reviewed by:
Joint Committee –18 July 2023
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	5X4	**20**
Current	**4X4**	**16**
Target	3X3	**9**



Groups discussed risk during period

CDGB
Corporate Services Team Meeting
Joint Committee
Integrated Governance Committee
RSG

What controls have we put in place for the risk:

- In the long term a workforce strategy will be considered to assist with succession planning and the long term planning risk concerning workforce capacity.
- An executive OD session held in November 2022 focussed on current and future workforce and organisational development requirements. A short term workforce plan was developed to assist with the immediate issue of resourcing the increasing workforce demand. This is currently being monitored by the CDGB and is being discussed at OD sessions.
- A number of key strategic pieces of work and a general increase in the number of services has resulted in another significant increase in workloads across the organisation. The number of posts being recruited to has increased significantly over the last few months.
- There is a lack of depth in workforce resource and cross cover as teams are small and this poses a risk to staff as workloads are increasing. In order to mitigate this in the short terms, workloads should be monitored and work should be prioritised.
- Some vacancies have arisen within the Finance department and there is a need to review the finance structure to ensure sufficient resource.
- There continues to be workforce pressures within the WKN due to some staff absences. Work has increased due to Value in Healthcare Programme.
- WHSSC has been asked to commission new services including Sacral Nerve Stimulation for faecal incontinence in South Wales and Neurophysiology. The workload will be absorbed into existing WHSSC team capacity. A review of the longer terms workload impact will inform the 2024-25 ICP.
- A review of National Commissioning has now reported and this may have an impact on staffing and resourcing across the organisation going forward. The review recommendations are in the implementation stage.
- The recruitment freeze is delaying the recruitment into some posts and this will have an impact on capacity and workloads. E.g. Network Manager resigned, job advertised then pulled by CTMUHB as a consequence of the current embargo on administrative posts.
- The Corporate services team has reduced staffing due to a number of factors. In addition there is additional work across the organisation due to the implementation of the new NHS Wales Joint Commissioning Committee (JCC).

What actions should we take:

Action	Lead	Date
JC approved a request to increase the Direct Running Costs (DRC) budget 2022-2023 on the 7 September 2021 to support the recruitment of the key posts to increase workforce capacity	Committee Secretary	7 September 2021
Workforce capacity review has been undertaken by CDGB and DRC shortfall to be utilised to recruit at risk for critical posts. **COMPLETED**	Committee Secretary	Oct 2021
Corporate services team are working with CTMUHB to identify short terms admin pool of resource to support the administrative requirements of WHSSC, which are putting pressure on the teams. **COMPLETED and since then WHSSC has recruited via the bank and agency to assist with short term recruitment issues.**	Committee Secretary	Oct 2021
An uplift to the DRC was approved by JC to allow for an additional Corporate resource. This post has now been filled substantively. **COMPLETED.**	Committee Secretary	May 2022
Workforce plan developed following the Executive OD session to be monitored to ensure that the short-term impacts concerning staffing issues can be addressed. The plan will be monitored and updated to consider a mid to long-term workforce strategy for 2023-2024. This will include succession planning and capacity issues on a more strategic level.	Committee Secretary	May 2023
Workloads to be monitored and work to be prioritised by Directors for their teams including planning meetings to discuss work priorities for departments affected by staff absences and vacant posts.	ALL	On-going
Review the longer terms workload impacts of new services (i.e. HPB surgery services) will form part of the ICP for 2024-25.	Director of Planning & Performance	Jan 2024
SL/JE/KE to discuss with CTMUHB the process for WHSSC for recruitment during the recruitment freeze.	Managing Director & Committee Secretary	Completed and process established.
Review workloads within Corporate Team to ensure that urgent work is prioritised and non-urgent work is deferred.	Committee Secretary	Ongoing at least until beginning of 2024

Additional comments:

Risk Ref: 29 – WHSSC IPFR ToR & Governance (CS8)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm) Population Health

Director Lead: Director of Nursing/Committee Secretary
Assuring Committee: Joint Committee

Risk - There is a risk that WHSSC will be unable to meet the TOR for the All Wales IPFR panel due to the inability to achieve quoracy in the membership and consequently this may lead to delayed decision-making. In addition, there is also a risk that the current IPFR governance arrangements are not robust and as a consequence this may also lead to legal challenges in the form of judicial reviews.

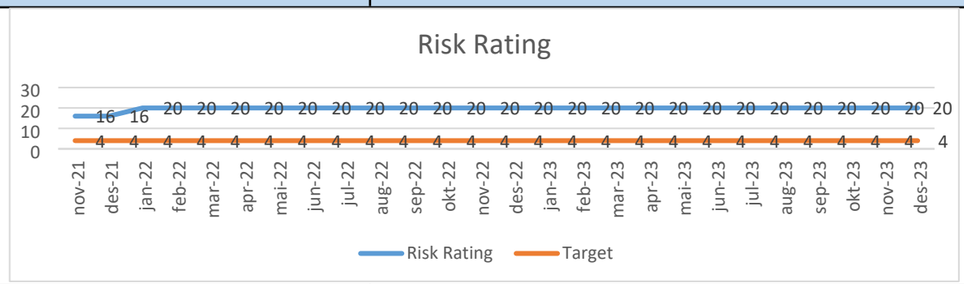
Date Added to Register:20/10/21

Provider/s: N/A

Date last reviewed by:
Joint Committee –18 July 2023
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	**4x5**	**20**
Target	2x2	**4**



Groups discussed risk during period

RSG
CDGB
Quality Patient Safety
Integrated Governance Committee

What controls have we put in place for the risk:

- The NHS Wales Board Secretaries Group have been informed of the risk concerning the IPFR panel, and a private briefing session was arranged for them on IPFR governance for 10 June 2022.
- A new HB IM Interim Chair has been appointed from 1 August 2022 to ensure business continuity for a 6 month period to ensure business continuity. The Joint Committee approved that this interim could be extended until 31 March 2023, at its meeting on 8 November 2023. This was subsequently extended again to 31 September 2023.
- The formal engagement process to review the WHSSC IPFR panel ToR and the specific and limited review of the all Wales IPFR policy, was launched on 10 November 2022 for a 6 week period following the Joint Committee supporting the proposed engagement process at its meeting on the 8 November 2022. The engagement exercise closed on the 22 December 2022.
- An IPFR stakeholder engagement event to review the WHSSC IPFR) panel ToR and a specific, limited review of the all Wales IPFR policy was held on the 2 December 2022, supported by a briefing from a Kings Counsel (KC) for the NHS Wales Medical Directors Peer Group and a stakeholder engagement session on the 2 December 2022.
- The updated WHSSC ToR were approved by the Joint Committee on 14 March 2023. In addition, the results of the engagement exercise for the All Wales Policy review were presented. Following approval of the ToR in March 2023 WHSSC are currently working on an implementation plan as the new ToR will involve some changes to the current membership and to ensure that HBs have sufficient time to review their WHSSC membership.
- The updated All Wales IPFR Policy was not discussed at the July 2023 JC meeting as issues were raised immediately before the meeting regarding the approval process. Since then it has been agreed that a Task and Finish Group will be formed to finalise the work on the IPFR policy.
- To address the concerns raised a Task & Finish group, consisting of the ABUHB Board Secretary, the All Wales IPFR Lead and the WHSSC Committee Secretary was established. Amendments to the ToR were agreed regarding the definition of quoracy and the requirement for the Chair to review membership, which have addressed the concerns. The group also considered how IPFR functions would feature within the new Standing Orders for the new single Joint Commissioning Committee, and further work is now being taken through the governance work-stream which supports the implementation of the national commissioning review.

What actions should we take:

Action	Lead	Date
An engagement process on the WHSSC IPFR panel ToR launched on 10 November 2022 for a 6 week period and included HBs, the AWTTC and IPFR QAG. The engagement exercise closed on the 22 December 203 and an update report will be taken to the JC in March 2023.	Committee Secretary	Complete
The updated WHSSC ToR were presented to the Joint Committee 14 March 2023 and were approved. In addition, the results of the engagement exercise for the All Wales Policy were presented.	Committee Secretary	Complete
The Committee Secretary to keep the NHS Wales Board Secretaries peer group and Welsh Government informed of progress on developments.	Committee Secretary	On-going
The updated All Wales IPFR Policy is scheduled to be presented to the Joint Committee in July 2023 for approval, prior to submission to the seven HBs for approval.	Committee Secretary	July 2023
Full implementation of the new ToR and amended policy is planned for Autumn 2023 subject to JC approval. This was not discussed at the July 2023 JC meeting but the recruitment of the new Chair was agreed in an extraordinary JC meeting on 1 August 2023.	Committee Secretary	By end of 2023
A Chair's Action was taken on 25 October 2023 to appoint Mrs Elizabeth Kathleen Abderrahim, as Chair to the WHSSC Individual Patient Funding Request (IPFR) Panel from 1 November 2023 for a period of up to 3 years. The JC ratified the decision on 21 November 2023.	Committee Secretary	25 October 2023
The Joint Committee supported the proposed changes to the All Wales IPFR Policy on 21 November prior to a report being submitted to each Health Board (HB) Board meeting for final approval in January 2024. Once the revised policy has been approved by the Health Boards (HBs) it will be shared with Welsh Government prior to adoption. The Joint Committee also approved the proposed changes to the WHSSC IPFR Panel ToR.	Committee Secretary	Feb 2024
A recruitment process to appoint new lay members will commence in December 2023 with a view to them taking up appointment in February 2024 to coincide with the application of the updated IPFR policy (once approved by the 7 x HBs)	Committee Secretary	Feb 2024

Additional comments: The IPFR process gained political attention during the Senedd's Plenary session on the 23 March 2022 and Members of the Senedd (MS) asked questions concerning the IPFR process.

Risk Ref: 34 - Lack of Paediatric Intensive Care Beds (P/21/02)
Risk Domain: Workforce

Director Lead: Director of Planning & Performance
Assuring Committee: Joint Committee

Risk: There is a risk that a paediatric intensive care bed, in the Children's Hospital for Wales, will not be available when required due to constraints within the service. There is a consequence that paediatric patients requiring intensive care will be cared for in, inappropriate areas where the necessary skills or equipment are not available or the patient being transferred out of Wales.

Date Added to Register:24/02/21

Provider/s: C&VUHB

Date last reviewed by:
Joint Committee –18 July 2023
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	3x4	12
Current	4x5	20
Target	2x2	4

Groups discussed risk during period

Commissioning Team – 19/12/22
Commissioning Team - 24/01/23
Commissioning Team - 21/02/23
Commissioning Team - 21/03/23
Commissioning Team - 20/04/23
Commissioning Team - 16/05/23
Commissioning Team – 20/06/23
Commissioning Team – 18/07/23
Commissioning Team – 15/08/23
Commissioning Team – 19/09/23
Commissioning Team - 18/10/23
Commissioning Team - 15/11/23
Commissioning Team – 20/12/23

What controls have we put in place for the risk:

- Investment through WHSSC 2019/20 ICP to increase bed capacity to meet demand
- Ongoing monitoring at Quarterly Commissioner Assurance Meeting with provider
- Completed winter surge plan for 2021/22 which sets out clear escalation management across the South West of England region
- Received Health Board surge plan for 2022/ 23
- Reviewed information on adverse incidents have occurred as a consequence of bed availability
- Discussed Collaborative working between Adult Critical Care and Paediatric Critical Care
- Health board escalated to level 2 in line with WHSSC escalation framework
- Health board escalated to level 3 in line with WHSSC escalation framework
- Offer of increase investment sent to the provider to provide financial support over the winter period

What actions should we take:

Action	Lead	Date

• Request information from Health Board in advance of Quarterly Commissioner Assurance Meeting to seek update on current capacity including:
  • Refusal rates against SLA
  • Staffing establishment
  • Implementation of investment
  • Commissioned bed availability
	W&C Planner	Quarterly

• Review risk score following analysis of data and assurances presented at Quarterly • Commissioner Assurance Meeting.	W&C	Quarterly
• Requested amended surge plan following collaborative working discussion with Adult Critical Care colleagues.	W&C planner	Complete
• Requested action plan against the escalation objectives	W&C planner	Complete
• Development of plan to formally commission High Dependency to stabilise the overall unit	W&C planner	31/03/24
• Executive to Executive meeting scheduled with C&VUHB	Director of Planning	Complete
• WHSSC JC Workshop - Paediatrics	Director of Planning	Complete
• Triple Escalation meeting to discuss detail and progress against action plan	W&C planner	17/01/24

Additional comments:
June 22 – Quarterly Assurance meeting has not taken place since last update (May 22)
July 2022 – W&C Commissioning team discussed and reviewed the risk. Quarterly Assurance meeting took place 18th July 2022 we were notified a number of refusals in quarter 1 as a result of staff shortages
Dec 22 – As service has been in a period of surge throughout December the risk score has increased.
Sept 23 - W&C commissioning Team reviewed the risk which remains unchanged. Service escalation increased to Level 3 due to limited progress on the action plan objectives, the daily dashboard returns deviate from nursing standards and the high refusal rates when they are not at capacity due to work force issues.
Nov 23 - W&C Commissioning team reviewed the risk which remains unchanged
Dec 23 - W&C Commissioning team reviewed the risk which remains unchanged

Risk Ref: 38 – Neo neonatal cot availability in South Wales due to staffing shortages (P/21/16)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)
Population Health

Director Lead: Director of Planning & Performance
Assuring Committee: Joint Committee

Risk: There is a risk that there will not be a Neonatal cot available across the south Wales region **due to** significant neonatal nursing shortages. **There is a consequence** that babies will need to travel to NHS England to receive their care or be cared for in an inappropriate setting whilst waiting for an available cot.

Date Added to Register: 26/07/2022

Provider/s: ABUHB, CTMUHB, CVUHB, HDUHB, SBUHB

Date last reviewed by:
Joint Committee –18 July 2023
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	**4x4**	**16**
Target	2x2	**4**

Groups discussed risk during period

Commissioning Team - 24/01/23
Commissioning Team - 21/02/23
Commissioning Team - 21/03/23
Commissioning Team - 20/04/23
Commissioning Team - 16/05/23
Commissioning Team – 20/06/23
Commissioning Team – 18/07/23
Commissioning Team – 15/08/23
Commissioning Team – 19/09/23
Commissioning Team - 18/10/23
Commissioning Team - 15/11/23
Commissioning Team – 20/12/23

What controls have we put in place for the risk:

- WHSSC are attending (the scheduled) SITREP meeting(s), hosted by the Maternity and Neonatal Network where the neonatal unit and maternity position is discussed. The daily SITREP meetings continue to take place, these meetings still show significant fragility within the system, and despite the cot work progressing there will be a lead in time before this will help.
- Notified Welsh Government and (WHSSC/Health Board) Directors of Nursing of current risk.
- Continue to monitor at Quarterly Commissioner Assurance Meeting encouraging an open dialogue in the interim, as necessary, with all providers, to understand refusal rates and staffing numbers.
- New cot day tariff implemented, overall investment of over £5m for the South & West Wales
- Letter issued to chief nursing officer and national clinical director highlighting system concern

What actions should we take:

Action	Lead	Date
• Requested information from all provider Health Boards in advance of Quarterly Commissioner Assurance Meeting, to seek update on current position: • Refusal rates and reasons for declined admissions • Staffing establishment • Adverse incidents / near misses as a consequence of closing cots and / or working over capacity	Planning Manager	Quarterly
• The NICU visits have taken place and have been very productive and well received. Reference to these visits and the outcomes have been made in the August Quality Patient Safety report. The final NICU visit is scheduled for 05/10/22 and therefore, the action will be closed on this date.	Head of Quality WHSSC	Completed
• WHSSC to arrange a workforce workshop	Planning Manager	31/08/23
• Meetings with each provider to discuss implementation of cot re-configuration	Associate Medical Director	AB UHB - complete C&V UHB - complete CTM UHB - complete HD UHB - complete SB UHB - complete
• Follow up meeting to discuss progress and next steps	Associate Medical Director	AB UHB - complete C&V UHB - complete CTM UHB - complete HD UHB – complete SB UHB - complete
• Next steps of the new neonatal cot configuration - All Health Boards	Associate Medical Director	Complete
• Paper to CDGB to consider 'go live' date for new baselines	Planning Manager	29/01/24

Additional comments:
Aug 22 - This risk replaces closed risk P/21/15 as the staffing shortages encountered are variable depending on the shift in question and are across all units.
Oct 22 – nursing shortage remain and therefore no change to score.
Dec 23 - W&C Commissioning team reviewed the risk which remains unchanged

Risk Ref: 40 Limited outpatient dialysis capacity in Swansea (WKN 08)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)

Director Lead: Programme Director, WKN
Assuring Committee: WKN Board

Risk: There is a risk that the number of patients receiving outpatient haemodialysis in Morriston will exceed capacity. **As a consequence,** there is need for expansion of outpatient service provision to include demand from the Neath Port Talbot area and Bridgend localities.

Date Added to Register: 14/12/22

Provider/s SBUHB

Date Last Reviewed by:
Joint Committee –18 July 2023
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	3x4	12
Current	**4x4**	**16**
Target	2x1	2

Groups discussed risk during period

October 19th WKN/SB Regional meeting
Oct 25th WKN Monthly Team Meeting

What controls have we put in place for the risk:

- Twilight dialysis shifts are opened 6 days weekly, some overflow provided in the acute dialysis facility.
- Active home haemodialysis programme to ease the pressure until expansion of existing resource is established.
- Procurement process for retender of existing units and establishment of two new units commenced Jan 2021.
- The funding release was agreed by the JC in January 2023 but there are awaiting WG sign-off. Any delays in the process has a knock on effect to the operational date of the two new builds.
- Procurement supported by WG. Contract awarded
- Implementation programme commenced
- New units in place
- NB risk score will not reach target until new units are in place and therefore additional capacity is available
  Risk will need to be tolerated until then.
- WKN has provided funding for a Project Manager role in SBU to support the implementation of the project/programme
- Funding release to assist with new equipment, consumables as per the new contract
- WKN participate in the SB & Fresanius implementation meetings to ensure delivery to project plan

What actions should we take:

Action	Lead	Date
Completion of procurement process. Preferred provider identified. Approval from JC and SBUHB Board provided. Awaiting WG sign-off.	SBUHB SRO/WKN Manager	Complete Contract awarded
Support mobilisation of contract to ensure efficiency of implementation, noting that new units unlikely to be operational until September 2023.	SBUHB SRO/WKN Manager	Contract awarded Implementation Programme started 12 month programme September 2023
Increase opportunity for home dialysis.	Home Dialysis Clinical Lead/WKN Manager.	Value in Health Bid supported investment of an additional £130K in Swansea Bay region to support home dialysis and transplantation Programme on-going Evaluation in 12 months April 2024 December 2022
Provision to be made in the WHSSC ICP to reflect the additional costs associated with the procurement process.	WKN Manager/WKN Finance Manager/ WHHSC Director	complete
Implementation Programme for new dialysis units in place	WKN Deputy Manager	complete
New units in place	SBUHB Project Team/	September 2024

Additional comments:
March 23 – The WKN core team discussed the risk and agreed the score remains the same due to delays in sign-off which will have a knock on effect to the operational date of the two new builds.
May 23 - The WKN team discussed the risk and agreed the score remains the same
July 23 – Risk score remains the same
August 23 – WKN/Regional meeting postponed rescheduled for 08.09.23, meeting held and risk score discussed and remains the same
October onwards – WKN invited to SBUHB Implementation meetings
November - WKN/SB Regional meeting risk discussed and remains the same

Risk Ref: 46 North Wales Outreach Plastic Surgery Clinic Management Arrangements (CB06)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm) Population Health

Director Lead: Director of Planning & Performance
Assuring Committee: Joint Committee Reviewed Assurance

Risk: There is a risk that patients may come to harm due to a lack of clinical prioritisation and oversight of waiting lists for outreach plastic surgery clinics in YG and YGC. This is caused by lack of clarity in the governance and management arrangements for these clinics. This could lead to poor patient experience and outcomes

Date Added to Register: 09/09/22

Provider/s: St Helens and Knowsley NHS Trust & BCUHB

Date Last Reviewed by:
Joint Committee –18 July 2023
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	3x3	9
Current	**3x5**	**15**
Target	2x2	**4**

Groups discussed risk during period
Commissioning Team 30/01/23
Commissioning Team 02/03/23
Commissioning Team 27/03/23
Commissioning Team 17/04/23
Commissioning Team 18/05/23
Commissioning Team 30/06/23
Commissioning Team 28/07/23
Commissioning Team 29/09/23
Commissioning Team 23/10/23
Commissioning Team 01/12/23
Commissioning Team 22/12/23

What controls have we put in place for the risk:

- BCUHB has established a Task & Finish Group to address the issue including colleagues from Mersey & West Lancashire NHST (MWL).
- WHSSC quality team meets regularly with the assistant director of quality BCUHB and has established links with the quality team at MWL.
- WHSSC has written formally to BCUHB to raise the concerns around the management of the outreach clinics and seek clarity on the reporting and accountability arrangements in the health board for the Task & Finish Group.
- BCUHB to report to WHSSC on progress of the T&F Gp at the interface planning meeting and the SLA meeting.
- It has been agreed that Welsh Government will lead the escalation of the management of the plastic surgery outreach clinics as a part of their wider escalation of the dermatology service in north Wales.
- Concern was expressed that progress appears to have slowed. It was noted that escalation is being taken forward within the Welsh Government special measures process rather than the WHSSC escalation process. WHSSC continues to engage through fortnightly meetings with Welsh Government and participation on the Task & Finish Group led by BCUHB.

What actions should we take:

Action	Lead	Date
WHSSC Quality team to continue to liaise closely with quality leads in BCUHB and MWL.	VDJ – Quality Lead	Nov 22
To follow up with regard to the letter to BCUHB to obtain a response and respond accordingly.	Planner	Complete
Meeting between WHSSC, MWL and BCUHB to ascertain what is required to review all patients on the waiting list.	LA – Senior Planner	Complete
Work with MWLand BCUHB to agree the terms of reference and implement the review.	LA – Senior Planner & VDJ – Quality Lead	Complete
Confirm WHSSC's role in the escalation led by Welsh Government	Director of Planning & Performance & Managing Director	Apr 23
Monitor the findings from the patient harm review currently being undertaken by MWL	LA – Senior Planner & VDJ – Quality Lead	From Mar 23 to Jun 23
Continue to work with BCUHB and MWL, and with Welsh Government, to support addressing the risks relating to the outreach clinics.	Director of Planning & Performance DGW - North Wales Assistant Planner, VJD – Quality lead, LA Planner.	On going
VDJ to contact BCUHB Head of Patient Safety (Tracey Radcliffe) regarding the two outstanding incidents	VDJ – Quality lead	Complete

Additional comments:
June 23 – It was noted that WHSSC DoP attends fortnightly meetings with WG and BCUHB. WHSSC also attends the fortnightly Task & Finish Group.
July 23 – position unchanged: work continues via the T&G Gp to address the issues. Escalation via the meeting with WG and BCUHB.
Aug 23 – Concern was expressed that progress appears to have slowed. It was noted that escalation is being taken forward within the Welsh Government special measures process rather than the WHSSC escalation process. WHSSC continues to engage through fortnightly meetings with Welsh Government and participation on the Task & Finish Group led by BCUHB.
Sept 23 – the Task & Finish Group continues its work and remains within the WG escalation process. Action plan being implemented but position remains unchanged.
Oct 23: No change to risk level. T& F Gp update: Timeline provided for completion of patient reviews – report expected by end of November (firstly for BCU QPSC and then to WHSSC QPSC). Demand & capacity assessment nearly completed. SLA between BCU and MWL drafted.
Nov 23: No change to risk level although it was noted that to date there has been no evidence of patients having come to harm. Harms Review report expected shortly (scheduled for end of November). Work remains in progress via the Task & Finish Group with regard to the demand/capacity assessment, BCUHB-MWL provider SLA, additional capacity options and commissioning plans for 2024/25.
Dec 23 : The C&B commissioning team agreed no change to score although progress is being made. Review to be completed by end January. Demand/capacity assessment has been drafted by BCU. Additional capacity has been found at Connah's Quay. SLA between BCU and MWL has been drafted and being finalised.

Risk Ref: 47 Sustainability and Delivery of Service provided by Cardiff and Vale University Health Board (IF14)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)
Population Health

Director Lead: Director of Planning & Performance
Assuring Committee: Joint Committee Reviewed Assurance

Risk: There is a risk that due to issues of provider sustainability and delivery, that Cardiff and Vale University Health Board will no longer be able to provide Intestinal Failure services to the welsh population and **as a consequence** resulting in no service available in Wales.

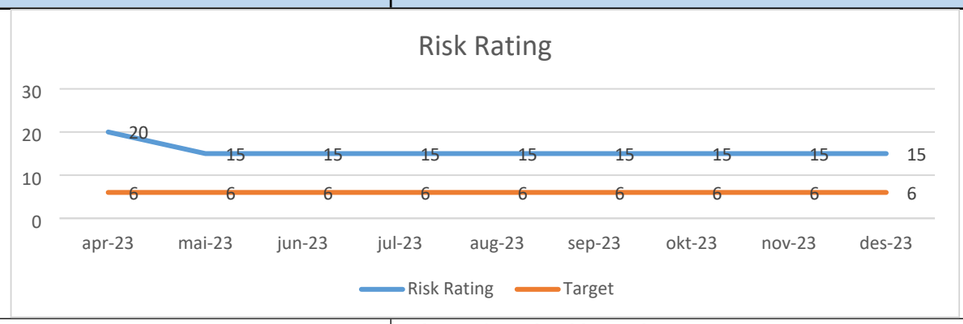
Date Added to Register: 17/05/23

Provider: Cardiff and Vale University Health Board

Date Last Reviewed by :
Joint Committee –18 July 2023
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	5x4	20
Current	**5x3**	**15**
Target	3x3	6



Groups discussed risk during period

Commissioning Team 17/05/23
Commissioning Team 14/06/23
Commissioning Team 12/07/23 Cancelled
Commissioning Team 09/08/23
Commissioning Team 16/10/23
Commissioning Team 09/11/23
Commissioning Team 27/12/23 - Cancelled

What controls have we put in place for the risk:

- Provision of Intestinal Failure service escalated to CDGB May 2023 and Chief Executive at CVUHB
- Written to CVUHB for a formal position
- Confirmation October 23 that IF lead consultant for the service will be leaving soon to work in another Health Board area
- Highlighted and advised the Quality Patient Safety Committee (October 23)
- Contingency Planning IF service meeting held with Managing Director (SL) and CDGB 08/11/23 to consider transferring service to Bristol. Outcome awaited.

What actions should we take:

Action	Lead	Date
Consultant cover in the Intestinal Failure service has become unsustainable and requires accelerated action for assurance of sustained delivery. Assurance received from CVUHB that the sustainability of the service is being reviewed. Consultant post currently advertised. Further discussion will be had in the Service Assurance meeting on the 24/10/23	Medical Director/ Assistant Director of Planning	October 2023
WHSSC Medical Director has written a formal letter to Meriel Jenney, CVUHB Medical Director raising concerns identified for the Intestinal Failure Service. Issues raised included: • The long term provision of Intestinal Failure services for patients from South East and West Wales and South Powys • Consultant provision • Promoting and growing the specialism • Commissioner Assurance An update on the above is expected in the next assurance meeting due to take place on the 21st November 2023.	Medical Director/ Assistant Director of Planning	November 2023

Additional comments:
May 23 - Commissioning Team reviewed the risk and agreed it remains the same score until further information received from the service.
June 23 – Commissioning Team reviewed the risk and confirmed confirmation had been received re: CVUHB provision of IF services. The team agreed to lower the score from 20 to 15 but for the risk to remain on the CRAF until actions had been formally agreed.
July 23 – Meeting was cancelled, therefore score remains the same
August 23 – group noted that an update was awaited from the Tertiary Services Oversight Group, however that assurance had been given by the clinical board that patients were continuing to receive care, and from the CEO letter there remains a commitment to deliver the service.
October 23 – Commissioning team agreed risk actions and reviewed the score, which remains the same
November 23- No commissioning team held in November but approval of risk register was completed via email communication. Risk remains the same until further meeting undertaken and update received.
December 23 – Risk score remains the same

Risk Ref: 48 Wales Fertility Institute (WFI) **P/21/20**
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)
Population Health

Director Lead: Director of Planning & Performance
Assuring Committee: Joint Committee Reviewed Assurance

There is a risk the Wales Fertility Institute (WFI) in Neath & Port Talbot Hospital are not providing a safe and effective service ***due to*** concerns with regards to the information flows from the service into WHSSC; late submission of contract monitoring which does not reconcile with finance returns.
There is a consequence that families who have treatment at this centre are not receiving the quality of care expected from the service and in turn impacting outcomes.

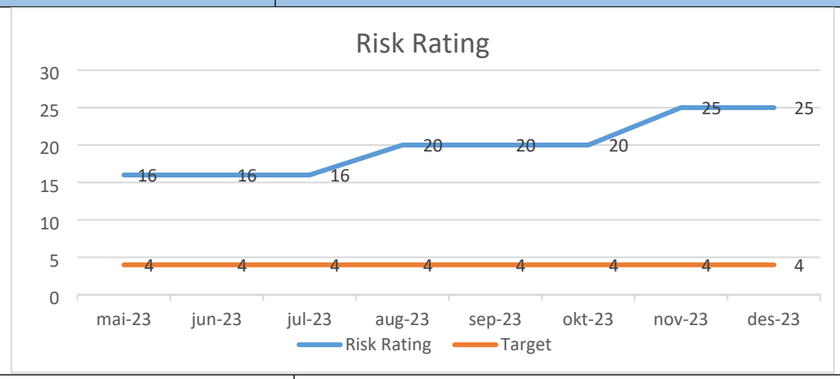
Date Added to Register: 16/05/23

Provider/s: SBUHB

Date Last Reviewed by:
Joint Committee –18 July 2023
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	**5x5**	**25**
Target	2x2	**4**



Groups discussed risk during period

Commissioning Team – 16/05/23
Commissioning Team – 20/06/23
Commissioning Team – 18/07/23
Commissioning Team – 15/08/23
Commissioning Team – 19/09/23
Commissioning Team - 18/10/23
Commissioning Team - 15/11/23
Commissioning Team - 20/12/23

What controls have we put in place for the risk:

- Received the report from the HFEA to support monitoring
- Requested action plan from the service to improve against the concerns identified by the HFEA.
- WHSSC attendance at SBUHB monthly Gold Command meeting attended 27/06/23
- Service escalated to level 3 formally requested action plan
- Executive to Executive action plan submitted to WHSSC
- Contents of Action Plan agreed
- Service escalated to level 4 in line with WHSSC escalation framework

Action	Lead	Date
Requested HFEA report from WFI	Head of Quality WHSSC	Complete
Requested Action plans from WFI based on HFEA report	Head of Quality WHSSC	complete
Formal recommendation to CDGB to escalate service to level 3	Assistant Specialised Planner WHSSC	Complete
Contract monitoring, MDS and RTT are due each month on 21st, these have been requested by WHSSC Information and planning. All Discussions between SBUHB and WHSSC have resulted in SBUHB submitting August data, October 2023. WHSSC have requested all data for April-August and September be submitted. WHSSC have reminded SBUHB data needs to be submitted monthly 21st of the month.	Assistant Specialised Planner WHSSC	Ongoing
Escalation meetings to be established and held monthly, last held 10/10/23	Assistant Specialised Planner WHSSC	Ongoing
Quality visit at WFI Neath Port Talbot and Cardiff sites. Due to increase in escalation level, the visit has been postponed, whilst staff are informed of the increase in escalation.	Assistant Specialised Planner WHSSC	14/11/23 postponed
Availability of PR to retain HFEA License. Discussions with HFEA and SBUHB	Assistant Specialised Planner WHSSC	Ongoing

Additional comments:
May 23 – New Risk – SBUHB escalated to Gold Command based on the HEFA report which identified 7 major concerns.
Aug 23 – W&C commissioning Team reviewed the risk, with the HFEA inspection and the HB reporting service fragility the risk score has increased to 20
Sept 23 - W&C Commissioning team reviewed the risk which remains unchanged
Oct 23 - W&C Commissioning team reviewed the risk which remains unchanged
Nov 23 - W&C Commissioning team reviewed the risk. Due to the concerns with regards to the HFEA license/ person responsible, sustainability of the service and the lack of assurance offered the service has been placed in escalation level 4.
Dec 23 - W&C Commissioning team reviewed the risk which remains unchanged

Risk Ref: 50 Deep Brain Stimulation and delays in communication with gatekeeper/referring clinician (NCC060)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)
Population Health

Director Lead: Director of Planning & Performance
Assuring Committee: Joint Committee Reviewed Assurance

Risk: There is a risk that patients with Parkinson's disease, tremor and dystonia who have undergone Deep Brain Stimulation at North Bristol NHS Trust do not receive the correct ongoing treatment including medication due to significant delays in communication with the gatekeeper and referring clinicians.

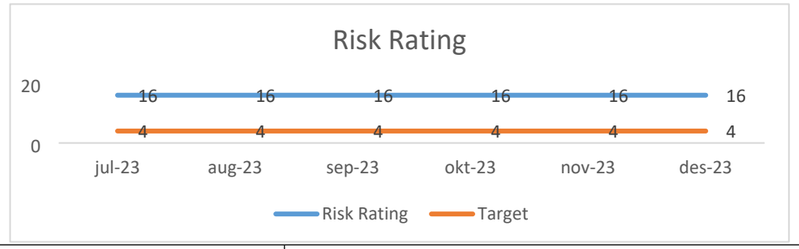
Date Added to Register: 25.7.23

Provider: North Bristol NHS Trust

Date Last Reviewed by:
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	**4x4**	**16**
Target	2x2	**4**



Groups discussed risk during period

Commissioning Team meeting 25/07/23
Commissioning Team meeting 22/08/23
Commissioning Team meeting 26/09/23
Commissioning Team meeting 17/10/23
Commissioning Team meeting 14/11/23 – Cancelled
Commissioning Team meeting 12/12/2023

What controls have we put in place for the risk:

- WHSSC and the gatekeeper met with the service on the 31st May 2023 and are meeting with the service on the 21st September 2023.
- Clinical safety concerns when alterations to medication and FP10 prescriptions are provided to patients in the absence of communicating this change to the primary caring team in south Wales have been raised.
- WHSSC have had internal discussions and are working with the gatekeeper.
- A Welsh single point of contact had been established for North Bristol Trust (NBT).
- Re-instated the south Wales DBS gatekeeper attendance at the weekly Multi-disciplinary team (MDT) meeting
- NBT to develop a Standing Operating procedure that covers both outpatient and discharge communication
- Expression of Interest Statement has been published on the WHSSC website – 30/10/23 to formally commission a Functional Neurosurgical service for complex movement disorders including Deep Brain Stimulation (DBS) for the South Wales population. Closing date 10th November 2023.
- Meeting arranged with the South Wales Gatekeeper 31st October 2023 to discuss next steps.
- Escalated the risk to CVUHB Director of Ops as the extended gatekeeper role has not been established – raising the issue at the next SLA meeting in Jan 24.

What actions should we take:

Action	Lead	Date
Met with North Bristol team on the 31s of May 2023 to understand the risks.	Planning Manager/Quality Manager	Quarter 1
Meeting with the North Bristol team on the 21st September 2023 postponed, meeting to be re-arranged.	Planning Manager	Quarter 2
October 2023 - A letter has been sent to Bristol to inform them that the resultant actions intended to address the identified risks – including a written pathway and a Standard Operating Procedure have not been delivered to the required standard. Next Steps WHSSC has instigated the designated provider process. An expression of interest statement has been published on the WHSSC website – 30/10/2023 to formally commission a Functional Neurosurgical service for complex movement disorders including Deep Brain Stimulation (DBS) for the South Wales population. The EOI will close on 10th November 2023. The Designated Provider information will be shared with the potential providers who will be required to submit a proposal by 15th December 2023. Adjudication of the potential designated providers will take place on 20th December 2023.	Planning Manager	Quarter 4

Additional comments:

July 23 - Following discussion at the July 25th 2023 Commissioning Team meeting it was agreed the risk should be added to the Neurosciences Risk Register scheme will be presented to CIAG prioritisation on the 10th of August 2023
August 23 - Risk reviewed and score remains the same
September 23 - Risk reviewed and score remains the same
October 23 – Risk reviewed and score remains the same
November 23 – no change to report
December 23 – no change to the risk – waiting for CVUHB to establish the extended Gatekeeper role – investment has been assigned for this risk. Escalated to the CVUHB Specialist Clinical Board Director of Ops

Risk Ref 51 - Deep Brain Stimulation – lack of awareness of eligibility criteria re unmet need (NCC061)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)
Population Health

Director Lead: Director of Planning & Performance
Assuring Committee: Joint Committee Reviewed Assurance

Risk: There is a risk that patients with Parkinson's disease, tremor and dystonia who could benefit from Deep Brain Stimulation are not being referred for assessment and treatment due to a lack of awareness of eligibility criteria and potential to benefit amongst referring clinicians

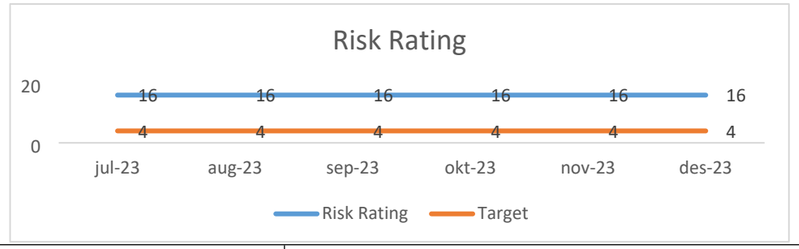
Date Added to Register: 25.7.23

Provider: North Bristol NHS Trust

Date Last Reviewed by:
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	**4x4**	**16**
Target	2x2	**4**



Groups discussed risk during period

Commissioning Team meeting 25/07/23
Commissioning Team meeting 22/08/23
Commissioning Team meeting 26/09/23
Commissioning Team meeting 17/10/23
Commissioning Team meeting 14/11/23 – Cancelled
Commissioning Team meeting 12/12/2023

What controls have we put in place for the risk:

- WHSSC and the gatekeeper met with the service on the 31st May 2023 and are meeting with the service on the 21st September 2023
- WHSSC have had internal discussions and are working with the gatekeeper
- A Welsh single point of contact had been established for NBT
- Re-instated the south Wales DBS gatekeeper attendance at the weekly Multi-disciplinary team (MDT) meeting
- Funding release paper approved by Sept CDBG to extend the south Wales gatekeeper role and provide additional administration support
- Expression of Interest Statement has been published on the WHSSC website – 30/10/23 to to formally commission a Functional Neurosurgical service for complex movement disorders including Deep Brain Stimulation (DBS) for the South Wales population. Closing date 10th November 2023.
- Meeting arranged with the South Wales Gatekeeper 31st October 2023 to discuss next steps.
- Escalated the risk to CVUHB Director of Ops as the extended gatekeeper role has not been established – raising the issue at the next SLA meeting in Jan 24.

What actions should we take:

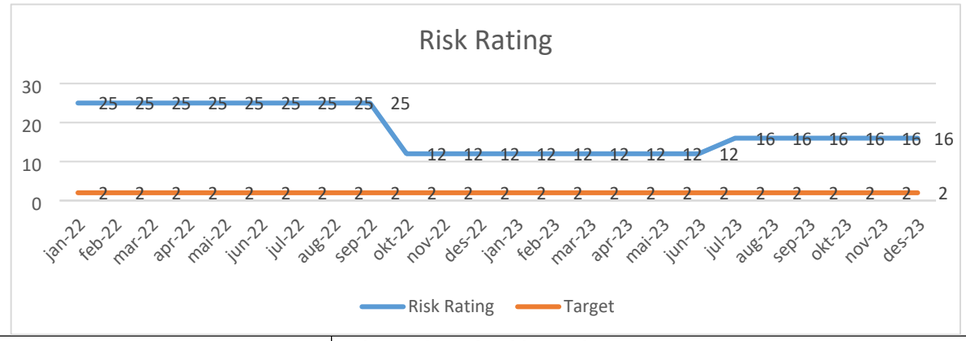
Action	Lead	Date
Met with North Bristol team on the 31s of May 2023 to understand the risks.	Planning Manager/Quality Manager	Quarter 1
Meeting with the North Bristol team on the 21st September 2023 postponed, meeting to be re-arranged.	Planning Manager	Quarter 2
October 2023 - A letter has been sent to Bristol to inform them that the resultant actions intended to address the identified risks – including a written pathway and a Standard Operating Procedure have not been delivered to the required standard. Next Steps WHSSC has instigated the designated provider process. An expression of interest statement has been published on the WHSSC website – 30/10/2023 to formally commission a Functional Neurosurgical service for complex movement disorders including Deep Brain Stimulation (DBS) for the South Wales population. The EOI will close on 10th November 2023. The Designated Provider information will be shared with the potential providers who will be required to submit a proposal by 15th December 2023. Adjudication of the potential designated providers will take place on 20th December 2023.	Planning Manager	Quarter 4

Additional comments:
Following discussion at the July 25th 2023 Commissioning Team meeting it was agreed the risk should be added to the Neurosciences Risk Register scheme will be presented to CIAG prioritisation on the 10th of August 2023
August 23 - Risk reviewed and score remains the same
September 23 - Risk reviewed and score remains the same
October 23 – Risk reviewed and score remains the same - please see action added in October 2023
November 23 – identified that the funding release has not been actioned by CVUHB –31/10/23 raised the issue with the Specialist Director of Ops- waiting a response – CT will escalate the matter if necessary - risk to remain in place with the same score
December 23 – no change to the risk – waiting for CVUHB to establish the extended Gatekeeper role – investment has been assigned for this risk. Escalated to the CVUHB Specialist Clinical Board Director of Ops and will raise at the SLA meeting in Jan 24

Risk Ref: 52 Additional Dialysis Sessions (WKN 12) **Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)** Risk Appetite Level:	**Director Lead:** WKN Programme Director **Assuring Committee: Joint Committee Reviewed Assurance**	
Risk: Dialysis capacity at Glan Clwyd Unit: There is a risk that due to the current physical environment of the unit that additional dialysis sessions will not be able to be accommodated. **As a consequence** patients may not be able to dialyse in the unit closest to home.	**Date Added to Register:** 04/05/21	**Date Last Reviewed by:** Quality Patient Safety Committee – 23 October 2023 CTMUHB Audit & Risk Committee –24 October 2023 Integrated Governance Committee – 25 October 2023 Risk Scrutiny Group – 22 November 2023 CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	5x5	25
Current	**4x4**	**16**
Target	2x1	2



Groups discussed risk during period

Oct 25th WKN Monthly Team Meeting
Nov 14th WKN/BCU regional meeting

What controls have we put in place for the risk:

- Ongoing discussion with provider regarding possible options for refurbishment/expansion.
- Six day patient transport service now available.
- Risk narrative has been changed to include the BCU position as a whole as this is the commissioning agreement.
- Formal letter issued to IHC Director for YGC regarding renal capacity 18.05.23
- Formal letter issued to CEO & Medical Director of BCU regarding Serious Concerns raised as part of the Peer Review Process for Unit Dialysis with BCU 15.06.23
- Raising within the WHSSC/BCU provider meetings

What actions should we take:

Action	Lead	Date
Review of obligations under contract to determine liability for costs of refurbishment/expansion	BCUHB Directorate Manager/ WKN Manager	April 23
Refurbishment of dialysis unit at YGC to accommodate a dedicated training area for Home Haemodialysis being completed. Expected to be operational by April 23	BCUHB Directorate Manager/ WKN Manager	April 2023
Review of patient residence to ensure all are dialysing in centre closest to home now additional transport capacity is available.	BCUHB Directorate Manager/ WKN Manager	April 23
Escalate through the WHSSC performance management structure within the WHSSC/BCU interfacing meeting	WKN Exec Lead	June 23
Meeting to take place with BCU CEO & Medical Director to discuss the BCU organisational structure which currently limits flexibility across the 3 Integrated Health Communities (IHC)ge and the ability of the north Wales services to meet demand	BCU CEO Exec/WHSSC Exec/WKN Management Team including Clinical and QPS lead	August/Sept 2023

Additional comments:
March 23 – The WKN core team discussed the risk and agreed the score remains the same
July 23 – Risk discussed in QPS, issues that have arisen from the lack of inability to flex the resources across Pan wide BCU organisational structure, which currently limits flexibility across the 3 IHCs and the ability of the north Wales services to meet demand, and the intervention required has resulted in the risk being increased from 12 to 16.
August 23 – Points addressed in joint meeting on 25.08.23, full suite of Peer reviews to be sent through to CEO. Risk remains the same.
Sept 23 – The WKN core team discussed and agree risk remains the same
Nov 23 - WKN/BCU Regional meeting risk discussed and remains the same

Risk Ref 53 C&VUHB Neurosciences Staffing issues/level (NCC062)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)
Population Health

Director Lead: Director of Planning & Performance
Assuring Committee: Joint Committee Reviewed Assurance

Risk: There is a risk that patients requiring admission to the Inpatient Neuro-rehabilitation Unit (C&VUHB) are unable to access specialist rehabilitation due to considerable staffing pressures as the service has a number of current vacancies which the service are unable to recruit to the posts. The gap in the number of posts that has been commissioned is not meeting the national standards

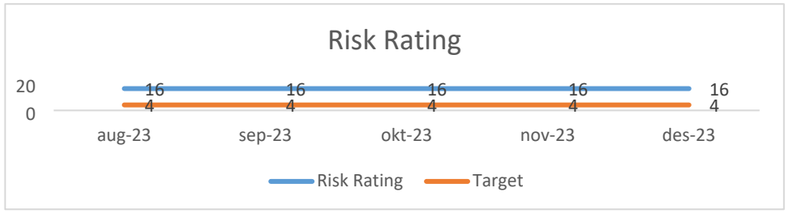
Date Added to Register: 30.8.23

Provider: Cardiff and Value University Health Board

Date Last Reviewed by:
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	**4x4**	**16**
Target	2x2	**4**



Groups discussed risk during period

Commissioning Team meeting 22/08/23
Commissioning Team meeting 26/09/23
Commissioning Team meeting 17/10/23
Commissioning Team meeting 14/11/23 – Cancelled
Commissioning Team meeting 12/12/2023

What controls have we put in place for the risk:

- WHSSC quality team have met with C&VUHB Neurosciences lead nurse on the 02/08/2023 to discuss the staffing issues/level.
- Receiving quarterly repatriation delay information and will have further discussions at the Neuroscience Performance meetings

What actions should we take:

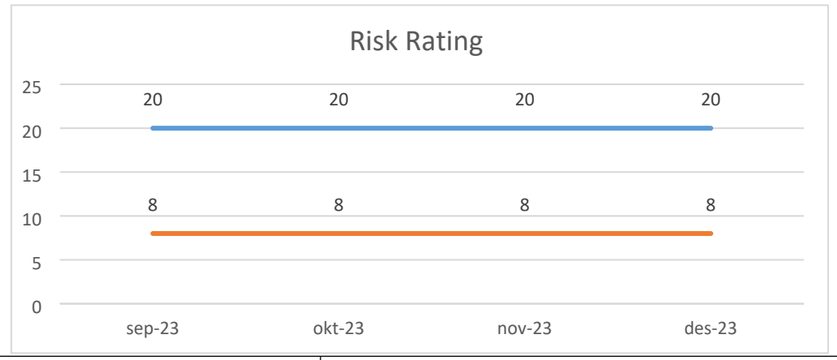
Action	Lead	Date
WHSSC has met with the C&VUHB team to understand the risks.	Planning Manager/Quality Manager	Quarter 2
The concerns raised by the Rehabilitation team will be addressed in the Rehabilitation Strategy which is due for consideration by WHSSC CDGB in January 2024.	Planning Manager	Quarter 4
Development of the strategy has been delayed due to capacity issues until Feb 24	Planning Manager	Feb 2024

Additional comments:
August 23 - WHSSC have met with C&VUHB to discuss the staffing issues/level. The quality team met with Neurosciences lead nurse on the 02/08/2023.
September 23 - Risk reviewed and score remains the same
October 23 – Risk reviewed and score remains the same – further discussions will take place with the Commissioning Team and at the Dec Neurosciences Performance meeting.
November 23 – no change to report.
December 23 – no change to the risk – this is strategically linked with the development of the Rehabilitation Strategy – in the meantime CT requested patient stories from the team to present at the next QPS meeting in Feb 23.

Risk Ref: 54 CAMHS Environment and Workforce (MH/23/16) **Risk Domain: I**mpact on the safety of patients, staff or public (physical/psychological harm)	**Director Lead: Director of Mental Health** **Assuring Committee:** Joint Committee Reviewed Assurance	
Risk: ***There is a risk*** that tier 4 providers for CAMHS cannot meet the service specification ***due to*** environmental and workforce issues, ***with a consequence that*** children could abscond/come to harm. (NWAS)	**Date Added to Register:25/09/23** **Provider/s**: BCUHB	**Date Last Reviewed by:** Quality Patient Safety Committee – 23 October 2023 CTMUHB Audit & Risk Committee –24 October 2023 Integrated Governance Committee – 25 October 2023 Risk Scrutiny Group – 22 November 2023 CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	**4x5**	**20**
Current	**4x5**	**20**
Target	4x2	**8**



Groups discussed risk during period

Commissioning Team 25/09/23
Commissioning Team 23/10/2023– Cancelled – Not quorate
Commissioning Team 27/11/23
Commissioning Team December 23 – Cancelled*

What controls have we put in place for the risk:

- Requested assurance from the unit regarding safety of the patients

What actions should we take:

Action	Lead	Date
The Unit have recorded and escalated this risk within BCUHB	BCUHB	October 2023

Additional comments:
September 23 Added to the risk register – this risk relates to an issue with the doors at NWAS and has been escalated accordingly. This risk will decrease when the matter has been resolved.
October 23 - Risk remains the same meeting cancelled as not quorate
November 23 – Risk score remains the same
December 23 – Meeting cancelled, risk remains the same.
*The December MH commissioning team was cancelled but a SLA meeting took place with BCU and this issue was discussed and it has been confirmed that all internal doors for NWAS will be included in the programme of work for Estates in this financial year and a number of other improvements requiring estates input have been agreed.

Risk Ref: 55 Neonatal Workforce (P/21/22)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)
Population Health

Director Lead: Director of Planning & Performance
Assuring Committee: **Joint Committee Reviewed Assurance**

There is a risk that neonates who require tertiary regional neonatal support in South Wales may be inappropriately cared for, ***due to*** the impact of the available workforce within UHW, to support the current intensive care demand. ***There is a consequence*** that a neonate may be cared for in an inappropriate care setting, where the necessary skills and/or equipment are not available.

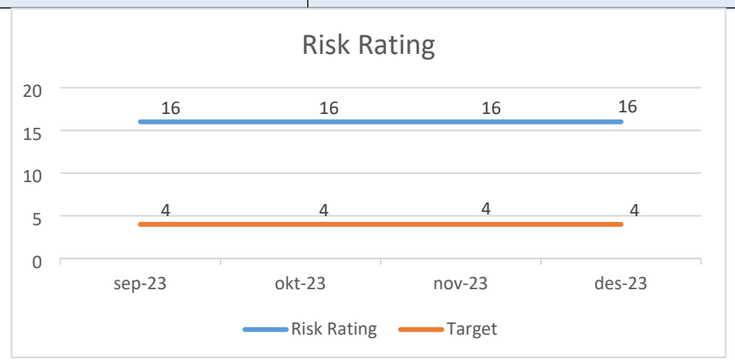
Date Added to Register: 19/09/23

Provider/s: CVUHB

Date Last Reviewed by :
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	**4x4**	**16**
Target	2x2	**4**



Groups discussed risk during period

Commissioning Team – 19/09/23
Commissioning Team - 18/10/23
Commissioning Team - 15/11/23
Commissioning Team - 20/12/23

What controls have we put in place for the risk:

- Service escalated to level 3 of WHSSC Escalation Framework
- Letter issued to WG highlighting capacity concerns

Action	Lead	Date
Executive to Executive meeting scheduled with C&VUHB	Director of Planning	Complete
Action Plan requested as part of escalation framework	W&C Planner	Complete
Triple Escalation meeting to discuss detail and progress against action plan	W&C planner	23/01/24

Additional comments:
Sept 23 – Evidence supplied to WHSSC highlighting staffing shortages impacting the neonatal service provided
Oct 23 - W&C Commissioning team reviewed the risk which remains unchanged
Nov 23 - W&C Commissioning team reviewed the risk which remains unchanged
Dec 23 - W&C Commissioning team reviewed the risk which remains unchanged

Risk Ref: 56 Neonatal Infection Control (P/21/23)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm)
Population Health

Director Lead: Director of Planning & Performance
Assuring Committee: **Joint Committee Reviewed Assurance**

There is a risk that neonates within the Neonatal Intensive Care Unit environment within UHW, are at greater risk of exposure to IP&C issues, whilst safer practice monitoring is being embedded. This is following a recent MRSA outbreak and identification of other organisms within the clinical area.
There is a consequence of increased neonatal morbidity, if processes to address these issues are not effectively implemented.

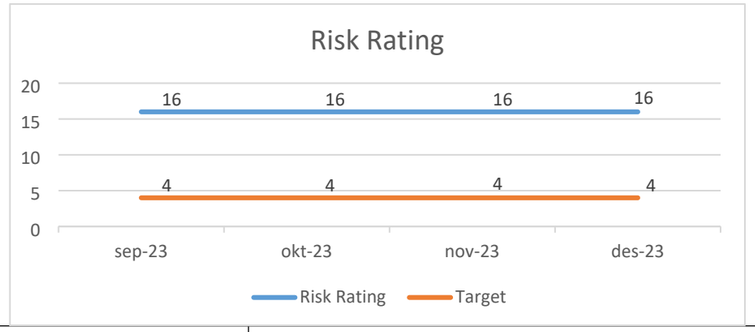
Date Added to Register: 19/09/23

Provider/s: CVUHB

Date Last Reviewed by:
Quality Patient Safety Committee – 23 October 2023
CTMUHB Audit & Risk Committee –24 October 2023
Integrated Governance Committee – 25 October 2023
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	**4x4**	**16**
Target	2x2	**4**



Groups discussed risk during period

Commissioning Team – 19/09/23
Commissioning Team - 18/10/23
Commissioning Team - 15/11/23
Commissioning Team - 20/12/23

What controls have we put in place for the risk:

- Service escalated to level 3 of WHSSC Escalation Framework

Action	Lead	Date
Executive to Executive meeting scheduled with C&VUHB	Director of Planning	Complete
Action Plan requested as part of escalation framework	W&C Planner	Complete
Triple Escalation meeting to discuss detail and progress against action plan	W&C planner	23/01/24

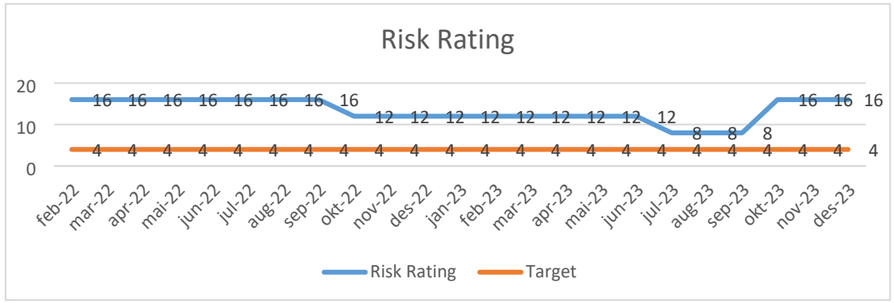
Additional comments:
Sept 23 – New Risk – Concern highlighted to WHSSC that IP&C pathways are not robust to prevent spread of infection increasing neonatal morbidity on the unit
Oct 23 - W&C Commissioning team reviewed the risk which remains unchanged
Nov 23 - W&C Commissioning team reviewed the risk which remains unchanged
Dec 23 - W&C Commissioning team reviewed the risk which remains unchanged

Risk Ref: 57 Delays in surgery due to insufficient theatre beds (NCC049) **Risk Domain:** Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Director Lead:** Director of Planning & Performance **Assuring Committee:** Joint Committee
Risk: There is a risk that patients in south Wales will have their surgery delayed due to insufficient theatre and inpatient bed capacity to deliver the required commissioned activity that meet the needs of the population with a consequence of deteriorating condition and disease progression. During the last ¾ months it has been indicated that the overruns are expensive. There are no theatre staff or anaesthetic staff to support the extended theatre sessions. Neurosurgery are trying to accommodate and consider their issues but it is now impacting on neurosurgery activity.	**Date Added to Register:27/01/21** **Provider/s:** CVUHB

Date Last Reviewed by Quality & Patient Safety Committee:
Risk Scrutiny Group – 22 November 2023
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	**4x4**	**16**
Target	4x1	**4**



Groups discussed risk during period

Commissioning Team meeting 07/02/23
Commissioning Team meeting 07/03/23
Commissioning Team meeting 04/04/23
Commissioning Team meeting 16/05/23
Commissioning Team meeting 13/06/23
Commissioning Team meeting 25/07/23
Commissioning Team meeting 22/08/23
Commissioning Team meeting 26/09/23
Commissioning Team meeting 17/10/23
Commissioning Team meeting 14/11/23 – Cancelled
Commissioning Team meeting 12/12/2023

What controls have we put in place for the risk:

- Gateway service review as part of the five year neurosciences strategy. Neurosciences gateway review paper was submitted to February Management Group meeting
- Neurosciences and complex conditions commissioning team (NCCCT) to monitor the recovery plan and continuing meeting with the team at the Risk and Assurance meetings.
- Full access restored to theatres 12 and 14 in September 22- extended theatre sessions have been identified as commencing in April 2023 to achieve RTT at pre- covid levels by March 2024 – as per WG targets.
- Bed capacity will be restored to pre- COVID levels - no timeline available at the moment. Bed capacity has increased but not quite back to pre-covid levels. This is continued to be monitored via the performance management meetings.
- WHSSC have had internal discussions and are working with the service
- The cessation of the extended theatre sessions will be raised at the next Cardiff SLA meeting in January 2024
- The Commissioning Team are continuing to monitor the situation through the quarterly Neurosciences Performance Meeting.
- The cessation of Tracheostomy Training for stroke services has been escalated to CVUHB Specialist Clinical Board Operational Director -12/12/23
- Continue to monitor the position via the quarterly Neurosciences Performance Meeting

What actions should we take:

Action	Lead	Date
Submit Specification to policy group May 2022 – Completed but further work required. NHS England are developing a service specification and WHSSC have asked to be included in the process. Service Specification Published	Planning Manager	Completed – Feb 2023
Neurosciences gateway review paper was submitted to February Management Group meeting.	Planning Manager	Completed
Further meeting has taken place to with the services to discuss the GIRFT neurosurgery recommendations. Review the 3 top impact changes to be included in the business Case for the ICP 2022-2023 scheme. Still waiting to receive the business case – due in quarter 1 2023/24	Planning Manager	Quarter 1 2023/24
WHSSC NCCCT to monitor the recovery plan through the bi-monthly Risk, Assurance and Recovery meetings. (Currently the service is operating at 80% of 2 theatres pre-covid they had access to 100% of the 2 theatres)	Planning Manager	Bi-monthly
Further review of this risk was undertaken by the CT in November 21 to recommend rewording the risk and incorporating Risk NCC050 into Risk NCC049	Planning Manager	completed
Further review of this risk was undertaken by the CTM in October 23, the CTM agreed to increase the risk score. The matter was raised at the Cardiff and Vale SLA meeting with the Director of Ops for Specialist Services – 19th Oct 2023. Action for the Health Board to raise with the Surgical Board.	Planning Manager	March 2024

Additional comments:
March 2023 - WLI's are continuing but have decreased due to capacity issues mainly staffing in the Radiology dept. The CT will continue to monitor performance at the quarterly performance management meetings.
A meeting is to be held with the Directorate Manager and Clinical Director on 24th May 2023 to discuss a number of issues including bed and theatre capacity.
July 23 - Risk reviewed, the team agreed to lower the risk score to 8 amber as theatre capacity is back to the pre-Covid level but the bed capacity has not been fully reinstated. CT members have discussed this with Director of Operations Cardiff & Vale on the 26th July 2023 and will continue to monitor the situation at the quarterly performance meeting.
October 23 – Risk reviewed and score has increased to 16. Theatre Surgical Directorate. There are no theatre staff or anaesthetic staff to support the extended theatre sessions. Neurosurgery are trying to accommodate and consider their issues but it is now impacting on neurosurgery activity. The issue was raised at the Cardiff and Vale SLA meeting on 19th October 2023. The Director or Ops for Specialist Services has taken the matter up with the Director of Op Surgical Board.
November 2023 - Awaiting a response from the Specialist Operational Director CVUHB re outcome of discussions with the Surgical Service Board about reinstating extended theatre lists – this risk may have to be escalated depending on the response received from the Health Board.
December 2023 – The extended theatre sessions that had recently been reinstated have now ceased. The service were still providing these sessions for the Skull base service but were required to cancel a morning session to meet working time directive regulations to give staff the necessary down time between theatre sessions. This has been escalated to the Specialist Clinical Board Operational Director – waiting for further information. It will be raised at the next Cardiff SLA meeting in January 2024.
CT have been advised that the provision of Tracheostomy Training for the Stroke teams has been ceased by the CVUHB Medicine Clinical Board due to large number of nursing vacancies – the impact is that Stroke patients with Trache's will be required to be managed on the Neurosurgery ward – potential to impact on neurosurgical clinical flow . Escalated to Specialist Clinical Board Operational Director -12/12/23

Risk Ref: 58 Goal methods and outcomes pressures (PT/13) **Risk Domain:** Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Director Lead:** Director of Planning & Performance **Assuring Committee:** Joint Committee	
Risk: There is a risk not all goal methods and outcomes will be achieved from the 2023/24 plan **due to** the financial pressures and request of savings **as a consequence** there is uncertainty on how these will be taken forward.	**Date Added to Register: 06/11/2023**	**Date Last Reviewed by:** Risk Scrutiny Group – 22 November 2023 CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	5x3	15
Current	**5x3**	**15**
Target	2x2	4

Groups discussed risk during period

Planning Team 06.11.23

What controls have we put in place for the risk:

- Engage with Management Group, Finance and individual Health Boards during the plan development to ensure commissioner support for their individual Health Board allocation within the ICP.

What actions should we take:

Action	Lead	Date
Provide regular updates to Joint Committee, Management group and Corporate Director Group Meeting on progress regarding annual planning and financial plan.	Director of Planning	6 November 2023

Additional comments:
November 2023 – Team discussed the PT/12 risk and agreed this would be an additional risk.

Risk Ref : 59 Calea Contract Renewal (IF15) **Risk Domain:** Impact on the safety of patients, staff or public (physical/psychological harm) Population Health Risk Appetite Level:	**Director Lead: Director of Planning** **Assuring Committee: Joint Committee Reviewed Assurance**	
Risk: There is a risk that HPN supply to patients could be impacted **due to** the current homecare provider contracts ending March 24 with no current arrangement to extend **which as a result** could leave patients without a service	**Date Added to Register: 09/11/23** Provider: Calea	**Date Last Reviewed by:** Risk Scrutiny Group – 22 November 2023 CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	5x3	15
Current	**5x3**	**15**
Target	4x3	12

Groups discussed risk during period

Commissioning Team 09/11/23
Commissioning Team 27/12/23 - Cancelled

What controls have we put in place for the risk:

- Urgent meeting to be arranged NWSSP and provider to discuss contract and severity of risk to service for patients from 2024.
- Escalated to Medical Director WHSSC
- Escalated risk to Director of Finance

What actions should we take:

Action	Lead	Date
NWSSP clear procurement timeline developed.	NWSSP	November 23
NWSSP and Intestinal Failure team to review the contract specification.	NWSSP	November 23
Update on progress paper submitted to CDGB 27/11/23.	Assistant Director of Planning	November 23

Additional comments:
November 23- No commissioning team held in November but approval of risk register was completed via email communication.
December 23 – Risk score remains the same

Risk Ref: 60 WFI treatment – Temporary pause (P/21/24)
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm) Population Health

Director Lead: Director of Planning
Assuring Committee: Joint Committee Reviewed Assurance

There is a risk all licensed HFEA activity at WFI will urgently and temporarily need to cease due to the fact that the Person Responsible (PR) has stood down from the role and there has been a failure to appoint a new PR to fulfil their duties.
There is a consequence that patients in active treatment will need to have their treatment plan temporarily paused and the centre would not be able to accept new patients on a temporary basis.

Date Added to Register: 30/11/23

Provider/s: SBUHB

Date Last Reviewed by:
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	5x4	**20**
Current	**5x4**	**20**
Target	2x2	**4**

Groups discussed risk during period

Commissioning Team – 30/11/23
Commissioning Team – 20/01/23

What controls have we put in place for the risk:

- Consideration to cease all activity, pause current treatment for patients and under no circumstances accept new patients.
- Discussion with SBUHB the license holder and the HFEA to consider the options with regards to ensuring a PR is in post including succession planning.

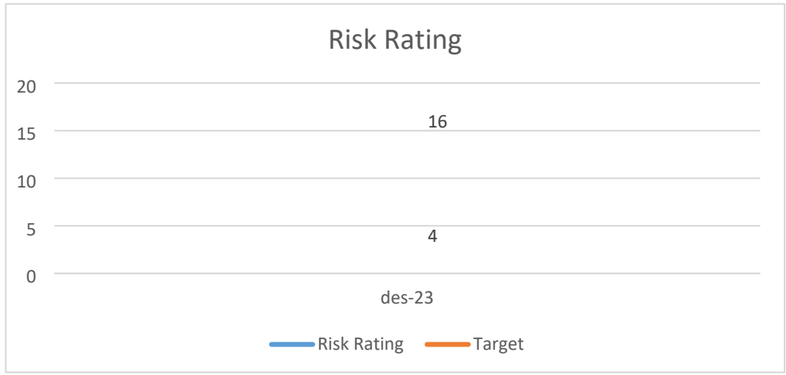
Action	Lead	Date
Formal recommendation to CDGB that there is a likelihood the person responsible may be unable to fulfil their duties casting doubt on the sustainability of the service in its current form.	Assistant Specialised Planner WHSSC	Complete
Monitoring of service continues through formal escalation	Assistant Specialised Planner WHSSC	30/01/24

Additional comments:
Nov 23 – New Risk - The post of PR is a legal requirement under the HFEA Act to be able to provide licensed activity, including the storage of embryo' and gametes. Paper taken to CDGB due to concerns of the sustainability of the service. If the PR is unable to fulfil their duties the HFEA will require all licensed activity to stop immediately. WFI are currently exploring options to identify staff who may be suitably qualified to take the HFEA prep exam and who could be nominated as a new PR.
Dec 23 - W&C Commissioning team reviewed the risk which remains unchanged

Risk Ref: 61 Obesity surgery waiting times (**CT050) – NEW RISK** **Risk Domain:** Impact on the safety of patients, staff or public (physical/psychological harm)	**Director Lead: Director of Planning** **Assuring Committee:** Joint Committee Reviewed Assurance	
Risk: There is a risk that patients from Betsi Cadwaladar University Health Board and North Powys awaiting obesity surgery in Salford Royal Hospital will have their treatment delayed due to long waiting times, which the hospital have advised will be unlikely to reduce significantly in the short to medium-term.	**Date Added to Register: 01/12/2023** **Provider/s:** Cardiff and Vale University Health Board; Swansea Bay University Health Board	**Date Last Reviewed by:** CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	4x4	**16**
Target	4x1	**4**



Groups discussed risk during period

Commissioning Team 01/12/23

What controls have we put in place for the risk:

- Salford Royal Hospital extending operating hours and working with private provider to increase the number of procedures undertaken
- WHSSC and BCUHB Level 3 service communicating proactively to ensure that the health board is fully cognisant of the identity of longer waiter
- WHSSC corresponding with Salford Royal to monitor current waiting list position

What actions should we take:

Action	Lead	Date
WHSSC to liaise with BCUHB Level 3 service to discuss proposal ask WIMOS to undertake additional procedures and for WHSSC to identify an alternative English provider	Senior Planning Manager	Complete
WHSSC to discuss with WIMOS the potential for SBUHB to undertake procedures for patients from BCUHB and North Powys	Senior Planning Manager	Complete
WHSSC to identify potential for resource used to support patients receiving procedures in Salford Royal Hospital can be used to address acute dietetics and psychology pressures in WIMOS	Senior Planning Manager	January 2024
WHSSC to convene meeting between representatives from WIMOS and BCUHB Level 3 service	Senior Planning Manager	January 2024

Additional comments:

December 2023 – In view of discussions with Salford Royal Hospital having identified that there was little prospect of the waiting list positon improving in the short to medium-term, the Cardiac Commissioning Team agreed that it should be included on the Commissioning Team Risk Register; risk reported to the Corporate Directors Group Board and Management Group via inclusion in the ABUHB Obesity Surgery Business Case assessment paper (November/December 2023)

Risk Ref: 62 TARN delays (CT051) – NEW RISK **Risk Domain:** Impact on the safety of patients, staff or public (physical/psychological harm)	**Director Lead: Director of Planning** **Assuring Committee:** Joint Committee Reviewed Assurance	
Risk: As a result of the TARN database being taken offline in June 2023, and owing to delays in the instituting of both interim arrangements and a sustainable long-term solution, the South Wales Major Trauma Network will be subject to risks relating to: • A large and growing TARN submission backlog • The unknown status of historical TARN data • Delays to the availability of reporting – including quarterly dashboards, clinical reports and TARN analytics – impeding the ability of the Network to monitor the implementation of the PBC and benchmark performance	**Date Added to Register: 01/12/2023** **Provider/s:** Cardiff and Vale University Health Board; Swansea Bay University Health Board	**Date Last Reviewed by:** CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	16
Current	4x4	16
Target	4x1	4

Groups discussed risk during period

Commissioning Team 01/12/23

What controls have we put in place for the risk:

- SWTN has agreed (via a meeting comprising the Trauma Network Clinical Directors and Managers, the TARN team and representatives from NHSE) that the TARN system will no longer be hosted by the University of Manchester
- TARN to issue standardised Excel spreadsheet for interim data collection
- Wales will be able to use the new TARN platform to be developed within the NHSE data repository as part of NHSE National Outcomes Registries Programme
- TARN coordinators have agreed that, as a result of their being insufficient resource nationally to support the submission of a case backlog, no data is submitted during the period that TARN is offline

What actions should we take:

Action	Lead	Date
Delivery Assurance Group to consider proposal to extend the South Wales Trauma Network Band 6 TARN Support Manager Role for a further 12 months in order to support the SWTN's mitigation response to TARN issue	Director of Planning/ Senior Planning Manager	Complete
WHSSC Director of Planning to write to Mr Robert Bentley (National Clinical Director for Major Trauma and Burns; Chair - NHS England Specialised Commissioning National Programme of Care – Trauma) to advise of ongoing risks and concerns with timescale for long-term solution	Director of Planning/ Senior Planning Manager	Complete
WHSSC to ensure that SWTN are appropriately represented in discussions pertaining to the development and initiation of a long-term solution for TARN data collection and storage	SWTN/ Senior Planning Manager	January 2024

Additional comments:
December 2023 – Following the risk being reported to the Cardiac Commissioning Team, it was agreed that it should be included on the Commissioning Team Risk Register; risk also being monitored and mitigating actions agreed via the South Wales Trauma Network Delivery Assurance Group

Risk Ref: 63 Neurosurgery Sustainability (NCC063) NEW RISK
Risk Domain: Impact on the safety of patients, staff or public (physical/psychological harm) Population Health

Director Lead: Director of Planning
Assuring Committee: Joint Committee Reviewed Assurance

Risk: There is a risk that the delay in progressing the Neurosurgery Sustainability and Standards CIAG scheme for the ICP 22/23 and not investing in key high risk posts (Intra operative Monitoring (IOM), CNS Skull Base and Neuromodulation) due to the financial pressures of NHS Wales would as a consequence result in the loss of the sub speciality services of Neurosurgery (Skull Base, Facial Pain, Complex Spine and elements of tumour surgery). The IOM post is recommended by NICE guidelines and the lack of ability to recruit to this post substantively, would mean that these subspecialty surgeries would have to cease in Wales with patients then being required to receive treatment in North Bristol Trust (NBT). Additionally there is no commissioned CNS posts for skull base and Neuromodulation services, the service is managed by single handed consultants resulting in consultant time being used inappropriately to deliver nurse led services – this does not meet national standards and patients would be denied timely access to neurosurgical advice and treatment.

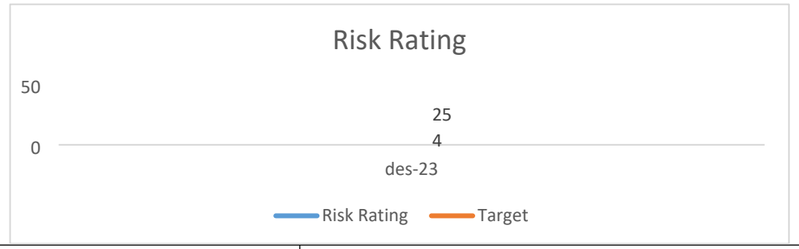
Date Added to Register: 12.12.23

Provider: Cardiff and Value University Health Board

Date Last Reviewed by:
CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	5x5	25
Current	**5x5**	**25**
Target	2x2	4



Groups discussed risk during period

Commissioning Team meeting 12/12/2023

What controls have we put in place for the risk:

- Continue to monitor the scheme via the Neurosciences Performance Meeting
- The scheme has been included in the ICP 24/25 – awaiting JC approval in quarter 4.

What actions should we take:

Action	Lead	Date
WHSSC has met with the C&VUHB team to understand the risks. The scheme has been risk assessed as part of the 10/20/30 WG efficiency saving project. It has recently been risked assessed using the Quality Impact Assessment tool. Both these sets of data have scored the risk very high (25). The scheme is currently on hold as a result of this piece of work.	Planning Manager/Quality Manager	Quarter 3
Awaiting the outcome of the ICP 24/25 to establish if these high risk posts will receive investment in 2024/25	Planning Manager	Quarter 4

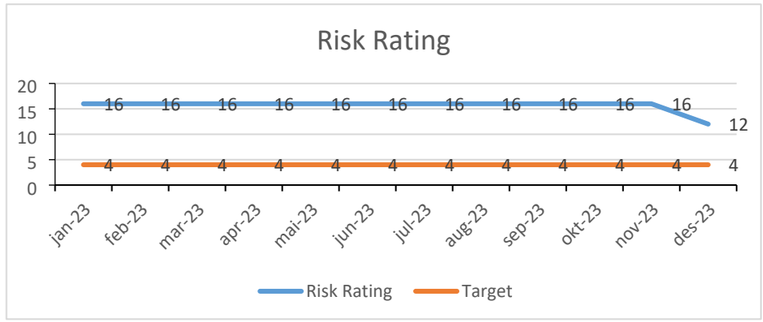
Additional comments:

De-escalated Reduced Risks For December 2023

Risk Ref: 44 Paediatric cardiac surgery (P/21/19) **Risk Domain:** Impact on the safety of patients, staff or public (physical/psychological harm) Population Health	**Director Lead:** Director of Planning & Performance **Assuring Committee:** Joint Committee Reviewed Assurance	
Risk: ***There is a risk*** that paediatric cardiac surgery patients will have longer waits than is clinically appropriate ***due*** *to* lack of availability of a PIC bed. ***There is a consequence*** that the condition of the patient could deteriorate whilst waiting.	**Date Added to Register: 24/01/23** **Provider/s**: University Hospital Bristol	**Date Last Reviewed by:** CDGB – 02 January 2024

Risk Rating
(impact x likelihood)

Initial	4x4	**16**
Current	**4x3**	**12**
Target	2x2	**4**



Groups discussed risk during period

Commissioning Team - 24/01/23
Commissioning Team - 21/02/23
Commissioning Team - 21/03/23
Commissioning Team - 20/04/23
Commissioning Team - 16/05/23
Commissioning Team – 20/06/23
Commissioning Team – 18/07/23
Commissioning Team – 15/08/23
Commissioning Team – 19/09/23
Commissioning Team - 18/10/23
Commissioning Team - 15/11/23
Commissioning Team - 20/12/23

What controls have we put in place for the risk:

- Fortnightly report requested from Bristol Children's Hospital requesting detail on patient waits, steps taken to reschedule and management plan.
- Meeting with clinical team in Bristol took place to understand the mitigations, agreed trajectories will be provided
- Health board escalated to level 3 in line with WHSSC escalation framework

What actions should we take:

Action	Lead	Date
Arrange meeting with Bristol Children's Hospital	W&C Planner	Complete
Trajectories for patients breaching waiting list standards to be shared with WHSSC.	W&C Planner	31/05/23
Fortnightly updates being issued by the Provider to support the monitoring of patients on the waiting list.	W&C Planner	Fortnightly
Formally write to Bristol Childrens to seek formal assurance on planned trajectories	W&C Planner	complete
Meeting scheduled with Bristol Childrens' Hospital to discuss outsourcing	W&C Planner	complete
Requested action plan from provider to address escalation objectives	W&C Planner	complete
Escalation meeting to monitor progress against action plan (monthly)	W&C Planner	December

Additional comments:
Sept 23 – W&C commissioning Team reviewed the risk which remains unchanged. Escalation due to concerns with the time patients are waiting for surgery. CDGB agreed that the service should be in escalation level 3.
Oct 23 - W&C Commissioning team reviewed the risk which remains unchanged
Nov 23 - W&C Commissioning team reviewed the risk which remains unchanged
Dec 23 – In light of improved performance and recommendation to lower escalation level from 3 to 2 the risk score has been reduced within the likelihood domain, reducing the overall score.

Risk Appetite Levels

Appetite Level	Described as:
None	**Avoid -** The avoidance of risk and uncertainty is a key organisational objective.
Low	**Minimal -** Preference for ultra-safe delivery options that have a low degree of inherent risk and may only have limited potential for reward.
Moderate	**Cautious -** Preference for safe delivery options that have a low degree of inherent risk and may only have limited potential for reward.
High	**Open -** Willing to consider all potential delivery options and choose while also providing an acceptable level of reward (and VfM).
Significant	**Seek -** Eager to be innovative and to choose options offering potentially higher business rewards despite greater inherent risk. **Mature -** Confident in setting high levels of risk appetite because controls, forward scanning and responsiveness systems are robust.

Risk Matrix

	Likelihood				
Consequence	**1**	**2**	**3**	**4**	**5**
	Rare	**Unlikely**	**Possible**	**Likely**	**Almost certain**
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

Likelihood Score (L) - What is the likelihood of the consequence occurring?				
1	**2**	**3**	**4**	**5**
Rare	**Unlikely**	**Possible**	**Likely**	**Almost certain**
This will probably never happen / recur	Do not expect it to happen / recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen / recur but it is not a persisting issue	Will undoubtedly happen / recur, possibly frequently

Consequence x Likelihood = Risk Score

Domains
Impact on the safety of patients, staff or public (physical/psychological harm)
Population Health
Quality/complaints/audit
Human resources/ organisational development/staffing/ competence
Statutory duty/ inspections
Adverse publicity/ reputation
Business objectives/ projects
Finance including claims
Service/business interruption
Environmental impact

WHSSC COMMISSIONING RISK ACTIVITY BETWEEN 1 JULY 2023 – 31 DECEMBER 2023

The Joint Committee last considered the June 2023 CRAF on the 18 July 2023. A review of all risks has been undertaken through the commissioning team meetings, the Risk Scrutiny Group (RSG), the Corporate Directors Group Board (CDGB), the Integrated Governance Committee (IGC) and the Quality and Patient Safety Committee (QPSC).

A summary of changes made since 1 July 2023 – 31 December 2023 is outlined below:

1. New Risks

13 new risks were received during the reporting period:

- **5** Neurosciences risks,
- **1** Mental Health risk,
- **3** Women and Children risks,
- **1** Organisational/Planning risk,
- **1** Intestinal Failure risk; and
- **2** Cardiac risks.

Ref	Initial Score	Score as at December 2023	Date added to CRAF	Rationale
Risk 50 (NCC060) Deep Brain Stimulation (DBS) and delays in communication with gatekeeper/referring clinician	**16**	**16**	July 2023	There is a risk that patients with Parkinson's disease, tremor and dystonia who have undergone Deep Brain Stimulation at North Bristol NHS Trust do not receive the correct ongoing treatment including medication due to significant delays in communication with the gatekeeper and referring clinicians. A scheme was presented to Clinical Impact Assessment Group (CIAG) prioritisation on the 10th of August 2023.

Ref	Initial Score	Score as at December 2023	Date added to CRAF	Rationale
				Investment has been assigned for this risk and expressions of interests to commission a DBS service for South Wales requested. Adjudication of the potential designated providers took place on 20th December 2023.
Risk 51 (NCC061) Deep Brain Stimulation – lack of awareness of eligibility criteria re unmet need	**16**	**16**	July 2023	There is a risk that patients with Parkinson's disease, tremor and dystonia who could benefit from Deep Brain Stimulation are not being referred for assessment and treatment due to a lack of awareness of eligibility criteria and potential to benefit amongst referring clinicians Scheme was presented to CIAG prioritisation on the 10th of August 2023. Adjudication of the potential designated providers will take place on 20th December 2023.
Risk 53 (NCC062) C&VUHB Neurosciences Staffing issues/level	**16**	**16**	August 2023	There is a risk that patients requiring admission to the Inpatient Neuro-rehabilitation Unit (C&VUHB) are unable to access specialist rehabilitation due to considerable staffing pressures as the service

Ref	Initial Score	Score as at December 2023	Date added to CRAF	Rationale
				has a number of current vacancies which the service are unable to recruit to the posts. The gap in the number of posts that has been commissioned is not meeting the national standards. This is strategically linked with the development of the Rehabilitation Strategy.
Risk 54 (MH/21/16) Children and Adolescent Mental Health Service (CAHMS) Environment and Workforce	**20**	**20**	September 2023	There is a risk that tier 4 providers for CAMHS cannot meet the service specification due to environmental and workforce issues, with a consequence that children could abscond/come to harm. There is an issue with the doors at NWAS and has been escalated accordingly. This risk will decrease when the matter has been resolved.
Risk 55 (P/21/22) Neonatal Workforce	**16**	**16**	September 2023	There is a risk that neonates who require tertiary regional neonatal support in South Wales may be inappropriately cared for, due to the impact of the available workforce within University Hospital Wales (UHW), to support the current intensive care demand. There is a consequence that a

Ref	Initial Score	Score as at December 2023	Date added to CRAF	Rationale
				neonate may be cared for in an inappropriate care setting, where the necessary skills and/or equipment are not available. This service is currently in escalation.
Risk 56 (P/21/23) Neo-natal Infection Control	**16**	**16**	September 2023	There is a risk that neonates within the Neonatal Intensive Care Unit environment within UHW, are at greater risk of exposure to IP&C issues, whilst safer practice monitoring is being embedded. This is following a recent MRSA outbreak and identification of other organisms within the clinical area. There is a consequence of increased neonatal morbidity, if processes to address these issues are not effectively implemented. Concern highlighted to WHSSC that IP&C pathways are not robust to prevent spread of infection increasing neonatal morbidity on the unit. This service is currently in escalation.
Risk 57 (NCC049)	**16**	**16**	October 2023	There is a risk that patients in south Wales will have their surgery

Ref	Initial Score	Score as at December 2023	Date added to CRAF	Rationale
Delays in surgery due to insufficient theatre beds				delayed due to insufficient theatre and inpatient bed capacity to deliver the required commissioned activity that meet the needs of the population, with a consequence of deteriorating condition and disease progression.
Risk 58 (PT/13) Goal methods and outcomes pressures	**15**	**15**	November 2023	There is a risk not all goal methods and outcomes will be achieved from the 2023/24 plan due to the financial pressures and request of savings as a consequence there is uncertainty on how these will be taken forward.
Risk 59 (IF15) Calea Contract Renewal	**15**	**15**	November 2023	There is a risk that Home Parenteral Nutrition (HPN) supply to patients could be impacted due to the current homecare provider contracts ending March 24 with no current arrangement to extend which as a result could leave patients without a service
Risk 60 (P/21/24) Wales Fertility Institute (WFI) treatment – temporary pause	**20**	**20**	November 2023	There is a risk all licensed Human Fertilisation and Embryology Authority (HFEA) activity at WFI will urgently and temporarily need to cease due to the fact that the Person Responsible (PR) has stood down from the role and there has been a failure to appoint a new PR to fulfil their duties. There is a consequence that patients in active

Ref	Initial Score	Score as at December 2023	Date added to CRAF	Rationale
				treatment will need to have their treatment plan temporarily paused and the centre would not be able to accept new patients on a temporary basis.
Risk 61 (CT050) Obesity surgery waiting times	**16**	**16**	December 2023	There is a risk that patients from Betsi Cadwaladr University Health Board and North Powys awaiting obesity surgery produces in Salford Royal Hospital will have their treatment delayed due to long waiting times, which the hospital have advised will be unlikely to reduce significantly in the short to medium-term. Due to discussions with Salford Royal Hospital having identified that there was little prospect of the waiting list positon improving in the short to medium-term.
Risk 62 (CT051) Trauma Audit and Research Network (TARN) delays	**16**	**16**	December 2023	As a result of the TARN database being taken offline in June 2023, and owing to delays in the instituting of both interim arrangements and a sustainable long-term solution, the South Wales Major Trauma Network will be subject to risks relating to: • A large and growing TARN submission backlog

Ref	Initial Score	Score as at December 2023	Date added to CRAF	Rationale
				• The unknown status of historical TARN data Delays to the availability of reporting – including quarterly dashboards, clinical reports and TARN analytics – impeding the ability of the Network to monitor the implementation of the PBC and benchmark performance
Risk 63 (NCC063) Neurosurgery Sustainability	**25**	**25**	December 2023	There is a risk that the delay in progressing the Neurosurgery Sustainability and Standards CIAG scheme for the ICP 22/23 and not investing in key high risk posts (Intra operative Monitoring (IOM), CNS Skull Base and Neuromodulation) due to the financial pressures of NHS Wales would as a consequence result in the loss of the sub speciality services of Neurosurgery (Skull Base, Facial Pain, Complex Spine and elements of tumour surgery). The IOM post is recommended by NICE guidelines and the lack of ability to recruit to this post substantively, would mean that these subspecialty surgeries would have to cease in Wales with patients then being required to receive treatment in North Bristol Trust (NBT).

2. Escalated Risks

1 Directorate Risk was escalated during the reporting period:

- **1** Welsh Kidney Network**.**

2 Commissioning Risks were escalated during the reporting period:

- **1** Neurosciences; and
- **1** Women and Children.

Ref	Initial Score	Score as December 2023	Date Escalated to CRAF	Rationale
Risk 52 (WKN12) Additional Dialysis Sessions	**25**	**16**	July 2023	There is a risk that due to the current physical environment of the unit that additional dialysis sessions will not be able to be accommodated. As a consequence patients may not be able to dialyse in the unit closest to home Issues that have arisen from the lack of inability to flex the resources across Pan wide BCUHB, and the intervention required has resulted in the risk being increased.
Risk 26 (NCC046) Neuropsychiatry patients waiting times	**15**	**20**	This has been on CRAF since February 2020, but increased from 15 to 20 in August 2023	There is a risk that neuropsychiatry patients will not be able to be treated in a timely manner with the appropriate therapy support due to staffing issues. The consequence patients will have long waiting times to access the service and the lack of availability of step down facilities to support the

Ref	Initial Score	Score as December 2023	Date Escalated to CRAF	Rationale
				acute centre will also result in delays. Risk score increased due to delays of funding release for Neuro to be revised following discussions around risk assessment verses financial plans.
Risk 48 (P/21/20) Wales Fertility Institute (WFI)	**16**	**20**	This has been on CRAF since May 2023, but increased from 16 to 20 in July 2023 and increased to 25 in November 2023	There is a risk the Wales Fertility Institute (WFI) in Neath & Port Talbot Hospital are not providing a safe and effective service due to concerns with regards to the information flows from the service into WHSSC; late submission of contract monitoring which does not reconcile with finance returns. There is a consequence that families who have treatment at this centre are not receiving the quality of care expected from the service and in turn impacting outcomes. **July-** Due to the HFEA inspection and the HB reporting that the service fragility is worse than expected the risk score has increased **November-** Due to the concerns with regards to the HFEA license/ person responsible, sustainability of the

Ref	Initial Score	Score as December 2023	Date Escalated to CRAF	Rationale
				service and the lack of assurance offered the service has been placed in escalation level 4.

3. De-escalated Risks

1 Organisational risk was de-escalated during the reporting period.

- **1** Welsh Kidney Network.

3 Commissioning risks were de-escalated during the reporting period:

- **1** Intestinal Failure,
- **1** Mental Health; and
- **1** Women and Children risk.

Reference	Score on CRAF	Score as at December 2023	Date de-escalated	Rationale
Risk 19 (WKN06) Renal Funding	**16**	**4**	July 2023	There is a risk that now there is an inability to meet service demand through ring fenced budget allocations that life maintaining treatment may not be available. As a consequence additional investment required through ICP process to sustain current services and manage growth and inflationary uplifts. Following confirmation of the approved growth funding agreed through ICP for 2023/24 position
Risk 49 (IF02) Calea Technical Issue	**15**	**8**	November 2023	There is a risk that the private provider Calea will again experience technical issues in the provision of HPN due to issues of compliance with standards which as a consequence will lead to issues of supply and potential patient harm WHHSC informed on the 24/10/23 that Calea were no longer in contingency

Reference	Score on CRAF	Score as at December 2023	Date de-escalated	Rationale
				measures and the service has returned to normal. CVUHB reported that there was no patient impact to be reported. Regular review meetings will continue with Calea
Risk 35 (MH/21/06) Bed Capacity Mental Health Patients	**16**	**12**	November 2023	There is a risk that mental health patients will be unable to gain a placement due to the lack of available UK beds, which as a consequence may result in inappropriate placement. D&C Report completed and the results have been taken into account in the development of the MH strategy.
Risk 44 (P/21/19) Paediatric cardiac surgery	**16**	**12**	December 2023	There is a risk that paediatric cardiac surgery patients referred to Bristol Children's Hospital, will have longer waits than is clinically appropriate due to lack of availability of a PIC bed within the Bristol Hospital. There is a consequence that the condition of the patient could deteriorate whilst waiting. In light of improved performance and recommendation to lower escalation level from 3 to 2 the risk score has been reduced within the likelihood domain, reducing the overall score.

4. Closed Risks

1 Commissioning risk was closed during the reporting period:

- **1** Mental Health.

Reference	Initial Score	Score as at date of Closing	Date Closed	Rationale
Risk 42 (MH/21/15) Referrals for adults with an eating disorder/disordered eating	**15**	**8**	November 2023	There is a risk that referrals for adults with an eating disorder/disordered eating, will require longer waiting times due to changes at NHSE and the loss of our main contract. The consequence is that additional placements may be needed, and admissions delayed due to the absence of ED beds in Wales. New unit being opened in Ebbw Vale

Report Title	**WHSSC Integrated Performance Report – November 2023**	**Agenda Item**	4.1
Meeting Title	**Joint Committee**	**Meeting Date**	30/01/2024
FOI Status	Open/Public		
Author (Job title)	Head of Information		
Executive Lead (Job title)	Director of Planning and Performance		

Purpose of the Report	The purpose of this report is to provide a summary of the performance of WHSSC commissioned services. Further detail by resident Health Board is provided in an accompanying Power BI Dashboard report.				
Specific Action Required	RATIFY ☐	APPROVE ☐	SUPPORT ☐	ASSURE ☐	INFORM ☒

Recommendation(s)

Members are asked to:

- **Note** the report

WHSSC INTEGRATED PERFORMANCE REPORT
NOVEMBER 2023

1.0 SITUATION

This report provides an integrated overview of the performance of services commissioned by WHSSC up to the end of November 2023.

Quality issues, services in escalation, financial performance, recovery rates, access comparisons across Health Boards and waiting lists are considered, along with the relevant Performance Measures set out by Welsh Government.

Breakdowns of the current data (inpatient activity, outpatient activity and patients waiting) by resident Health Board is provided in an associated Power BI report, available online to all direct recipients of this report and their colleagues, upon request. Health Boards can use the filters on that report to see their own individual positions.

2.0 BACKGROUND

The performance report is presented on a monthly basis to the WHSSC Corporate Directors Board and Management Group, and presented at each Joint Committee meeting. The purpose of the report is to provide a monthly overview of the performance of commissioned services and the measures that are being taken by the WHSST team with the provider if they are not performing in line with relevant contract requirements and/or Ministerial Measures.

3.0 ASSESSMENT

WHSSC has used the national data sources from DHCW, together with monthly contract monitoring information received from providers to inform this report. Members are asked to note that the DHCW data for Admitted Patient Care and Patients Waiting includes all Welsh activity at providers with a WHSSC contract, and also includes some non-specialist activity that may be included in local Health Board contracts. The DHCW data used in this report was refreshed on January 8th 2024; this data is available to all NHS Wales organisations on an anonymised basis, and is also the data that underlies the Welsh Government statistics reported online.

4.0 RECOMMENDATIONS

Members are asked to:

- **Note** the report.

Governance and Assurance	
Link to Strategic Objectives	
Strategic Objective(s)	Implementation of the Plan Governance and Assurance Choose an item.
Link to Integrated Commissioning Plan	This report provides assurance on delivery of the ICP.
Health and Care Standards	Governance, Leadership and Accountability Choose an item. Choose an item.
Principles of Prudent Healthcare	Reduce inappropriate variation Choose an item. Choose an item.
Institute for HealthCare Improvement Triple Aim	Reducing the per capita cost of health care Choose an item. Choose an item.
Organisational Implications	
Quality, Safety & Patient Experience	Any issues are identified in the report.
Finance/Resource Implications	Any issues are identified in the report.
Population Health	Any issues are identified in the report.
Legal Implications (including equality & diversity, socio economic duty etc)	Any issues are identified in the report.
Long Term Implications (incl. WBFG Act 2015)	Any issues are identified in the report.
Report History (Meeting/Date/ Summary of Outcome	
Appendices	

WHSSC Integrated Performance Report

November 2023

WHSSC

Contents

1. Key Information for November 2023

Services in escalation: At the end of December there were 9 services in escalation, the same as last month; there were 4 services at level 2, 4 services at level 3 and 1 service at level 4. There is also one related service which is under Welsh Government escalation (North Wales Plastics Outreach clinics).

As previously reported there are three Women and Children's services in CVUHB at Level 3 escalation. There are a number of themes underpinning these service risks; namely workforce, financial frameworks and regional service provision. All three services have been brought together for the purposes of managing the escalation, through monthly meetings covering all three sets of objectives, with action plans to address the underlying themes, particularly around workforce and quality.

Quality: There have been 10 incidents recorded within Quarter 1 (April-June 2023), and 14 within Quarter 2, with 23 so far in Quarter 3. There have been 8 complaints/concerns recorded within Quarter 1 (April-June 2023), and 16 within Quarter 2 (9 of which relate to the Wales Fertility Institute), with 4 so far in Quarter 3.

Finance: The annual budget for WHSSC is currently £1.07 billion, with about a quarter of this relating to EASC and NCCU budgets. At month 8 there is a year to date underspend of (£3.362m), and an improvement in the year end forecast position to an underspend of (£9.743m).

The Welsh provider performance variance has increased from £11.2m to £13.5m, with the main cost pressures in haemophilia blood products, cardiac devices and cardiology activity.

Welsh Government performance targets: At the end of Quarter 1 Welsh Government announced revised Ministerial Measures for 2023/24. The main ones affecting WHSSC services are the requirements to have:

- Improvement towards no patients waiting over 52 weeks for a new outpatient appointment, then leading to no patients waiting over 36 weeks.
- Improvement towards no patients waiting over 104 weeks for treatment (97% expected to achieve this by December 2023, and 99% by March 2024), then leading to no patients waiting over 52 weeks for treatment.
  All main specialty services are meeting the 104 week target, except for Plastic Surgery at Swansea Bay UHB. This service is in escalation (see section below).

Key Planned Care Specialties

Cardiac Surgery: By the end of November 2023, waiting lists for Cardiac Surgery treatments had halved at the Welsh providers compared to pre-Covid levels, although the waiting lists have increased at Liverpool Heart & Chest. Very few patients are currently waiting over 36 weeks. Work is underway to investigate the

continuing growth in the number of TAVI procedures and resultant impact on Cardiac Surgery as a whole.

Specialised Cardiology: The volume of specialist cardiology activity at Cardiff and Vale and Swansea Bay University Health Boards is significantly greater than that delivered by other providers, reflecting the greater range of procedures undertaken, population sizes, and the relative stage of development of the different services. Overall inpatient activity since 2021/22 has been relatively flat, noting a degree of (occasionally significant) month-on-month volatility.

Bariatric Surgery: Swansea Bay UHB's significant improvement in meeting contract volumes and waiting times in 2023/24 continues to be evident.

Thoracic Surgery: Whilst the Welsh centres are not performing to the full inpatient contract levels, waiting lists have improved compared to pre-Covid figures, and are approximately half of the total at the end of 2019/20. It is important to note that collaborative arrangements are in place between the two South Wales services to use their joint capacity to ensure equitable access.

Plastic Surgery: Patients continue to breach the Ministerial Measures waiting times for treatment at Swansea Bay UHB. There were 942 patients that were recorded at the end of November that have been waiting for inpatient treatment for over 1 year, including 353 that have been waiting over 2 years (down from 395 last month). In both categories this is a reduction from last month and the number of patients in both categories has been steadily reducing. The service has cleared the longest waiters for new outpatient appointments and is now achieving the WG performance target of no New outpatient waits over a year. The SBUHB service is at escalation Level 2 for performance reasons.

Small numbers of patients have been formally reported as waiting more than a year for any part of the pathway at Mersey & West Lancashire Trust (formerly known as St. Helens & Knowsley); there are also a small number at Countess of Chester, although this is a local BCU contract and not paid for through WHSSC. The BCUHB part of the North Wales pathway is in escalation via Welsh Government for quality reasons. Following investigation, the waiting times for the West and Central areas of BCUHB are now being reported to Welsh Government by the Health Board (not via the WHSSC contract). There are patients waiting over 156 weeks on the list and a backlog reduction exercise has commenced with an additional capacity planned which aims to improve the waiting list position and remove patients waiting over 156 weeks. Further work is being progressed in relation to the demand and capacity and backlog reduction plans to further improve the waiting list position.

Paediatric Surgery: The end of November position at Cardiff & Vale UHB includes 95 patients waiting over 1 year for treatment; however, the 104 week target for inpatient and 52 week target for first outpatient appointments continue to be met. The service is in Escalation level 3. In November the Joint Committee agreed an objective to achieve 52 weeks for inpatients by the end of March 2024 and the Health Board has provided a robust plan to achieve this.

Alder Hey NHS Foundation Trust has reported that activity is higher than pre-Covid and the small number (<5) of patients waiting over 52 weeks was cleared during the summer.

Paediatric ICU (PICU): The C&VUHB service was put into escalation Level 3 in September, around concerns regarding capacity, staffing levels, bed availability and related adverse incidents. Weekly data has been requested to monitor the service, along with regular update meetings.

Neonatal ICU (NICU): Badgernet is the system that collates all the NICU activity from Welsh providers. The patient level data for analysis has historically been received annually, but it has recently been agreed that WHSSC will receive this monthly going forward. The service was put into escalation Level 3 in September for reasons of quality and cot availability.

In-Vitro Fertilisation (IVF): A number of concerns regarding the safety and quality of service at the Welsh Fertility Institute (WFI) have been raised through different routes, including the HFEA re-inspection report of January 2023, WHSSC Quality and Assurance meetings, and WFI/IPFR requests. WFI was placed into escalation level 3 in July 2023, and due to increasing concerns with regards to the HFEA licence the escalation level was increased to level 4 at the end of October.

Neurosurgery: The C&VUHB service have met the Welsh Government target of zero patients waiting over 52 weeks. In November 2023 there were 9 patients waiting over 36 weeks for admission, intentions are that these will be cleared by March 2024.

The Walton Centre performance trajectory was discussed at a recent SLA meeting, and there are now no patients waiting over 52 weeks. There were 21 patients in September 2023 waiting over 36 weeks, and the centre still plan to clear the backlog by March 2024. WHSSC will continue to monitor the situation at the regular quarterly SLA meetings.

Performance of other areas by exception

PET: Breaches of the 10-day turnaround time for reports had been gradually increasing at all centres. This was due to increased demand over the past 4 years, and scanner breakdowns. A first in the UK digital scanner became live in Cardiff in July 2023. Although image optimisation is still ongoing, the site in Cardiff capacity has increased from 75 to 91 scans per week. Business cases are expected from SBUHB (fully tendered single case) and BCUHB (OBC) shortly.

Artificial Limbs Service: Posture & Mobility and Prosthetics - after an initial lull in referrals since Covid-19, these have now increased again. There has been a significant reduction in numbers waiting since last month with 8 patients waiting over 52 weeks for the North Wales Posture and Mobility services, and 14 in total for the Cardiff/Swansea services.

CAMHS: CAMHS Out of Area (OoA) performance is much improved and has been consistently below target for an extended period. The NHS inpatient units are close again to pre-Covid activity levels. The FACTS service was de-escalated completely in August 2023, and Ty Llidiard in September 2023.

Adult Medium Secure: While both NHS inpatient units are delivering fewer bed-days than pre-Covid, the use of other providers has increased. Performance meetings are occurring with both units monthly to monitor progress and a repatriation plan is in place for each unit and is on profile.

Neuropsychiatry: A risk has been logged internally that Neuropsychiatry patients may not be able to be treated in a timely manner with the appropriate therapy support, due to staffing issues within the Cardiff & Vale service. Consequently, patients may have long waiting times to access the service, and the lack of availability of step down facilities to support the acute centre may also result in delays.

Renal Network: There are 3 regional providers of renal activity, with various over and underperforming service areas. Dialysis demand has been increasing over recent years.

English provider activity (those with a WHSSC contract, DHCW data): On average, English provider activity is 3% lower to date in 2023/24 than in 2019/20. It is noteworthy that A&E and Trauma are still seeing lower levels within that (18% less to date), which indicates higher recovery in the other treatment specialties.

Episodes by provider - full years except current year (data: DHCW inpatient episodes)

Main HB	2019/20	2021/22	2022/23	2023/24	Total	2019/20 (M1-8)	2021/22 (M1-8)	2022/23 (M1-8)	2023/24 (M1-8)	Episodes 2023/24 % diff from 19/20
⊞	4,213	3,515	3,711	2,883	14,322	2,957	2413	2,513	2,883	-3%
⊞ Major North Wales provider	14,853	12,731	13,278	9,251	50,113	10,008	8423	9,013	9,251	-8%
⊞ Major Powys provider	17,650	15,685	16,768	11,887	61,990	11,913	10668	11,182	11,887	-0%
Total	36,716	31,931	33,757	24,021	126,425	24,878	21504	22,708	24,021	-3%

Summary of main specialty inpatient activity and waiting lists (DHCW data):

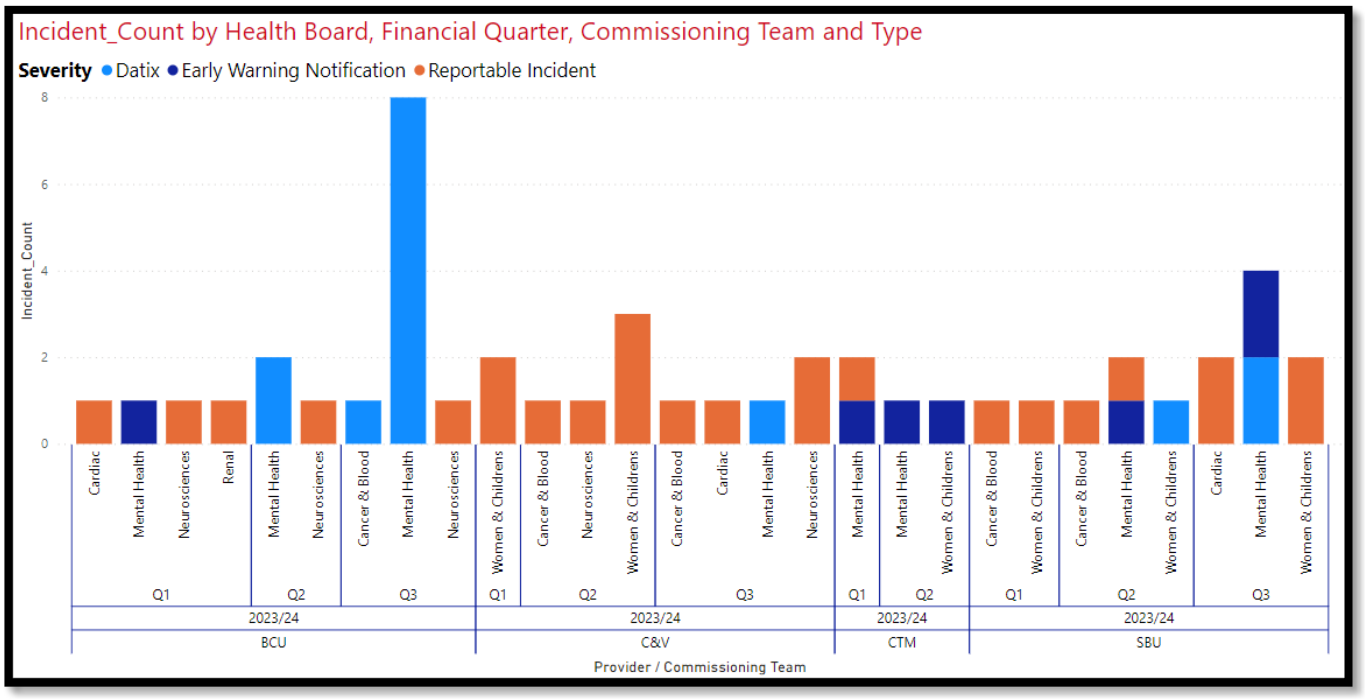
Episode comparison to current month (DHCW data warehouse)						Current Waiting List totals (DHCW data)				
Specialty_WHSSC	Episodes for 2019/20 (M1-8)	Episodes for 2021/22 (M1-8)	Episodes for 2022/23 (M1-8)	Episodes for 2023/24 (M1-8)	Episodes 2023/24 % diff from 19/20	202306 Admitted diagnostic intervention	FUP OP appointment	New OP appointment	Unknown	Total
Cardiac Surgery	**1,453**	**1208**	**1,259**	**1,232**	**-15%**	**126**	**53**	**94**	**220**	**493**
Cardiff and Vale University Local Health Board	558	436	446	422	-24%	87	35	48		170
Liverpool Heart And Chest Hospital nhs foundatio	293	317	290	328	12%				210	210
Swansea Bay University Local Health Board	511	390	421	411	-20%	39	18	46		103
University Hospitals Birmingham Nhs Foundation t	47	30	52	48	2%				5	5
University Hospitals Of North Midlands nhs trust	44	35	50	23	-48%				5	5
Neurosurgery	**2,285**	**1927**	**1,993**	**1,976**	**-14%**	**226**	**135**	**392**	**532**	**1,285**
Cardiff and Vale University Local Health Board	1,452	1240	1,313	1,301	-10%	226	135	392		753
The Walton Centre Nhs Foundation trust	734	587	595	576	-22%				514	514
University Hospitals Of North Midlands nhs trust	99	100	85	99	0%				18	18
Paediatric Surgery	**1,973**	**1515**	**1,587**	**1,560**	**-21%**	**486**	**85**	**291**		**862**
Alder Hey Children's Nhs Foundation trust	294	228	280	251	-15%					
Cardiff and Vale University Local Health Board	1,679	1287	1,307	1,309	-22%	486	85	291		862
Plastic Surgery	**7,746**	**5847**	**6,110**	**6,571**	**-15%**	**2,607**	**239**	**1,169**	**453**	**4,468**
Countess Of Chester Hospital Nhs foundation trus	465	319	361	453	-3%					
Mersey and West Lancashire nhs trust	936	738	810	897	-4%				453	453
Swansea Bay University Local Health Board	6,345	4790	4,939	5,221	-18%	2,607	239	1,169		4,015
Thoracic Surgery	**914**	**872**	**846**	**941**	**3%**	**66**	**107**	**59**	**30**	**262**
Cardiff and Vale University Local Health Board	428	423	380	453	6%	44	96	45		185
Liverpool Heart And Chest Hospital nhs foundatio	150	196	177	195	30%				29	29
Swansea Bay University Local Health Board	314	232	266	276	-12%	22	11	14		47
University Hospitals Of North Midlands nhs trust	22	21	23	17	-23%				1	1
Total Specialty	**14,371**	**11369**	**11,795**	**12,280**	**-15%**	**3,511**	**619**	**2,005**	**1,235**	**7,370**

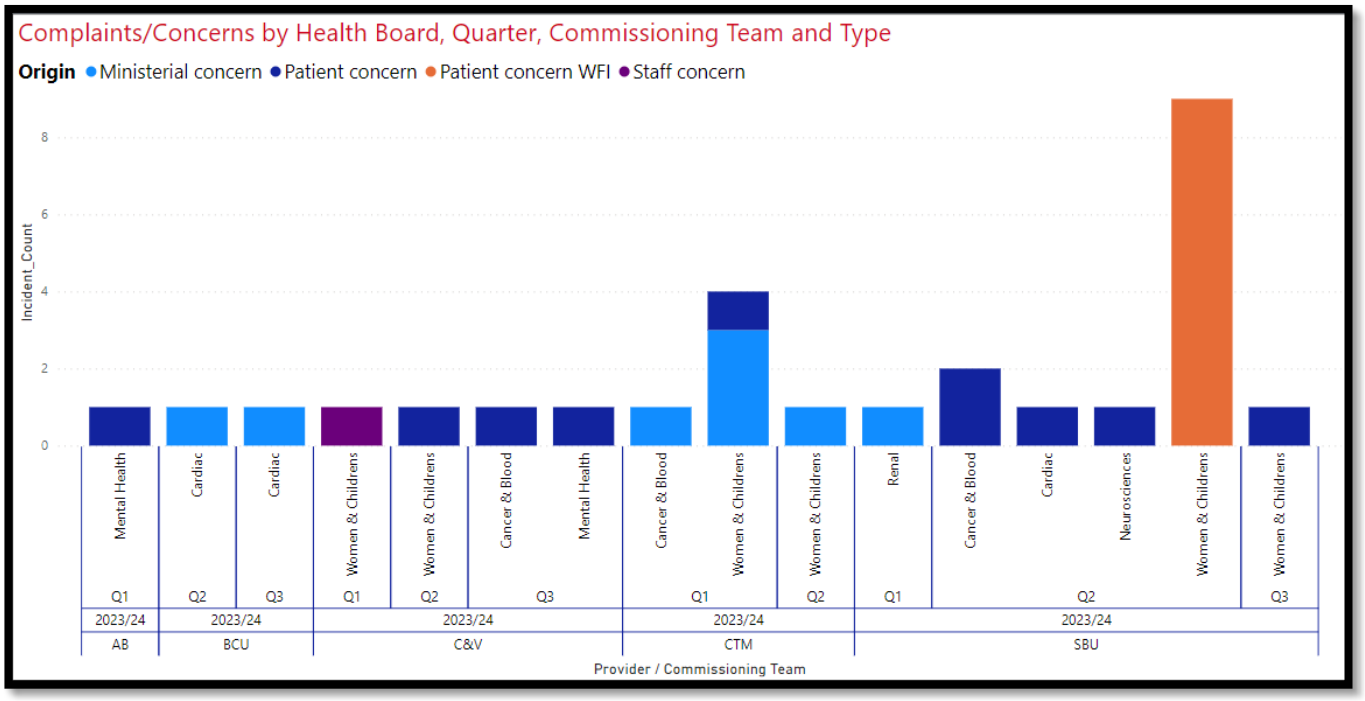
2. Overview of services in escalation

Escalation level	Movement	Provider	Service	Notes
WG Escalation	same	English providers	Plastic Surgery Outreach	Note: Welsh Government leading the escalation process along with a wider escalation of Dermatology issues in North Wales
Level 4	same	Swansea Bay UHB	Welsh Fertility Institute (WFI)	In escalation since June 2023 due to concerns about the safety and quality of the service at the Welsh Fertility Institute (WFI). These were identified by a Human Fertilisation and Embryology Authority (HFEA) inspection report, leading the service being placed in escalation level 3. Further raised to level 4 in October 2023.
Level 3	same	Cardiff & Vale UHB	Neonatal Intensive Care (NICU)	In escalation since September 2023 due to similar concerns about PICU and Paediatric Surgery at C&VUHB. These concerns are being jointly addressed at Executive level.
Level 3	same	Cardiff & Vale UHB	Paediatric Intensive Care	In escalation since May 2023 due to concerns regarding capacity, staffing levels, bed availability and related adverse incidents. Weekly data has been requested to monitor the service, along with regular update meetings.
Level 3	same	Cardiff & Vale UHB	Paediatric Surgery	In escalation since November 2022, level increased to Level 3 in March 2023; weekly performance data requested to give assurance on delivery against baseline for future recovery, and monthly escalation meetings being held.
Level 3	same	University Hospitals Bristol & Western Foundation Trust	Paediatric Cardiac Surgery	In escalation since October 2023 due to concerns about the waiting times for patients and the pace of improvement in this. An action plan is being developed by the Children's Hospital.
Level 2	same	Cardiff & Vale UHB	Cardiac Surgery	In escalation since July 2021 for not implementing the GIRFT review or addressing issues identified by HEIW; SMART action plan has now been developed, leading to de-escalation to Level 2 in May 2023.
Level 2	same	Swansea Bay UHB	Adult Burns	In escalation since November 2021; At the time of initial escalation, the burns service at SBUHB was unable to provide major burns level care due to staffing issues in burns ITU. An interim model was put in place allowing the service to reopen in February 2022. The current escalation concerns the progress of the capital case for the long term solution and sustainability of the interim model. Estimated capital completion: end of 2023. De-escalated to level 2 in December 2023.
Level 2	same	Swansea Bay UHB	Cardiac Surgery	In escalation since July 2021 due to GIRFT review highlighting a high rate of poor clinical outcomes; de-escalated on immediate actions required by GIRFT review. De-escalation to Level 2 implemented in March 2023.
Level 2	same	Swansea Bay UHB	Plastic Surgery	In escalation since November 2022 due to significant waiting list numbers including long waiters over 2 years, escalation increased to level 2 in July 2023
Total				

Please see the bi-monthly Quality & Patient Safety (QPS) reports from the Quality team for more details.

3. Quality Dashboard





There have been 10 incidents recorded within Quarter 1 (April-June 2023), 14 within Quarter 2, with 23 so far in Quarter 3. There have been 8 complaints/concerns recorded within Quarter 1, 16 within Quarter 2 (9 of which relate to the Wales Fertility Institute), with 4 so far in Quarter 3.

Please see the bi-monthly Quality & Patient Safety (QPS) reports from the Quality team for more details.

4. Financial Summary

Heading	Annual Budget £'000	Actual to Date £'000	Variance to date £'000	Forecast Variance Year-end £'000
Income	**(1,070,368)**	**(713,579)**	**3,362**	**9,743**
Spend - NHS Wales				
Aneurin Bevan Health Board	11,773	8,335	486	729
Betsi Cadwaladr University Health Board Provider	48,118	32,623	544	816
Cardiff & Vale University Health Board	291,470	197,530	3,217	5,304
Cwm Taf Morgannwg University Health Board	11,246	7,497	-	-
Hywel Dda Health Board	2,110	1,407	-	-
Swansea Bay University Health Board	124,133	86,269	3,514	5,271
Velindre NHS Trust	56,290	38,427	900	1,405
Total	**545,139**	**372,087**	**8,662**	**13,526**
Spend - Other				
2021/22 Reserves	-	(10,183)	(10,183)	(15,274)
2022/23 Plan Developments	34,801	13,791	(9,410)	(13,705)
Direct Running Costs	5,042	3,553	192	(36)
EASC (incl WAST and EASC/QAT team costs)	254,486	169,643	(14)	(21)
IPFR	60,149	41,374	1,275	(697)
IVF	5,071	3,326	(55)	(173)
Mental Health	43,147	31,142	2,377	2,355
Non Welsh SLAs	129,059	89,857	3,818	4,312
Phasing adjustment	-	-	-	-
Prior Year Developments	(11,510)	(7,145)	528	698
Renal	4,984	2,771	(552)	(729)
Total	**525,230**	**338,130**	**(12,024)**	**(23,269)**
Total	**(0)**	**(3,362)**	**0**	**0**

At month 8 there is a year to date underspend of (£3.362m), and an improvement in the year forecast position to an underspend of (£9.743m).

The Welsh provider performance forecast variance has increased from £11.2m to £13.5m, with the main cost pressures remaining in haemophilia blood products, cardiac devices and cardiology activity. The NHS England provider performance continues at £4.3m above baseline particularly for pass through drugs and devices.

The Mental Health forecast position has deteriorated by £1.4m, as provision for 2 excessive high cost complex patients that have presented within CAMHS and Eating disorders in November, are included in the year to date position whilst funding responsibility is clarified.

The target ICP savings of (£9.2m) are currently assessed to be £0.698m off track at M8 and this is mitigated by a number of plan provisions and prior year releases that are supporting the forecast year end position. An assessment of the non-recurrent slippage, savings and reserve releases supporting the current in year forecast, is that there is an underlying funding deficit of £12m carried forward into to 2024/25.

Further savings identified to contribute towards the additional 1% pathway savings requirement are assessed at (£5m) and these are included in the M8 forecast underspend of (£9.7m).

Please see the monthly Finance report and Risk-sharing tables for more details.

5. Welsh Government Performance measures

New performance measures were announced by Welsh Government in January 2022, with a new Performance Framework for 2022/23. Some targets were amended in June 2023/24 for this current financial year. The measures relevant to WHSSC activity are listed below:

Performance Measure		Target	Reporting Frequency	Source	Ministerial Priority	Status
28	**Number of patients waiting more than 52 weeks for a new outpatient appointment**	**Improvement trajectory towards a national target of zero**	**Monthly**	**Referral to Treatment (combined) Dataset (DHCW)**	**Planned Care Recovery, Diagnostics & Pathways of Care**	**Revised**
		Rationale: The number of patients waiting for a new outpatient appointment has increased year on year whilst capacity has been unable to meet demand. NHS organisations are required to improve service planning and clinical pathways to deliver sustainable planned care services, where waiting lists are reduced to a manageable level.				
29	**Number of patients waiting more than 36 weeks for a new outpatient appointment**	**Improvement trajectory towards a national target of zero**	**Monthly**	**Referral to Treatment (combined) Dataset (DHCW)**	**Planned Care Recovery, Diagnostics & Pathways of Care**	**New**
		Rationale: As above.				
31	**Number of patients waiting more than 104 weeks for referral to treatment**	**Improvement trajectory towards a national target of zero**	**Monthly**	**Referral to Treatment (combined) Dataset (DHCW)**	**Planned Care Recovery, Diagnostics & Pathways of Care**	**Revised**
		Rationale: Patients receiving timely access to high quality elective treatment and care should experience improved outcomes. Reducing the time that a patient waits for treatment reduces the risk of the condition deteriorating and alleviates the patient's symptoms, pain and discomfort sooner. This measure provides greater transparency and encourages improvement in the timeliness of treatment across NHS services.				
32	**Number of patients waiting more than 52 weeks for referral to treatment**	**Improvement trajectory towards a national target of zero**	**Monthly**	**Referral to Treatment (combined) Dataset (DHCW)**	**Planned Care Recovery, Diagnostics & Pathways of Care**	**New**
		Rationale: As above.				

Welsh Government have confirmed that there are no target dates for the revised targets, but they expect over 97% of NHS Wales services to meet the 104 week treatment target by December 2023, and 99% by March 2024.

Most services are meeting the required trajectories; please see the detailed pages in the underlying WHSSC Performance Dashboard report in Power BI for specific figures, including splits by resident Health Board.

The exceptions/services worth noting are (October 2023 DHCW data):

- Plastic Surgery (Swansea Bay UHB) – 942 waiting over 52 weeks for treatment, including 353 waiting over 104 weeks. This is an improvement from 958 waiting over 52 weeks, and 395 over 104 weeks in last month's report.
- Paediatric Surgery (Cardiff & Vale UHB) – 95 waiting over 52 weeks for treatment
- English providers – of the main specialist specialties that WHSSC reports on, there were 105 patients that had been waiting longer than 52 weeks in total across all parts of the pathway (ie. inpatients and outpatients totalled together). WHSSC has been working with DHCW to start separating the pathway stages in the English provider data shortly, where possible.

6. Service Performance Scorecard

Performance Scorecard

Specialty / Provider Name	Measure	Tolerance Levels			Sep 2023		Oct 2023		Nov 2023		Latest Movement
Cardiac Surgery	RTT < 36 weeks - admissions	<95%	95-99%	100%	86.03%	⊗	95.37%	◐	94.70%	⊗	↓
Cardiothoracic Surgery	RTT < 36 weeks - admissions	<95%	95-99%	100%	100.00%	✓	#DIV/0!		#DIV/0!		
Neurosurgery	RTT < 36 weeks - admissions	<95%	95-99%	100%	97.24%	◐	98.92%	◐	98.85%	◐	↓
Paediatric Surgery	RTT < 36 weeks - admissions	<95%	95-99%	100%	71.22%	⊗	73.71%	⊗	76.28%	⊗	↑
Plastic Surgery	RTT < 36 weeks - admissions	<95%	95-99%	100%	65.18%	⊗	66.56%	⊗	67.44%	⊗	↑
Spinal Surgery Service	RTT < 36 weeks - admissions	<95%	95-99%	100%	78.13%	⊗	#DIV/0!		#DIV/0!		
Thoracic Surgery	RTT < 36 weeks - admissions	<95%	95-99%	100%	93.53%	⊗	95.36%	◐	92.18%	⊗	↓
Bariatric Surgery	RTT < 36 weeks - admissions	<95%	95-99%	100%	67.19%	⊗	70.49%	⊗	74.24%	⊗	↓
PET Scans	Pet scan < 10 days after referral	<90%	90-95%	>=95%	82.59%	⊗	81.48%	⊗	63.71%	⊗	↓
Posture & Mobility RTT - Adult	RTT < 36 weeks	<90%	90-95%	>=95%	94.09%	◐	94.12%	◐	↑		
Posture & Mobility RTT - Paeds	RTT < 36 weeks	<90%	90-95%	>=95%	95.68%	✓	96.89%	✓	↑		
CAMHS Beddays (excl. Out of Area)	NHS Beddays against contract	<85%,>105%	< 90%, >100%	90% - 100%	66.67%	⊗	67.57%	⊗	78.98%	⊗	↑
CAMHS Home Leave (excl. Out of Area)	NHS Home Leave against total	<20%, >40%	<25%, >35%	25%-35%	18.99%	⊗	14.12%	⊗	20.49%	◐	↑
Medium Secure Beddays	NHS Beddays against contract	<90%,>110%	< 95%, >105%	95% - 105%	76.37%	⊗	80.99%	⊗	77.62%	⊗	↓

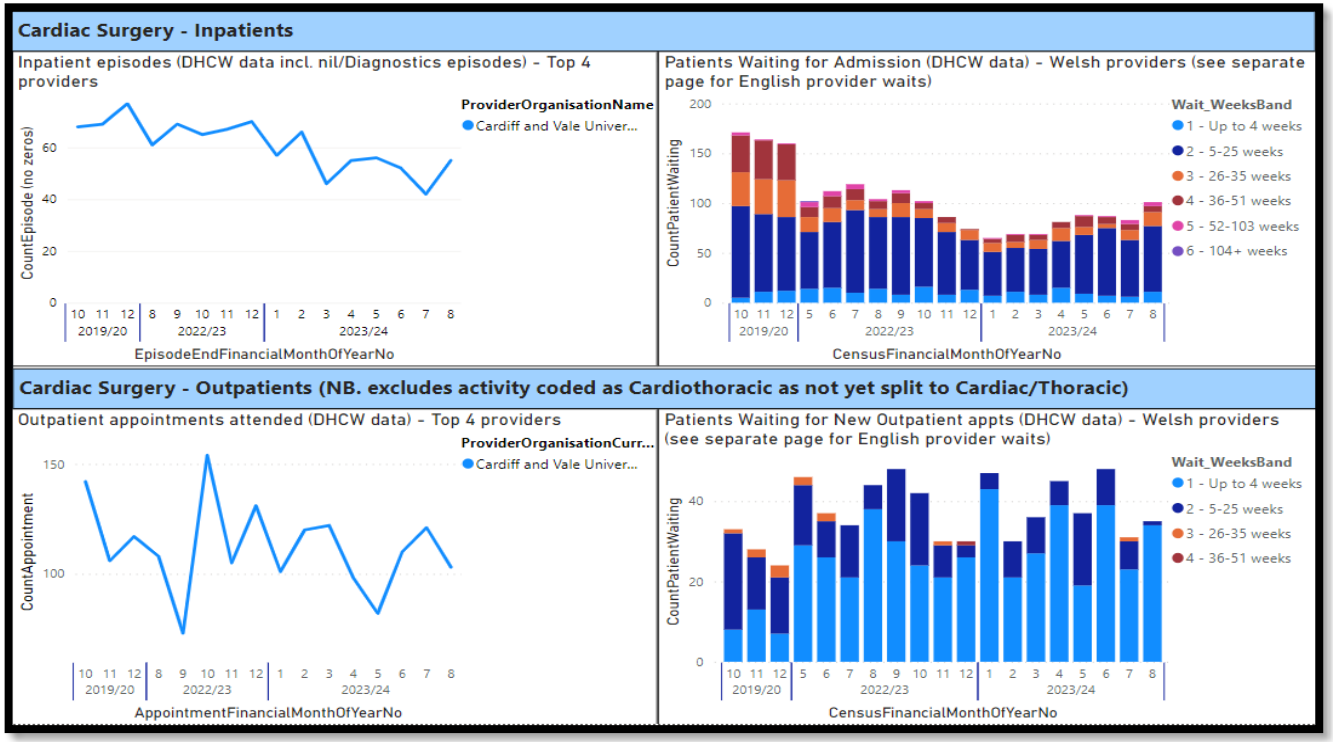
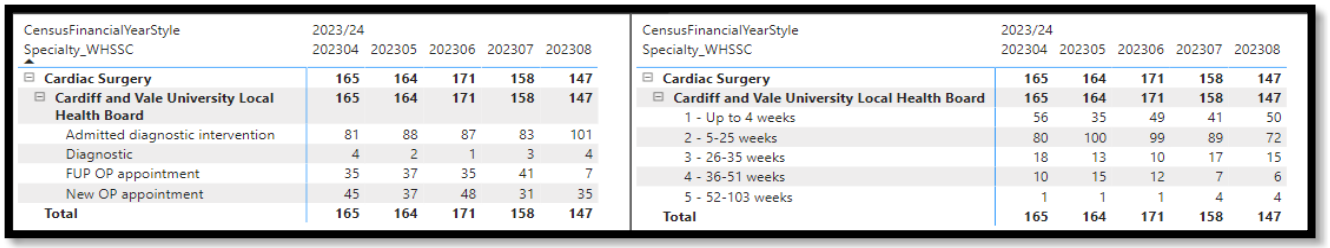
Welsh Government Post COVID Targets

Note: OP figures relate to Welsh providers only as pathway stage not known for English providers

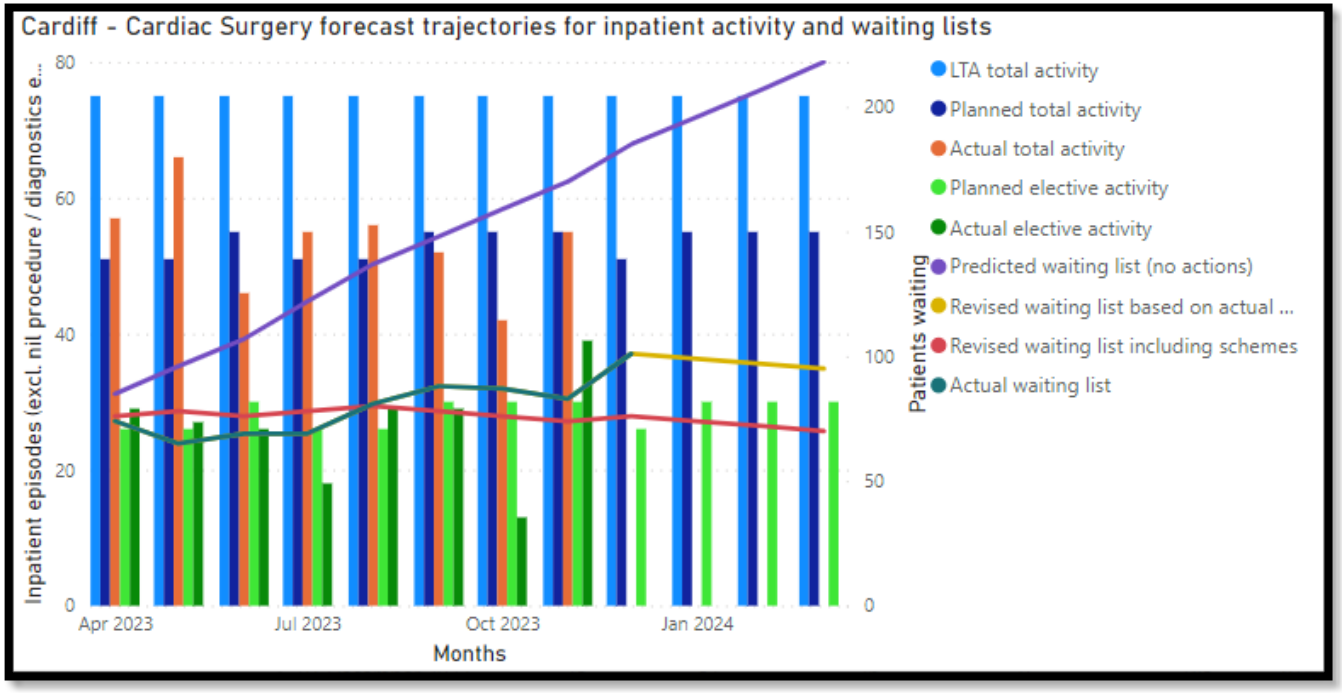
Cardiac Surgery	RTT < 105 weeks - admissions	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Cardiothoracic Surgery	RTT < 105 weeks - admissions	<95%	95-99%	100%	100.00%	✓	#DIV/0!		#DIV/0!		
Neurosurgery	RTT < 105 weeks - admissions	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Paediatric Surgery	RTT < 105 weeks - admissions	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Plastic Surgery	RTT < 105 weeks - admissions	<95%	95-99%	100%	90.63%	⊗	90.74%	⊗	91.95%	⊗	↑
Spinal Surgery Service	RTT < 105 weeks - admissions	<95%	95-99%	100%	100.00%	✓	#DIV/0!		#DIV/0!		
Thoracic Surgery	RTT < 105 weeks - admissions	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Bariatric Surgery - Swansea Bay UHB	RTT < 105 weeks - admissions	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Bariatric Surgery - Salford Royal	RTT < 105 weeks - admissions	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Cardiac Surgery	RTT < 52 weeks - admissions	<95%	95-99%	100%	95.72%	◐	98.58%	◐	98.68%	◐	↑
Cardiothoracic Surgery	RTT < 52 weeks - admissions	<95%	95-99%	100%	100.00%	✓	#DIV/0!		#DIV/0!		
Neurosurgery	RTT < 52 weeks - admissions	<95%	95-99%	100%	99.77%	◐	100.00%	✓	100.00%	✓	→
Paediatric Surgery	RTT < 52 weeks - admissions	<95%	95-99%	100%	85.20%	⊗	86.35%	⊗	89.15%	⊗	↑
Plastic Surgery	RTT < 52 weeks - admissions	<95%	95-99%	100%	77.99%	⊗	76.52%	⊗	77.39%	⊗	↑
Spinal Surgery Service	RTT < 52 weeks - admissions	<95%	95-99%	100%	90.63%	⊗	#DIV/0!		#DIV/0!		
Thoracic Surgery	RTT < 52 weeks - admissions	<95%	95-99%	100%	99.28%	◐	98.73%	◐	98.32%	◐	↓
Bariatric Surgery	RTT < 52 weeks - admissions	<95%	95-99%	100%	82.81%	⊗	80.33%	⊗	86.36%	⊗	↓
Cardiac Surgery	< 36 weeks for First OP	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Neurosurgery	< 36 weeks for First OP	<95%	95-99%	100%	100.00%	✓	100.00%	✓	99.52%	◐	↓
Paediatric Surgery	< 36 weeks for First OP	<95%	95-99%	100%	87.76%	⊗	90.33%	⊗	91.77%	⊗	↑
Plastic Surgery	< 36 weeks for First OP	<95%	95-99%	100%	94.87%	⊗	97.32%	◐	99.27%	◐	↑
Thoracic Surgery	< 36 weeks for First OP	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Bariatric Surgery - Swansea Bay UHB	< 36 weeks for First OP	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Cardiac Surgery	< 52 weeks for First OP	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Neurosurgery	< 52 weeks for First OP	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Paediatric Surgery	< 52 weeks for First OP	<95%	95-99%	100%	95.57%	◐	97.71%	◐	98.20%	◐	↑
Plastic Surgery	< 52 weeks for First OP	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Thoracic Surgery	< 52 weeks for First OP	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→
Bariatric Surgery - Swansea Bay UHB	< 52 weeks for First OP	<95%	95-99%	100%	100.00%	✓	100.00%	✓	100.00%	✓	→

7. Specific Service details

7.1 Cardiac Surgery

Cardiff & Vale UHB - Performance data and forecasts	Current Performance
Cardiac Surgery current performance:  Waiting list analysis:  CensusFinancialYearStyle: 2023/24 Specialty_WHSSC: 202304 202305 202306 202307 202308 Cardiac Surgery: 165 164 171 158 147 Cardiff and Vale University Local Health Board: 165 164 171 158 147 Admitted diagnostic intervention: 81 88 87 83 101 Diagnostic: 4 2 1 3 4 FUP OP appointment: 35 37 35 41 7 New OP appointment: 45 37 48 31 35 Total: 165 164 171 158 147 CensusFinancialYearStyle: 2023/24 Specialty_WHSSC: 202304 202305 202306 202307 202308 Cardiac Surgery: 165 164 171 158 147 Cardiff and Vale University Local Health Board: 165 164 171 158 147 1 - Up to 4 weeks: 56 35 49 41 50 2 - 5-25 weeks: 80 100 99 89 72 3 - 26-35 weeks: 18 13 10 17 15 4 - 36-51 weeks: 10 15 12 7 6 5 - 52-103 weeks: 1 1 1 4 4 Total: 165 164 171 158 147	Inpatient waits had been decreasing, but have begun to gradually increase over the past few months, and the number of longer waiters has increased slightly. WHSSC has been advised that recent falls in activity have been a result of staff availability. To address these concerns, the Cardiac Surgery service has advertised for two additional anaesthetists, and although the agency scrub team that had previously helped to maintain capacity are no longer engaged, the concerns with capacity that compelled the team's retention are understood to have been addressed. Cardiff and Vale have also highlighted evidence that referrals have still not returned to pre-pandemic levels, and it is planned that the risk of an unanticipated increase in referrals included on the Cardiac Commissioning Team Risk Register is due to be removed. Waits will continue to be monitored via Risk, Recovery and Assurance meetings with a view to ensuring that recent progress is maintained. These meetings are also used to discuss the service's escalation status (currently level 2), mindful that the service believes that the delivery of many of the remaining escalation actions are dependent on the

Cardiac Surgery 2023/24 forecasts:



repatriation of the service back to the University Hospital of Wales.

What actions are WHSSC taking?

WHSSC is continuing to investigate the growth in the number of TAVI procedures, the profile of devices employed, and any resultant impact on the volume of WHSSC-commissioned cardiac surgery. It was agreed in January 2023 that this work would be taken forward as a two-phase review.

Phase 1 will seek to re-baseline the TAVI/cardiac surgery contract, ascertain whether the TAVI policy remains fit for purpose, and consider the differential costs of TAVI valve types. The outcomes of Phase 1 will be reported to Management Group in December 2023, to be followed by a negotiation with health boards relating to the TAVI/cardiac surgery contract.

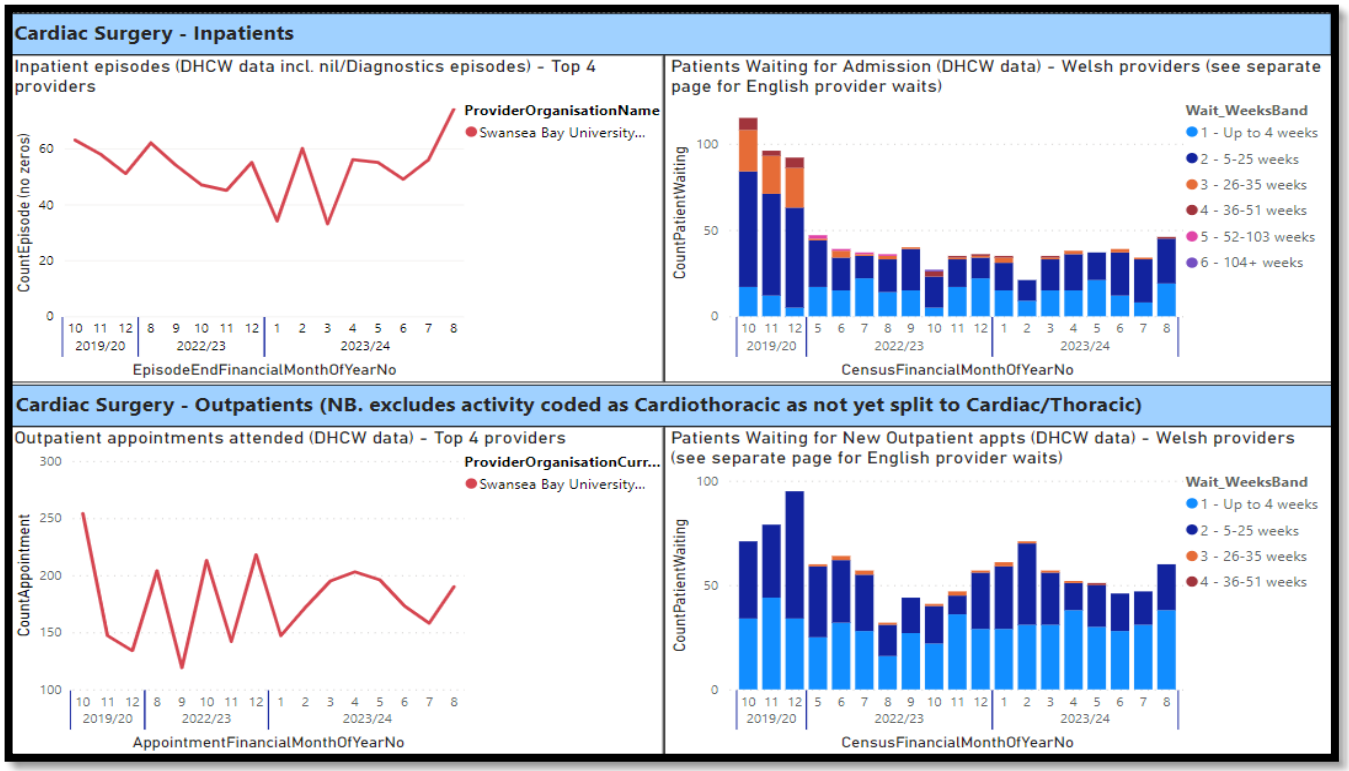
What are the main areas of risk?

At this point, Cardiff looks on track to hit the WG target of no waiters for admissions over 52 weeks, with just 4 patient waiting over this at the end of November 2023.

The service is not planning to meet the contracted inpatient levels, but lower demand is currently allowing the levels of patients waiting not to increase. However, the Health Board forecasts includes assumptions of additional activity through a sustainable theatre staffing/ agency scheme, plus the recruitment of a 6th consultant. If these do not materialise, the waiting lists would increase.

Swansea Bay UHB - Performance data and forecasts

Cardiac Surgery current performance:



Waiting list analysis:

CensusFinancialYearStyle	2023/24				
Specialty_WHSSC	202304	202305	202306	202307	202308
Cardiac Surgery	**127**	**130**	**130**	**123**	**155**
Swansea Bay University Local Health Board	**127**	**130**	**130**	**123**	**155**
Admitted diagnostic intervention	38	37	39	34	46
Diagnostic	10	14	27	16	17
FUP OP appointment	27	28	18	26	32
New OP appointment	52	51	46	47	60
Total	**127**	**130**	**130**	**123**	**155**

CensusFinancialYearStyle	2023/24				
Specialty_WHSSC	202304	202305	202306	202307	202308
Cardiac Surgery	**127**	**130**	**130**	**123**	**155**
Swansea Bay University Local Health Board	**127**	**130**	**130**	**123**	**155**
1 - Up to 4 weeks	62	56	45	43	64
2 - 5-25 weeks	61	68	76	71	81
3 - 26-35 weeks	3	5	9	7	4
4 - 36-51 weeks	1	1		2	6
Total	**127**	**130**	**130**	**123**	**155**

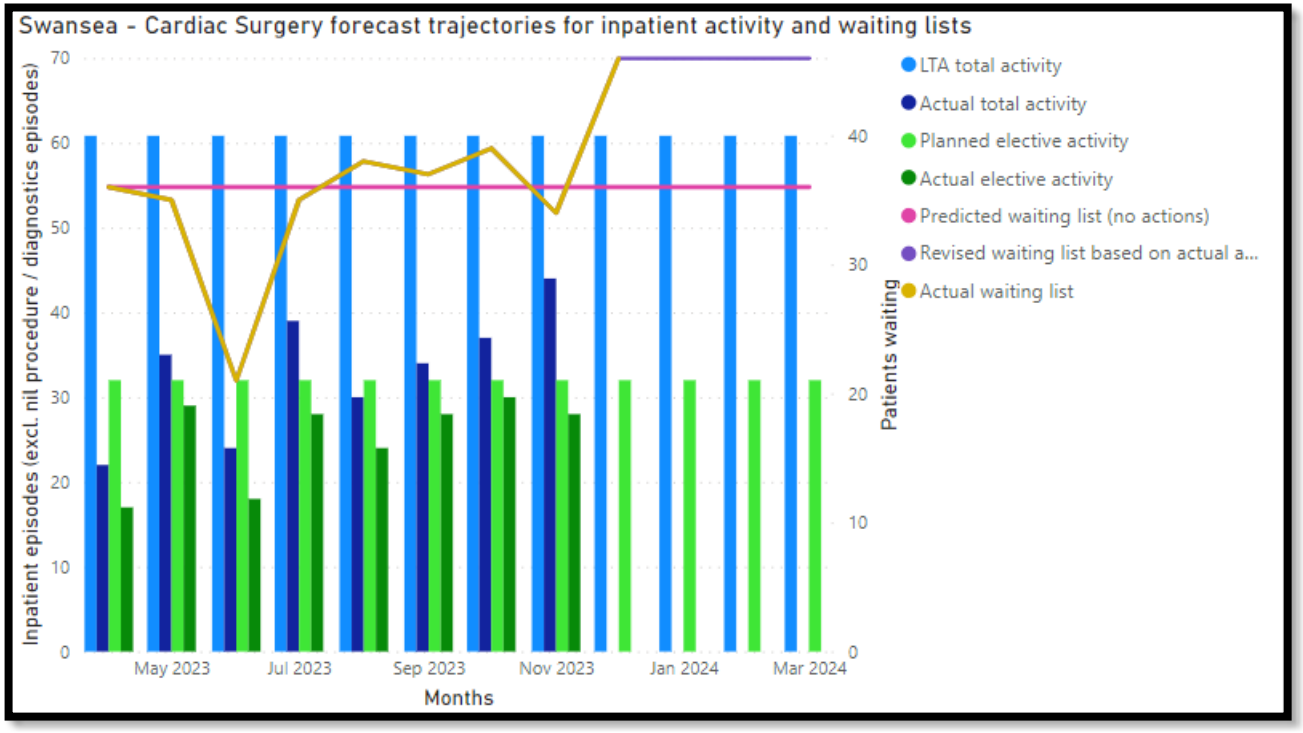
Current Performance

The data indicates a decrease in the number of inpatient waiters though 2022/23, followed by a more variable picture during 2023/24. A decrease in the number of outpatient waiters through 2023/24 is also evident. Both inpatient and outpatient waits are notable for the very small number of longer waiters, with the majority of patients waiting up to 4 weeks, or between 4 and 25 weeks.

The cardiac surgery service has highlighted that it has additional inpatient capacity, which has been offered to NHSE cardiac surgery centres as a way of ameliorating ongoing service pressures. At the time of writing (December 2023), it is understood that this offer is yet to be taken up.

The monitoring of Welsh patients will continue to be undertaken via cardiac services Risk, Assurance and Recovery meetings. These meeting are also used to monitor the Cardiac Surgery service's current escalation status (currently Level 2). It had been planned that the service's escalation level would be discussed by the Commissioning Team in December 2023 following the planned submission of an escalation actions update by the cardiac surgery service, but this submission was delayed, and the service will remain in level 2 until discussed in 2024.

Cardiac Surgery 2023/24 forecasts:



What actions are WHSSC taking?

WHSSC is continuing to investigate the growth in the number of TAVI procedures, the profile of devices employed, and any resultant impact on the volume of WHSSC-commissioned cardiac surgery. It was agreed in January 2023 that this work would be taken forward as a two-phase review.

Phase 1 will seek to re-baseline the TAVI/cardiac surgery contract, ascertain whether the TAVI policy remains fit for purpose, and consider the differential costs of TAVI valve types. The outcomes of Phase 1 will be reported to Management Group in December 2023, to be followed by a negotiation with health boards relating to the TAVI/cardiac surgery contract.

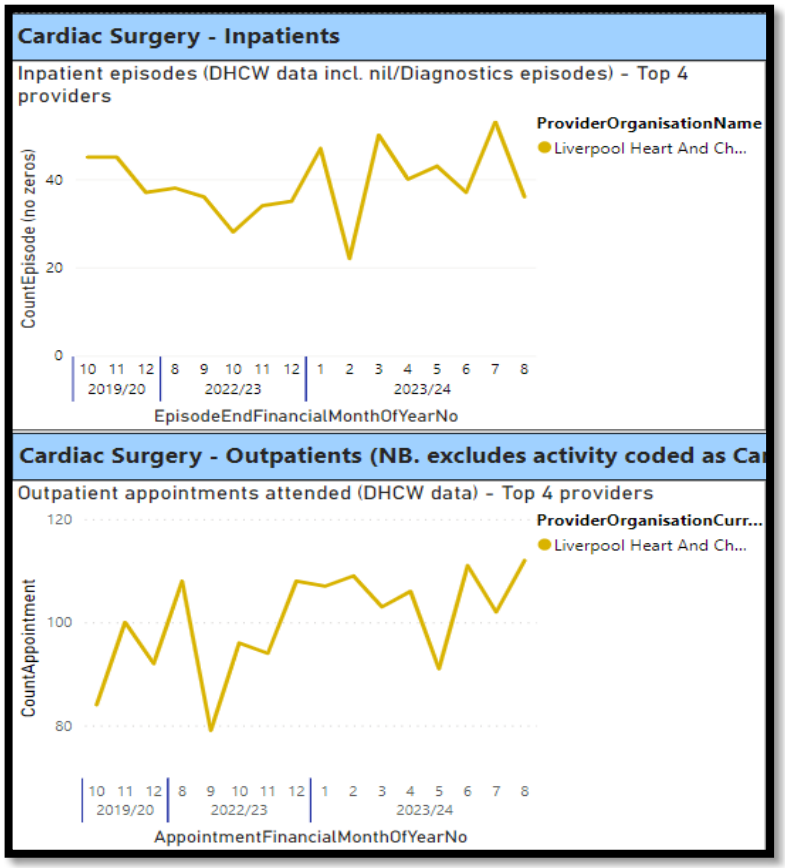
What are the main areas of risk?

Swansea Bay has hit the WG target of no waiters for admissions over 52 weeks, with the longest current waiters being 1 patient in the 36-51 week wait band.

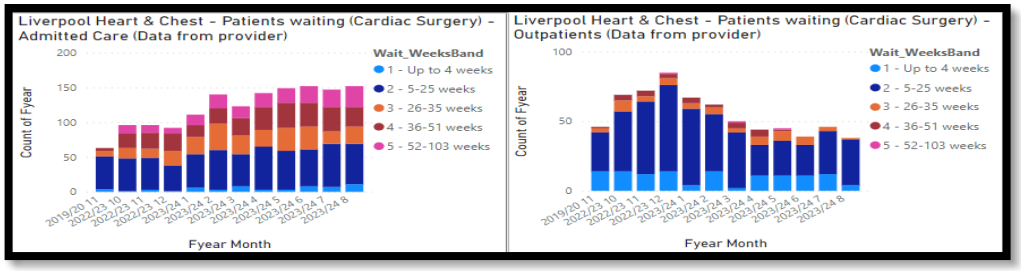
The service is not planning to meet the contracted inpatient levels, but demand is also appearing lower, hence the waiting lists do not appear to be affected adversely.

Liverpool Heart & Chest - Performance data and forecasts

Cardiac Surgery current performance:



Waiting list analysis:



Current Performance

As noted in previous updates, although Liverpool Heart & Chest Hospital has recovered well when compared to pre-Covid levels, inpatient waiting lists have been steadily rising for the last six months, tailing off only slightly in the last month. It is understood that such pressures are evident across NHSE cardiac surgery services; the potential for LHCH to utilise the NHSE Interim Policy Position Statement for TAVI (which would facilitate TAVI being used as an alternative to cardiac surgery for intermediate and low risk patients) was discussed at the most recent SLA meeting, at which it was indicated that the policy is in line with extant clinical practice.

Outpatient waits had reduced significantly over the course of 2023/24, before increasing in the last month. These will be monitored moving forward, lest this recent increase be the beginning of a trend upwards.

What actions are WHSSC taking?

WHSSC continues to hold regular meetings with LHCH to monitor the waiting list position.

What are the main areas of risk?

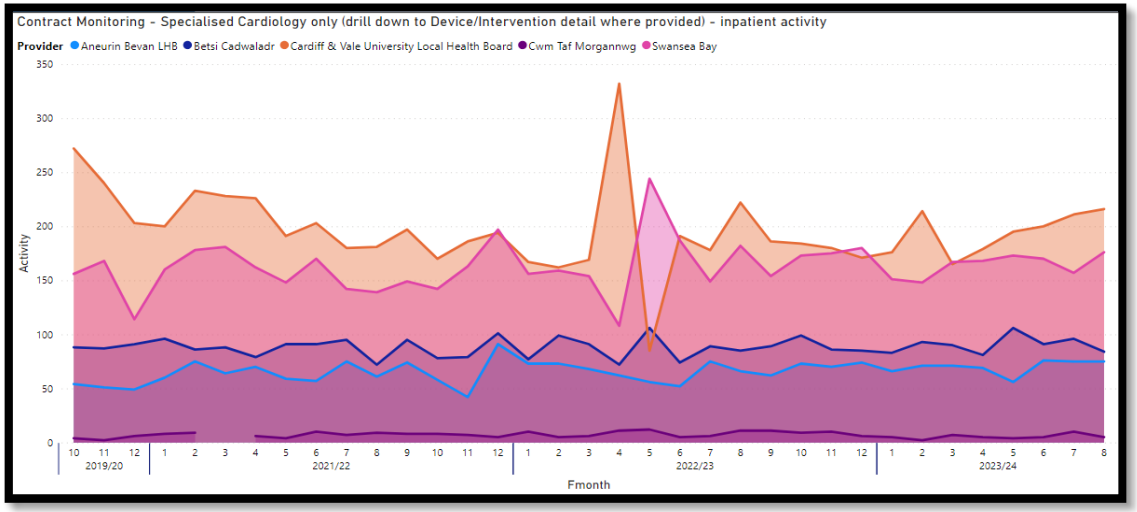
Liverpool appears on track to hit the WG target of no waiters for admissions over 52 weeks, with the longest waiters currently being 25 patients in that wait band, although waiting lists have marginally increasing lately.

The New outpatient target of no waiters over 36 weeks also appears on track with no patients currently waiting longer than that.

7.2 Cardiology (specialised Cardiology only)

Cardiology - Performance data and forecasts

Cardiology current performance (specialised inpatient activity):



Cardiology Waiting list analysis (Note: ALL Specialised and Non-specialised):

DHCW Patients waiting - Cardiology

CensusFinancialMonthNo	Admitted diagnostic intervention	Diagnostic	FUP OP appointment	New OP appointment	Unknown	Total
202305	**1,424**	**2,905**	**7,358**	**21,380**	**1,488**	**34,555**
Cardiology	**1,424**	**2,905**	**7,358**	**21,380**	**1,376**	**34,443**
Aneurin Bevan University Local Health Board	110	270	199	5,600		6,179
Betsi Cadwaladr University Local Health Board	65	884	407	4,423		5,779
Cardiff and Vale University Local Health Board	552	411	1,338	3,832		6,133
Countess Of Chester Hospital Nhs foundation trus					180	180
Cwm Taf Morgannwg University Local Health Board	195	723	115	4,214		5,247
Guy's And St Thomas' Nhs foundation trust					20	20
Hywel Dda University Local Health Board	110	42	5,111	1,971		7,234
Liverpool Heart And Chest Hospital nhs foundatio					298	298
Powys Teaching Local Health Board		54	11	200		265
Shrewsbury And Telford Hospital Nhs trust					411	411
Swansea Bay University Local Health Board	392	521	177	1,140		2,230
University Hospitals Birmingham Nhs Foundation t					15	15
University Hospitals Bristol And Weston nhs foun					71	71
Wye Valley Nhs Trust					381	381
Paediatric Cardiology					**112**	**112**
Alder Hey Children's Nhs Foundation trust					50	50
University Hospitals Bristol And Weston nhs foun					59	59
Wye Valley Nhs Trust					3	3
Total	**1,424**	**2,905**	**7,358**	**21,380**	**1,488**	**34,555**

Current Performance

It is evident that the volume of specialist cardiology activity at Cardiff and Vale and Swansea Bay University Health Board is significantly greater than that delivered by Aneurin Bevan, Betsi Cadwaladr and Cwm Taf Morgannwg University Health Boards, reflecting the greater range of procedures undertaken, population sizes, and the relative stage of development of the different services.

Although overall inpatient activity through 2021/22, 2022/23 into 2023/24 has been relatively flat, Cardiff and Vale's activity levels have steadily increased over the last few months. The Cardiac Commissioning Team has observed that the CTMUHB device service has been undertaking less activity during 2023/24 than during 2022/23. Investigations have indicated that the temporary loss of an implanter (now resolved) has been keenly felt, mindful particularly that is evidence of significant waits at earlier stages of the device pathway.

What actions are WHSSC taking?

WHSSC monitors specialist cardiology performance in Cardiff and Vale University Health Board and Swansea Bay University Health Board via Risk, Assurance and Recovery meetings, agreeing mitigating actions as required. The performance of Aneurin Bevan, Betsi Cadwaladr and Cwm Taf Morgannwg University Health Boards is monitored via SLA meetings.

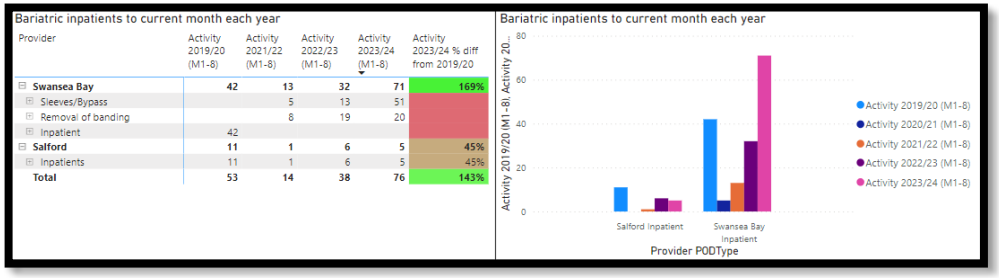
What are the main areas of risk?

WHSSC will be working to agree performance baselines performance baselines for Aneurin Bevan, Betsi Cadwaladr and Cwm Taf Morgannwg University Health Boards (per 2024/24 ICP) in order to facilitate robust performance monitoring and the gauge the success (or otherwise) of recent repatriations.

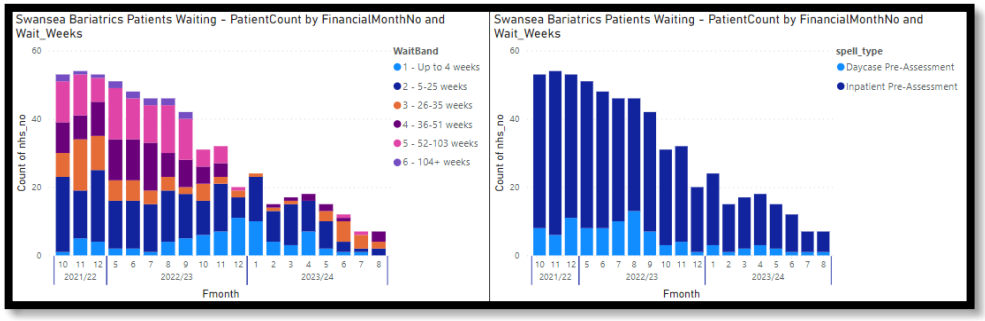
7.3 Bariatric Surgery

Bariatric Surgery - Performance data and forecasts

Bariatric Surgery current performance:



Swansea Bay Waiting list analysis:



Current Performance

As highlighted in previous updates, the Swansea Bay Bariatric Surgery service has delivered significant increases in the volume of inpatient and outpatient activity since January 2023, significantly reducing both the overall waiting list and the number of long waiters. Although, in line with the service's expectations, activity levels have reduced slightly from April 2023, the Health Board has advised that it is still likely to exceed its contract target for 2023-24.

In view of concerns with the waits experienced by patients from north Wales and north Powys seeking to access the service provided by Salford Royal Hospital, WHSSC is investigating whether patients can be referred to WIMOS in the short term in order to avoid regional inequity.

What actions are WHSSC taking?

WHSSC continues to meet with the service on a bi-monthly basis to monitor the position and agree any mitigating actions as required. WHSSC also continues to work with the National Healthy Weight Pathway Steering Group in order to understand and enable the integration of Level 4 services and the Level 1-3 weight management pathway, and continues to correspond with the Welsh Government concerning the post-surgical follow-up need of patients returning from private surgery abroad and potential for agreement of a 'four nations' position.

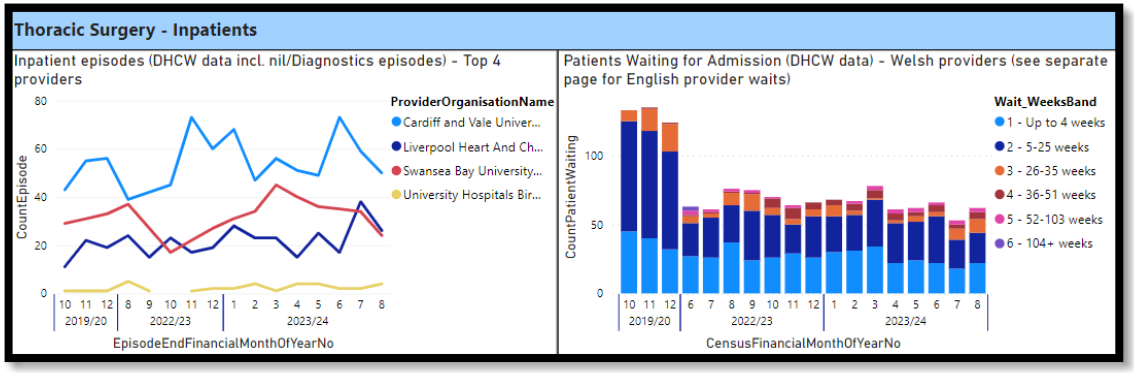
What are the main areas of risk?

The good progress at Swansea needs to be maintained to avoid a repeat of the waiting list deterioration, and referrals from the weight management pathway need to be maintained if the service is to operate at full capacity.

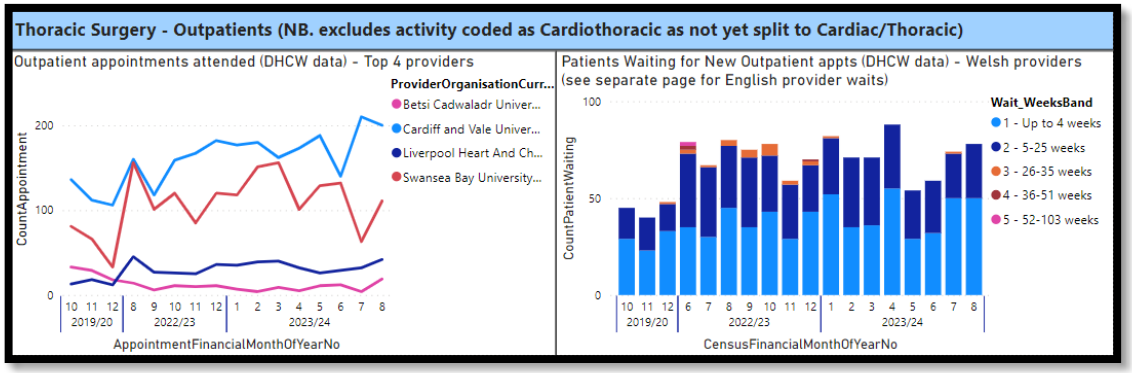
7.4 Thoracic Surgery

Thoracic Surgery - Performance data and forecasts

Thoracic Surgery current inpatient performance and Welsh provider waits:



Thoracic Surgery current outpatient performance and Welsh provider waits:



Forecast trajectories for 2023/24 have been received from Cardiff & Vale. It shows lower planned inpatient activity than contracted, but does not forecast material increases in the waiting lists, or breaches of the Welsh Government targets.

Current Performance

Whilst the Welsh centres are not performing to the full inpatient contract levels, this has not impacted waiting list levels compared to pre-Covid figures. The waiting list for inpatients has actually halved compared to the end of 2019/20.

What actions are WHSSC taking?

In interpreting the data, it is important to note that collaborative arrangements are in place between the two South Wales Thoracic surgery services to use the joint capacity across the 2 services to ensure equitable access. This ensures that if the usual centre is capacity constrained and there is available capacity at the other south Wales service, patients can be cross referred and access treatment on the basis of clinical need. This means that activity at a particular centre does not directly translate into access for residents of Health Boards for which it is the usual provider.

To date, the joint meeting has focused on primary lung cancer patients. The service has been providing elective operations for non-cancer patients, but a small number of long waiters still remain within the backlog.

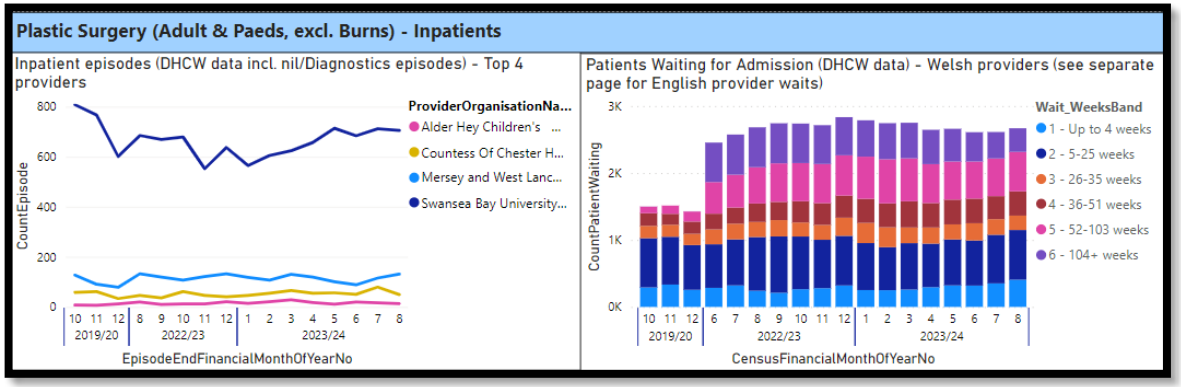
What are the main areas of risk?

With increasing activity for New outpatients, this demand will increasingly put pressure on the waiting lists for admission and treatment.

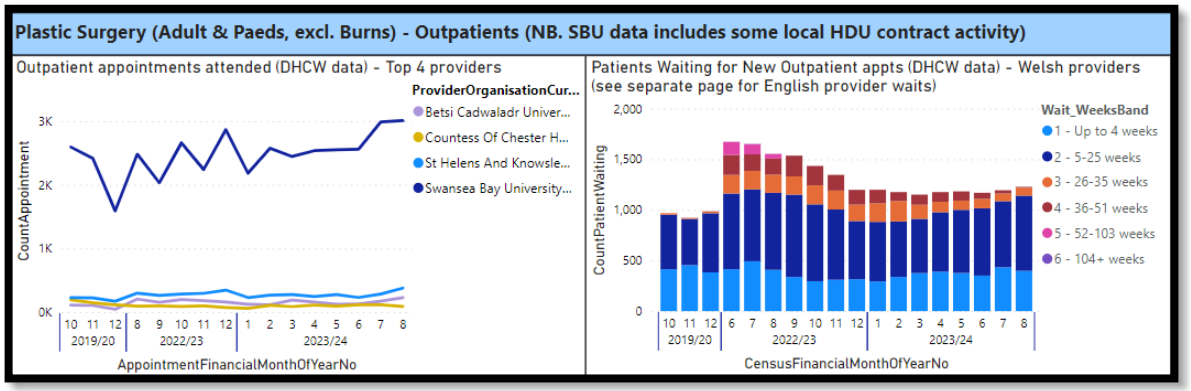
7.5 Plastic Surgery

Swansea Bay UHB - Performance data and forecasts

Plastic Surgery current inpatient performance and patient waits:



Plastic Surgery current outpatient performance and patient waits:



Current Performance

The service at Swansea Bay has been struggling with treatment and patients waiting for some time, even before Covid-19. Over 2,600 patients are waiting for admission, including 353 patients that have been waiting over 2 years, and almost 1,000 that have been waiting over 1 year.

Please note the numbers of patients waiting is as per DHCW data for November 2023, and had reduced from last month; the service have advised that they have cleansed the waiting list and have removed some of the patient numbers.

What actions are WHSSC taking?

WHSSC put the service into level 1 escalation in December 2022, which has since been increased to level 2 in July 2023.

Since the original escalation, the new outpatients waiting have reduced significantly, usually with no patients now waiting over a year, which will meet the WG New outpatient target. The total of patients waiting for admission has remained static i.e. not continued to deteriorate.

What are the main areas of risk?

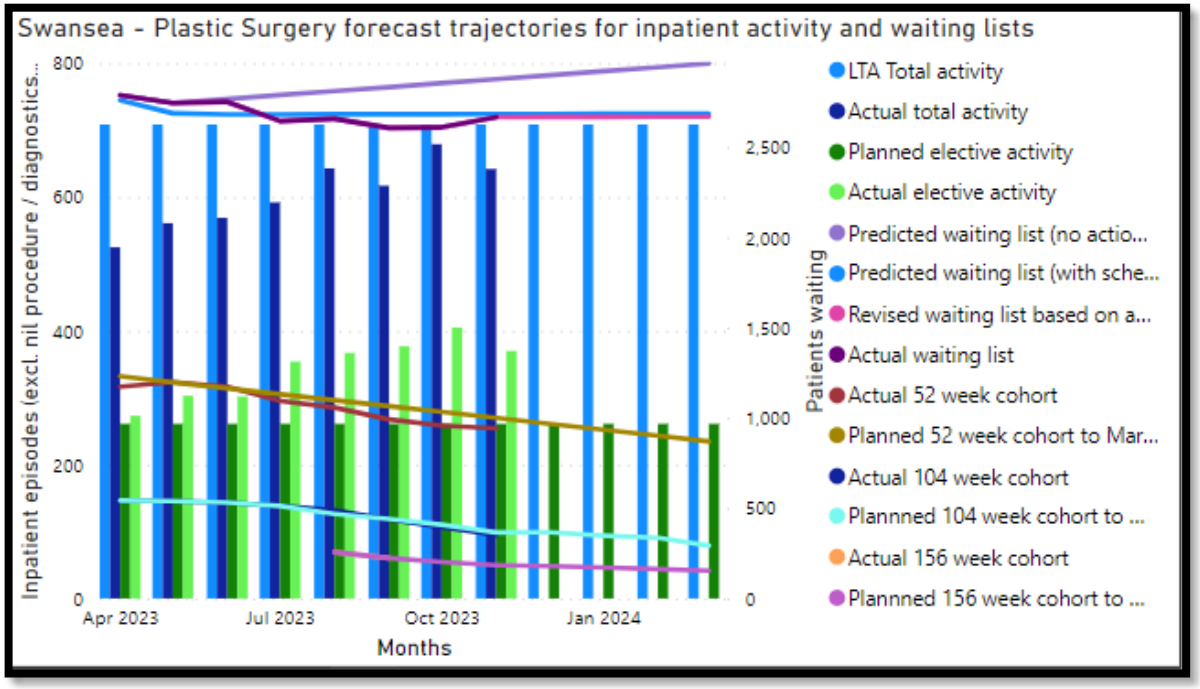
The 2023/24 forecast provided by the service assumes some small additions to capacity from various schemes, which would lead to a static total waiting list. However, within that total, they estimate the patients waiting over a year

Breakdown of patients waiting:

CensusFinancialYearStyle	2023/24				
Specialty_WHSSC	202304	202305	202306	202307	202308
Plastic Surgery	**2,645**	**2,658**	**2,607**	**2,610**	**2,667**
Swansea Bay University Local Health Board	**2,645**	**2,658**	**2,607**	**2,610**	**2,667**
Admitted diagnostic intervention	**2,645**	**2,658**	**2,607**	**2,610**	**2,667**
1 - Up to 4 weeks	294	319	319	352	407
2 - 5-25 weeks	651	686	671	723	740
3 - 26-35 weeks	241	225	257	233	215
4 - 36-51 weeks	365	370	368	344	363
5 - 52-103 weeks	581	569	554	563	589
6 - 104+ weeks	513	489	438	395	353
Total	**2,645**	**2,658**	**2,607**	**2,610**	**2,667**

CensusFinancialYearStyle	2023/24				
Specialty_WHSSC	202304	202305	202306	202307	202308
Plastic Surgery	**1,175**	**1,183**	**1,169**	**1,194**	**1,228**
Swansea Bay University Local Health Board	**1,175**	**1,183**	**1,169**	**1,194**	**1,228**
New OP appointment	**1,175**	**1,183**	**1,169**	**1,194**	**1,228**
1 - Up to 4 weeks	390	377	351	433	398
2 - 5-25 weeks	587	624	665	653	743
3 - 26-35 weeks	103	91	93	76	78
4 - 36-51 weeks	95	91	60	32	9
Total	**1,175**	**1,183**	**1,169**	**1,194**	**1,228**

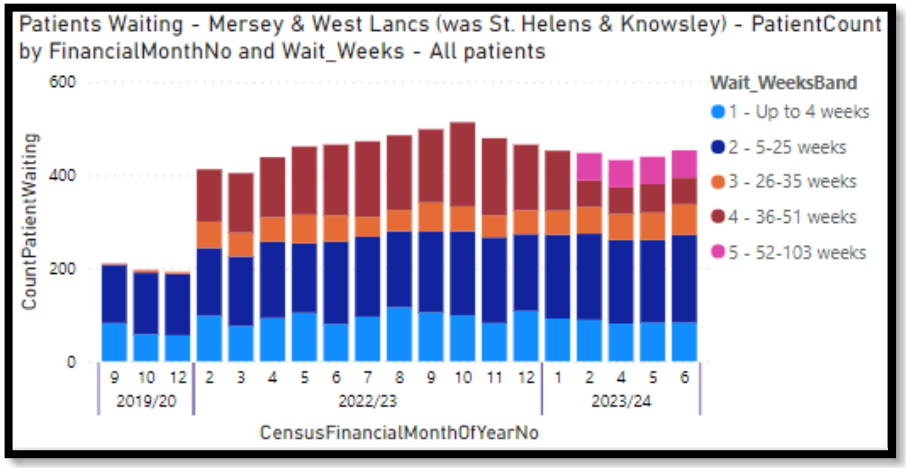
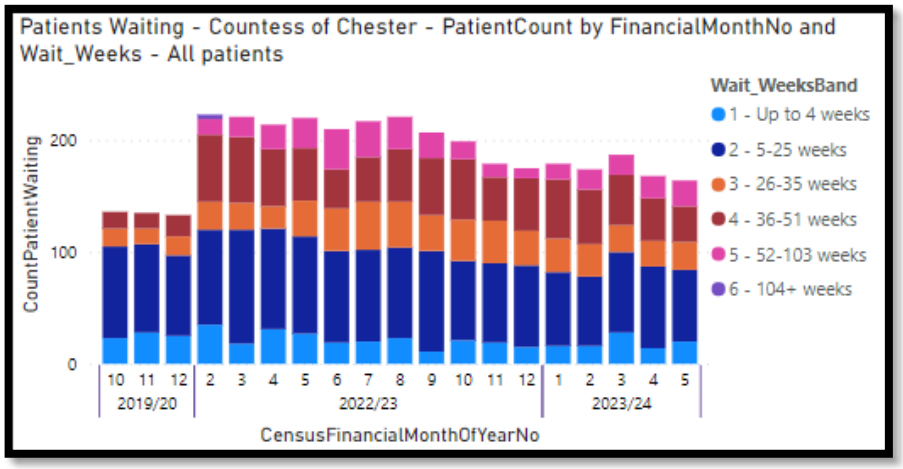
Swansea Bay UHB - Plastic Surgery 2023/24 forecasts:



would reduce from 1,231 to 870, although this would still breach the WG inpatient target.

The risk is that demand would increase and negate the impact of the additional capacity schemes.

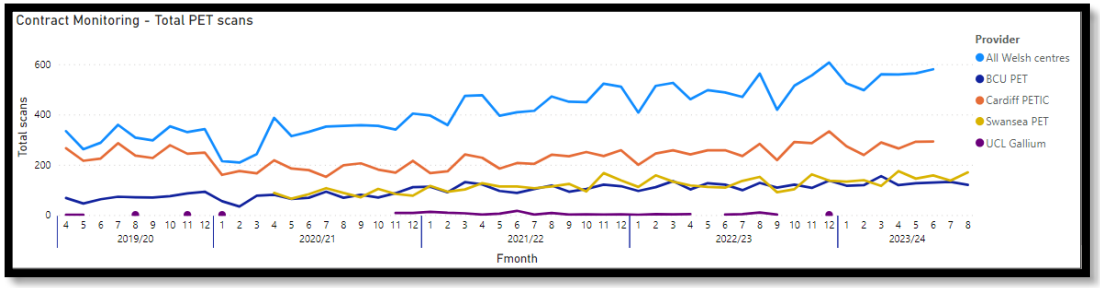
Please note that it has been agreed that the commissioning of Plastic Surgery as a Specialty will return to Health Boards, with WHSSC retaining only an agreed sub-section of Specialised activity. A Project group is being formed to work out the details.

Plastic Surgery English providers - Performance data and forecasts	Current Performance
English providers waiting list analysis (total pathway, as the pathway point is not provided for English data):   	Mersey and West Lancashire Teaching Hospital NHS Trust operate outreach clinics (outpatient, minor operations and dressing clinics) into 3 BCUHB sites. These are inconsistent across the sites. There are a number of concerns with regards to the outreach model currently in place: • Access to appropriate facilities across the sites leading to different levels of service • The number of vacancies in Dermatology, with referrers increasingly referring into Plastic Surgery, as the waiting lists in this area are lower compared to Dermatology • The differing IT systems across the BCUHB sites, which has led to different waiting list management arrangements. The BCUHB element of the North Wales Plastics pathway has been put into escalation by Welsh Government due to concerns about the quality of the service. Following investigation, the waiting times for the West and Central areas of BCUHB are now being reported to Welsh Government by the Health Board (not via the WHSSC contract). There are patients waiting over 156 weeks on the list and a backlog reduction is being progressed, with additional clinics commissioned to reduce the back log.
	What actions are WHSSC taking?
	Regular meetings with WG and BCUHB, with a request for BCUHB to convene a Task & Finish group to address the concerns Mersey and West Lancashire have been requested to undertake a Harms review of the waiting lists. BCUHB have been requested to model the demand and capacity of this service. An SLA has been developed by BCUHB for the outreach clinics from MWLT, BCUHB are waiting for feedback from MWLT on the proposed SLA.
	What are the main areas of risk?
	Lack of Dermatology services within BCUHB which is impacting on the demand for plastic surgery and appropriate clinic space across the localities. Lack of clarity in relation to the waiting list held by BCUHB for the clinics held at Ysbyty Glan Clwyd and Ysbyty Gwynedd, including a lack of reporting arrangements about these patients.

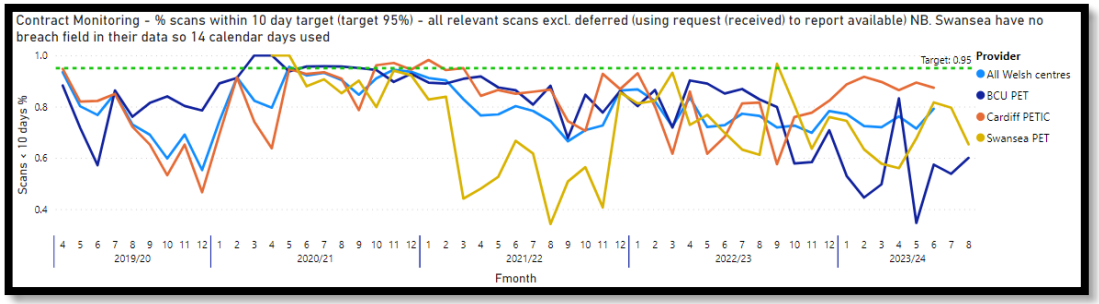
7.6 PET Scans

PET Scans - Performance data and forecasts

PET Scans current performance:



Performance against 10 working day target from PET scan request to the report being available:



Current Performance

PET scanning is an area with increasing growth and interest, which has led to capacity pressures. Cardiff recently provided significant support to Swansea when their site had major mobile scanner failures; this is now longer necessary.

What actions are WHSSC taking?

Welsh Government (WG) requested WHSSC to lead the all-Wales PET Programme, which has an oversight and assurance function for the capital replacements across Wales. A small team sit within WHSSC to facilitate all aspects of capital replacement at PET sites, and are funded from WG until early 2025.

The programme has made significant input to the PET service across Wales. A first in the UK digital scanner became live in Cardiff in July 2023. Although image optimisation is still ongoing, the site in Cardiff capacity has increased from 75 to 91 scans per week. Business cases are expected from SBUHB (fully tendered single case) and BCUHB (OBC) in November and September 2023 respectively.

WHSSC are also working with all 3 Welsh providers to improve and standardise data collection across all sites, to ensure consistency and additional analysis opportunities.

What are the main areas of risk?

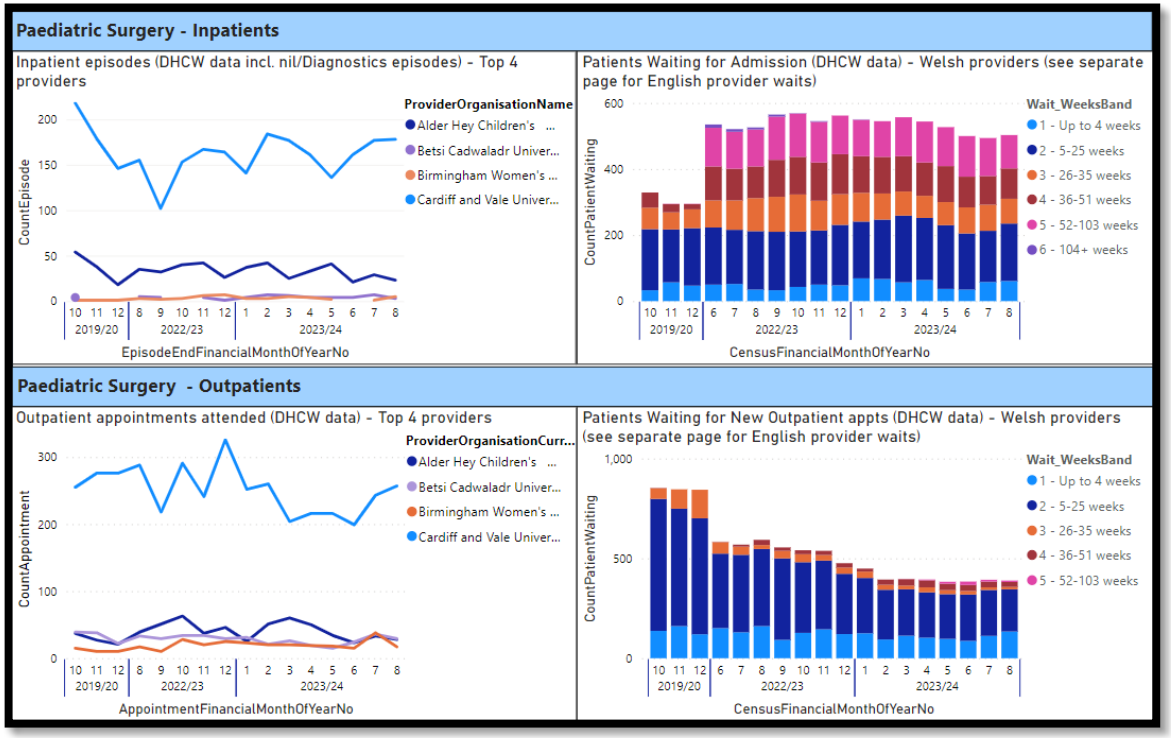
Increased demand has put significant pressure on the service, with the resulting drop of achievement of the 10 working day target of the PET scan report being available to the referring clinician.

The continued use of mobile scanners at BCUHB and SBUHB is resulting in frequent service failures due to scanner breakdown and radiopharmaceutical supply issues.

7.7 Paediatric Surgery

Cardiff & Vale UHB - Performance data and forecasts

Paediatric Surgery current performance:



Waiting list analysis:

CensusFinancialYearStyle	2023/24				
Specialty_WHSSC	202304	202305	202306	202307	202308
Paediatric Surgery	521	503	486	481	480
Cardiff and Vale University Local Health Board	521	503	486	481	480
Admitted diagnostic intervention	521	503	486	481	480
1 - Up to 4 weeks	58	34	35	58	52
2 - 5-25 weeks	175	174	157	147	170
3 - 26-35 weeks	66	69	79	75	71
4 - 36-51 weeks	100	109	93	87	92
5 - 52-103 weeks	122	117	122	114	95
Total	521	503	486	481	480

CensusFinancialYearStyle	2023/24				
Specialty_WHSSC	202304	202305	202306	202307	202308
Paediatric Surgery	300	288	291	311	311
Cardiff and Vale University Local Health Board	300	288	291	311	311
New OP appointment	300	288	291	311	311
1 - Up to 4 weeks	90	87	86	105	126
2 - 5-25 weeks	203	198	202	205	182
3 - 26-35 weeks	6	2	2	1	3
4 - 36-51 weeks	1	1	1		
Total	300	288	291	311	311

Current Performance

Cardiff and Vale is reporting a significant number of patients waiting over 52 weeks for treatment. In dialogue with the provider, there are a number of contributing factors to the waiting list including paediatric intensive care pressures, nurse capacity, bed capacity, anaesthetic support and theatre availability.

What actions are WHSSC taking?

Following concerns around performance, WHSSC put the service into Level 1 escalation in December 2022, with weekly performance updates now being submitted. The escalation was increased to Level 3 in March 2023.

An improvement plan is in place to achieve contract volumes and is being monitored at Executive-led Escalation meetings, and a revised trajectory has been received. Outsourcing remains in place.

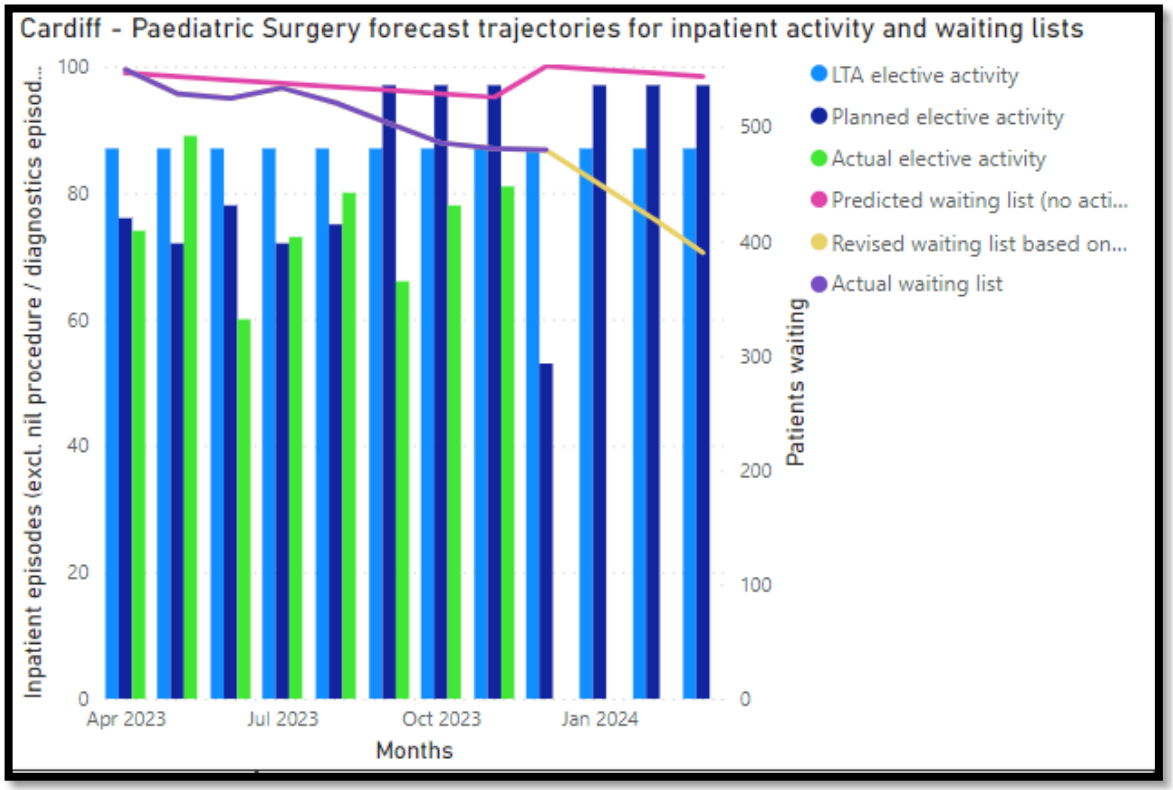
What are the main areas of risk?

At this point, the Cardiff service is hitting the amended WG targets for 2023/24 of zero patients waiting more than 52 weeks for new outpatient appointments, or over 104 weeks for inpatients.

Further improvements to improve the patients waiting over 52 weeks for treatment will need increased delivery above contract volumes.

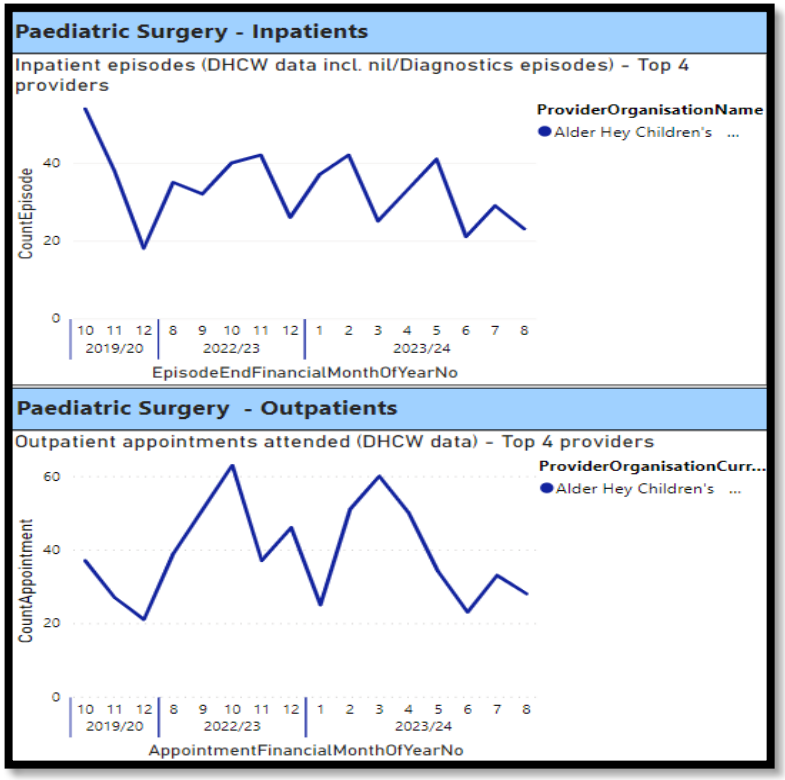
The recent "10/20/30" cost reduction work could also mean a reduction in performance, which would lead to waits increasing again.

Cardiff & Vale UHB - Paediatric Surgery 2023/24 forecasts:



Alder Hey Childrens Hospital - Performance data and forecasts

Paediatric Surgery current performance:



Waiting list analysis:

CensusFinancialYearStyle	2019/20			2023/24			
Specialty_WHSSC	201910	201911	201912	202302	202303	202304	202305
Paediatric Surgery	**50**	**49**	**54**	**99**	**95**	**90**	**89**
Alder Hey Children's Nhs Foundation trust	**50**	**49**	**54**	**99**	**95**	**90**	**89**
Unknown	**50**	**49**	**54**	**99**	**95**	**90**	**89**
1 - Up to 4 weeks	18	14	13	16	18	17	18
2 - 5-25 weeks	32	35	41	60	58	51	42
3 - 26-35 weeks				15	15	18	19
4 - 36-51 weeks				7	4	4	10
5 - 52-103 weeks				1			
Total	**50**	**49**	**54**	**99**	**95**	**90**	**89**

Current Performance

Whilst activity totals are very close to pre-Covid levels, however the number of patients on the waiting list has increased. The increase in patient numbers is due to a number of contributing factors including increased referrals, post-Covid backlog and recent junior doctor strikes.

What actions are WHSSC taking?

A face to face visit took place in Quarter 1 and Alder Hey reported to WHSSC a robust plan is in place to manage the small number of patients waiting over 52 weeks. This has been achieved.

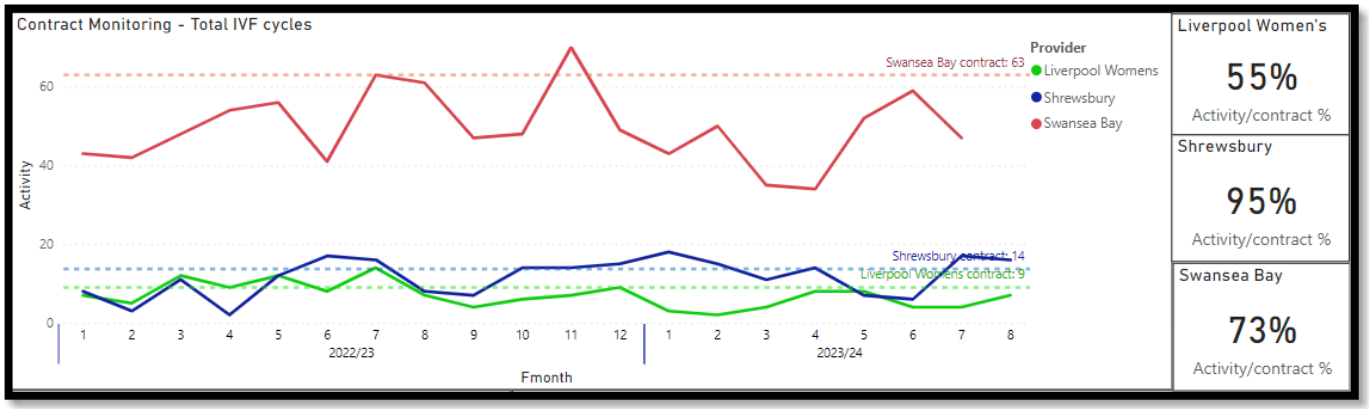
What are the main areas of risk?

Before Covid, no patients at Alder Hey were waiting over 26 weeks, but this now applies to about a third of the patients. However, there are currently no patients waiting over 104 or 52 weeks, and just 10 waiting over 36 weeks at the end of August.

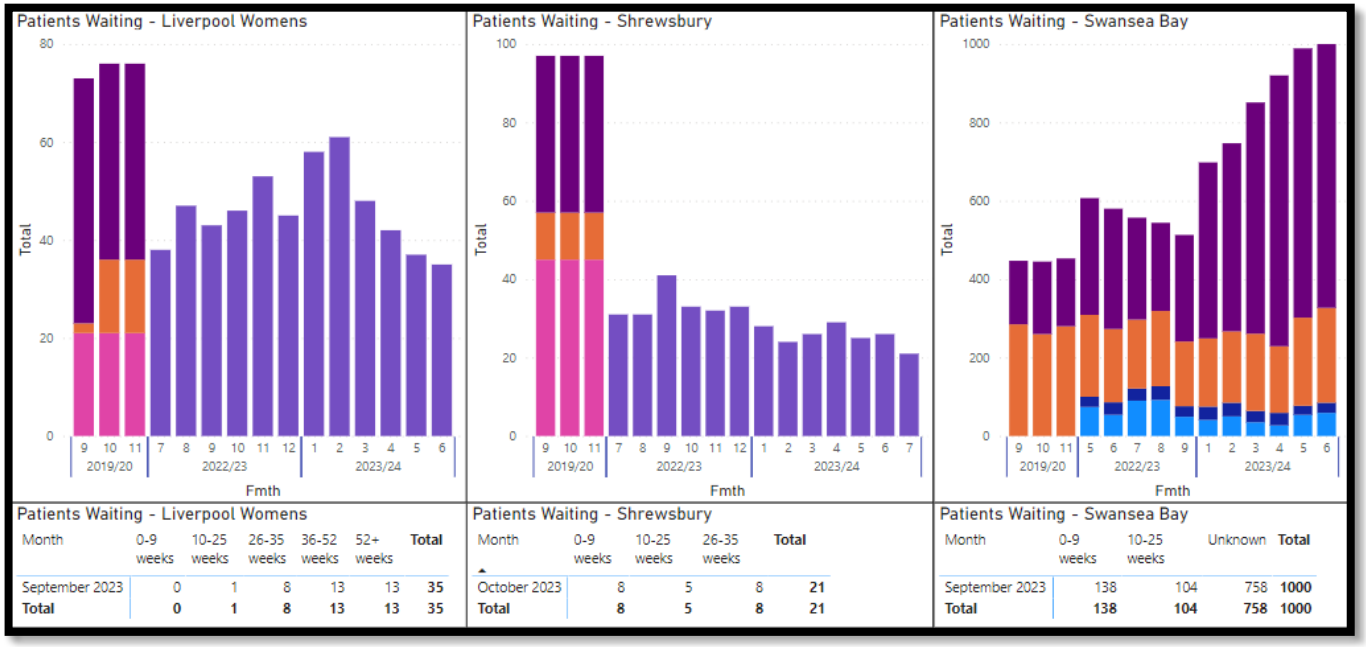
7.8 In Vitro Fertilisation (IVF)

IVF - Performance data and forecasts

IVF current performance:



Waiting list analysis:



Patients Waiting - Liverpool Womens

Month	0-9 weeks	10-25 weeks	26-35 weeks	36-52 weeks	52+ weeks	Total
September 2023	0	1	8	13	13	35
Total	**0**	**1**	**8**	**13**	**13**	**35**

Patients Waiting - Shrewsbury

Month	0-9 weeks	10-25 weeks	26-35 weeks	Total
October 2023	8	5	8	21
Total	**8**	**5**	**8**	**21**

Patients Waiting - Swansea Bay

Month	0-9 weeks	10-25 weeks	Unknown	Total
September 2023	138	104	758	1000
Total	**138**	**104**	**758**	**1000**

Current Performance

A number of concerns regarding the safety and quality of service at the Welsh Fertility Institute (WFI) have been raised through different routes, including the HFEA re-inspection report of January 2023, WHSSC Quality and Assurance meetings, and WFI/IPFR requests.

What actions are WHSSC taking?

WHSSC have progressively increased the escalation of the WFI service, with it now at level 4 as of October 2023.

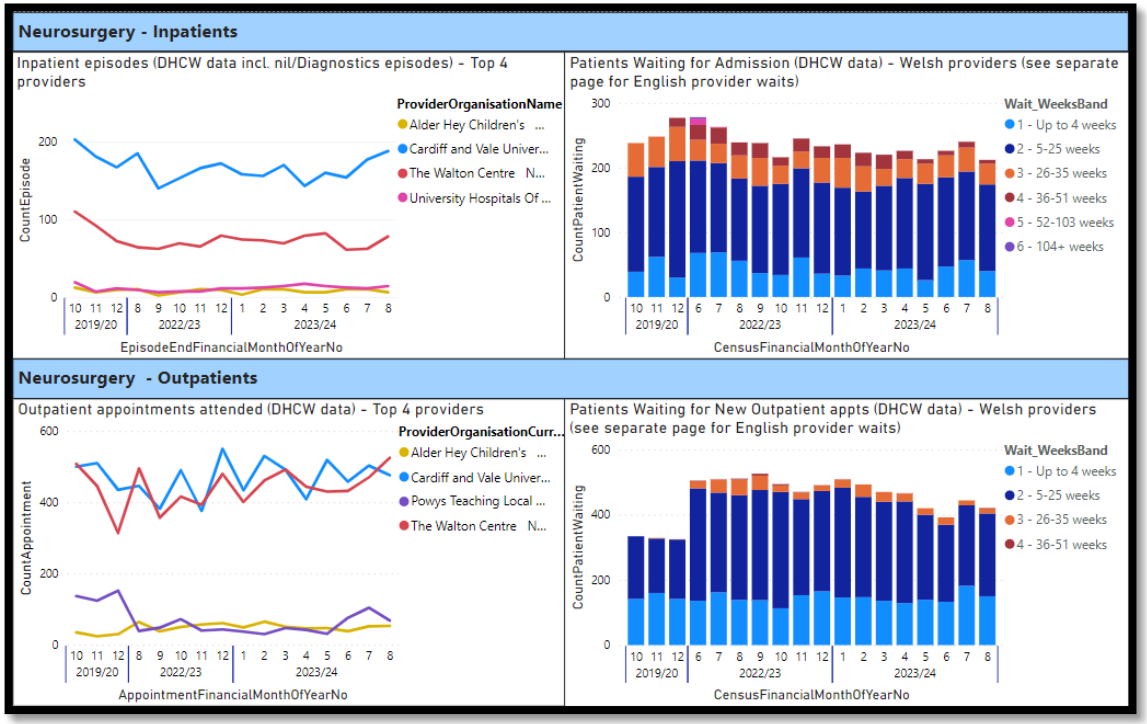
What are the main areas of risk?

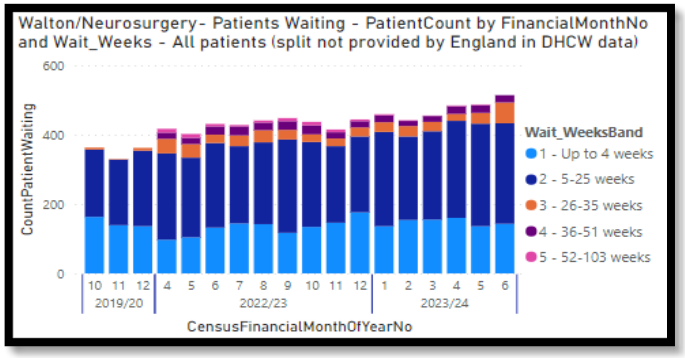
Quality and outcomes of the service in general, along with issues obtaining current activity and wait data.

7.9 Neurosurgery

Neurosurgery - Performance data and forecasts

Neurosurgery current performance:





Current Performance

The Neurosurgery services have been stretched over recent years, but total waiting lists are still comparable to pre-Covid levels at Cardiff, and no patient is waiting over 52 weeks for treatment. Total patients waiting for New outpatients have increased at Cardiff, but 7 patients are waiting longer than 36 weeks. This figure has greatly reduced in comparison to the previous year's position where there were 41 patients waiting >36 weeks.

Total patients waiting at the Walton are also comparable to pre-Covid levels, although the data shows this has been reducing steadily over the past few months. Actual IP activity is below elective contract activity. The trajectory for expected non-elective and actual activity are on target.

What actions are WHSSC taking?

Cardiff have provided a 2023/24 forecast of their activity and waiting lists. Their projections showed a reducing waiting list during quarter 1, based on over-performing against their contracted elective activity, however the waiting list has increased during in October - the evening theatre sessions are no longer being provided. WHSSC is continuing to monitor the situation and will be addressing the issue at the next Performance meeting. This issue may require escalation.

The Walton Centre have been requested at a recent SLA meeting to provide a trajectory position.

What are the main areas of risk?

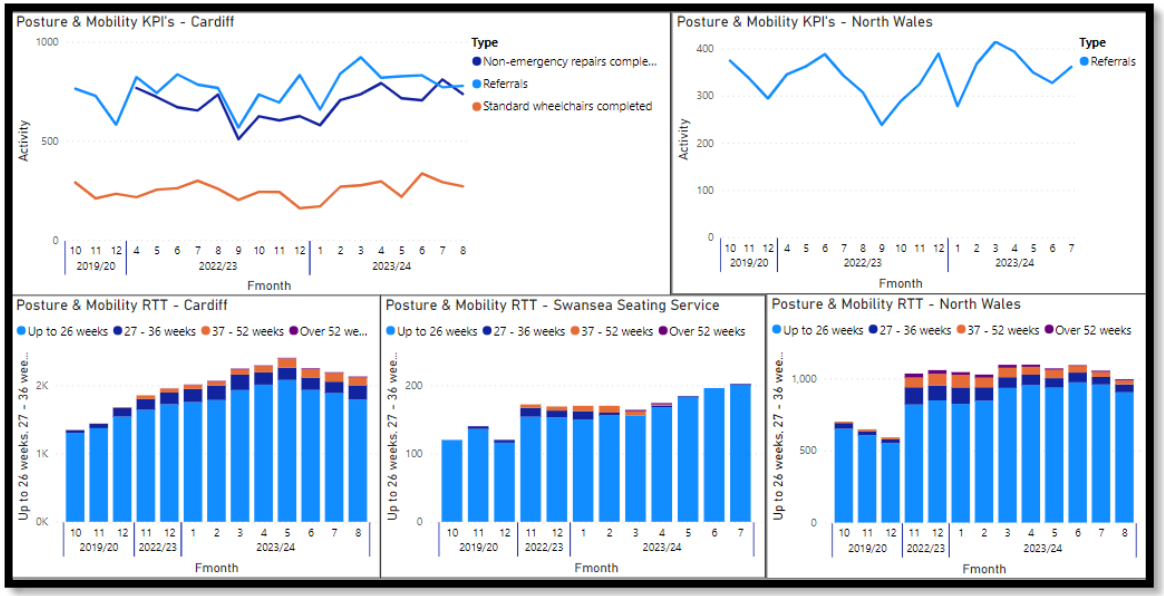
At this point, no patients have been waiting over 52 weeks at Cardiff or the Walton.

However, with increasing waiting lists for New outpatients, this demand will increasingly put pressure on the waiting lists for admission and treatment.

7.10 ALAS (Artificial Limbs Service)

ALAS - Performance data and forecasts

Posture and Mobility referrals and waiting lists:



Month	October 2023					November 2023				
Area	Up to 26 weeks	27 - 36 weeks	37 - 52 weeks	Over 52 weeks	Total waiting	Up to 26 weeks	27 - 36 weeks	37 - 52 weeks	Over 52 weeks	Total waiting
EAT RRT	174	21	5	3	203	156	28	3		187
North Wales - Posture & Mobility RTT	959	53	34	9	1,055	905	55	27	8	995
North Wales - Prosthetics RTT	130	1			131					
South Wales - Posture & Mobility RTT - Cardiff	1,885	169	126	11	2,191	1,794	206	116	13	2,129
South Wales - Posture & Mobility RTT - Swansea	100	1			101					
South Wales - Prosthetics RTT - Cardiff	351	40	8		399	352	34	8	1	395
South Wales - Prosthetics RTT - Swansea	223	8	2		233					
South Wales - Welsh Artificial Eye Service	301				351	328	34	12	7	381
Total	**4,123**	**293**	**175**	**23**	**4,664**	**3,535**	**357**	**166**	**29**	**4,087**

Current Performance

Posture and Mobility services have been struggling with rising waiting lists, with the Cardiff service having a setback in relation to the major flooding just before Covid-19 hit.

After an initial lull in referrals, these have now increased again. There are 9 patients waiting over 52 weeks for the North Wales Posture and Mobility services with a plan to clear the backlog by November 2023, and 14 in total for the Cardiff/Swansea services.

Key challenges have been delays in the supply chain, complexity of clients having increased due to the impact of Covid in accessing services, and lengthier appointments due to complexity needs and staff recruitment challenges.

What actions are WHSSC taking?

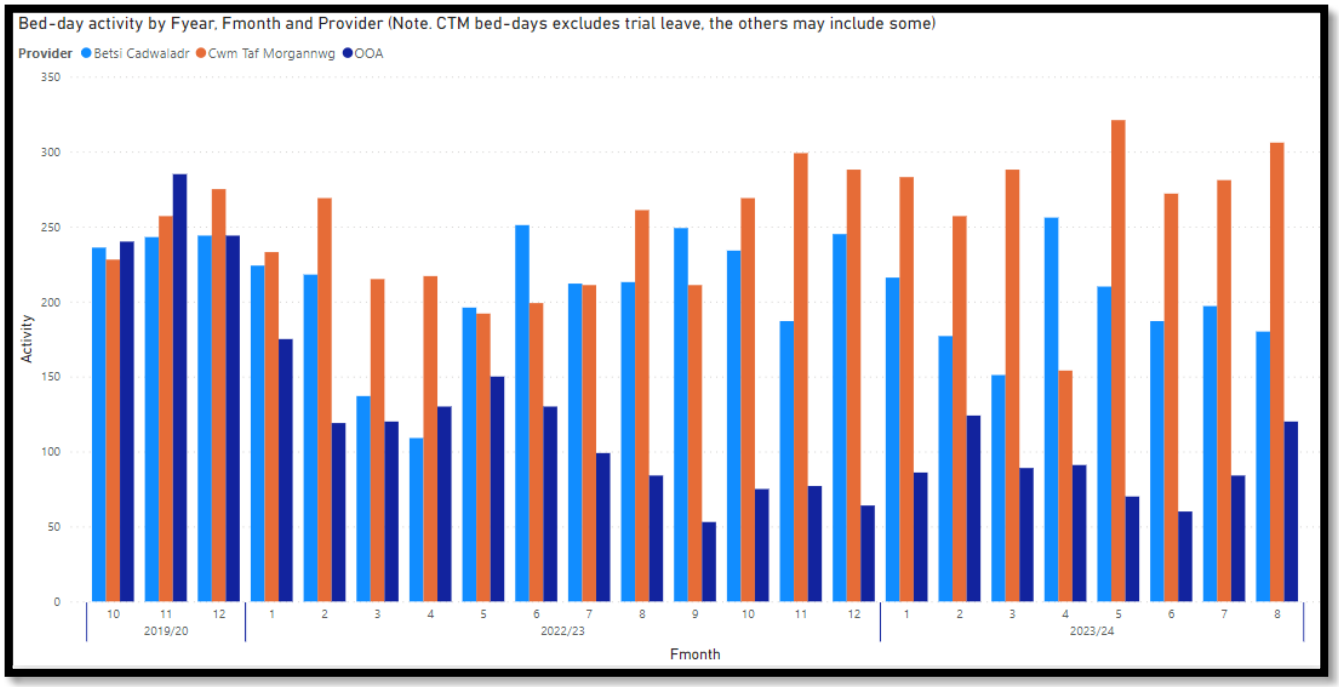
Regular performance meetings with the services, which have led to patient level activity data now being received from all 3 centres, along with the data around patients waiting.

There is also a new PROMS system being developed, with data to be received this financial year.

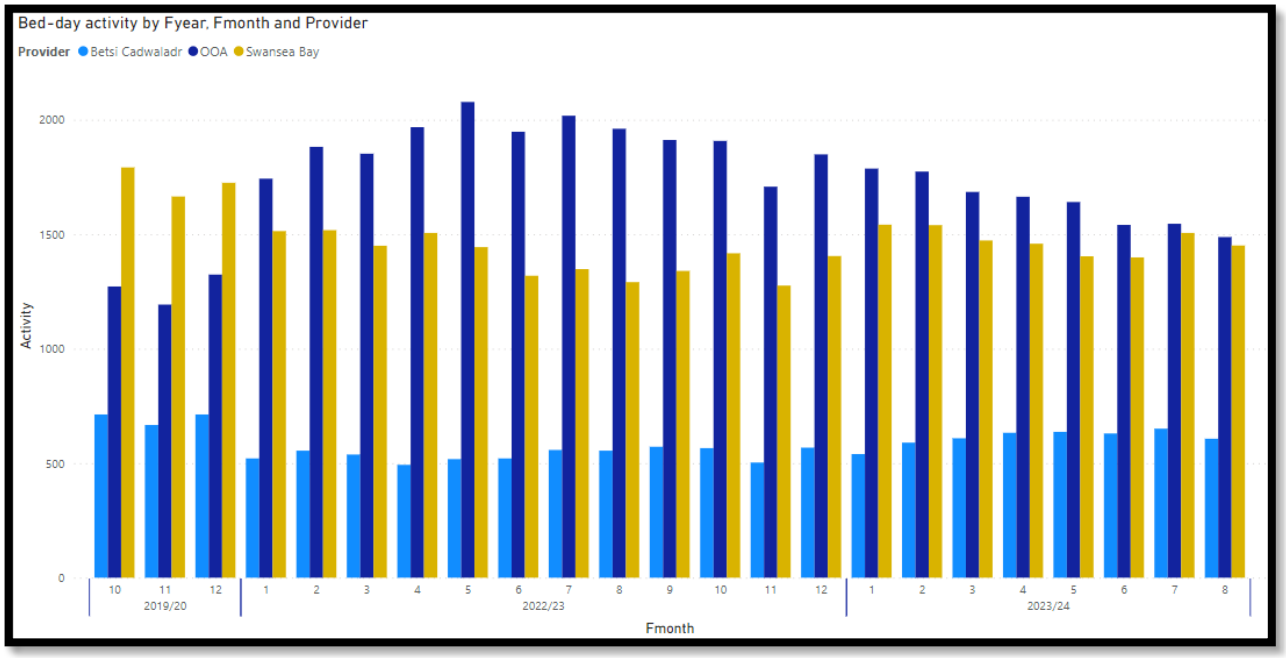
What are the main areas of risk?

Patients waiting a long time can deteriorate in the meantime.

7.11 CAMHS – NHS and Out of Area Placements (OOA)

CAMHS - Performance data	Current Performance
CAMHS current performance:  	Whilst the NHS inpatient CAMHS units are close to pre-Covid bed-days, the use of other providers has reduced. The Ty Lidiard service was de-escalated completely in September 2023. **What actions are WHSSC taking?** Monthly performance meetings have been set up to monitor progress of NWAS. Ty Llidiard had been discussing performance through the escalation process. Bed Panel occurs weekly and discusses bed state with a significant improvement for bed occupancy at Ty Llidiard. **What are the main areas of risk?** Circumstances where units have closed to admissions have seen an increase in out of area placements for that time period. There is a risk that these patients will not be able to be repatriated unless it is safe and appropriate to do so.

7.12 Adult Medium Secure – NHS and Out of Area Placements (OOA)

Adult Medium Secure - Performance data and forecasts	Current Performance
Adult Medium Secure current performance:  	Whilst both NHS inpatient Medium Secure units are performing with less bed-days than pre-Covid, the use of other providers has increased. **What actions are WHSSC taking?** Regular performance meetings are taking place with both units on a monthly basis. Repatriation plans are in place for both units and are on profile. **What are the main areas of risk?** Lack of seclusion suites in both units limits the acuity of patients that can be repatriated or admitted. There is a risk that patients remain out of area due to this.

7.13 Welsh Kidney Network activity

Welsh Kidney Network - Performance data and forecasts

Region		LTA baseline	2023-24 YTD	2023-24 proj.	Variance	Variance (%)
North Wales - West	UHD: Bangor & Alltwen (sessions)	13260	7533	11300	-1961	-14.8%
	HHD: Bangor (patients)	7	26	26	19	271.4%
	PD: Bangor (patients)	38	11	11	-27	-71.1%
North Wales - Central	UHD: Glan Clwyd (sessions)	12792	8365	12548	-245	-1.9%
	HHD: Glan Clwyd (patients)	1	13	13	12	1200.0%
	PD: Glan Clwyd (patients)	25	23	23	-2	-8.0%
North Wales - East	Unit haemodialysis activity (sessions)	17316	13418	20127	2811	16.2%
	HHD: Wrexham (patients)	6	5	5	-1	-16.7%
	PD: Wrexham (patients)	40	24	24	-16	-40.0%
SE Wales	UHD (sessions)	87025	63553	95330	8305	9.5%
	HHD (sessions)	5920	5174	7761	1841	31.1%
	PD (sessions)	27185	13023	19535	-7651	-28.1%
SW Wales	UHD: Morriston (sessions)	34929	25454	38181	3252	9.3%
	UHD: West Wales (sessions)	26645	17696	26544	-101	-0.4%
	HHD (patients)	38	30	30	-8	-21.1%
	CAPD (patients)	31	27	27	-4	-12.9%
	APD (patients)	34	26	26	-8	-23.5%

>5% above baseline
>5% below baseline

Current Performance

BCUHB region:
Based upon Month 7 data, the trajectory for both the Centre and West areas are increasing month on month for both the unit and home dialysis, with West currently on a reduction in activity. However, the overall pan BCU activity is increasing from 2022/23 position, which is reflective of the service demands across the WKN commissioned services.
What is apparent from comparing the figures across all sites is that the 3 areas are currently at different levels of performance with specific hotspots particularly in unit dialysis, demonstrating that working within 3 sub-structures doesn't align itself to flex and level off demand pan BCU.

C&VUHB region:
Based on Month 7 data, the trajectory for unit dialysis approximately 5% growth, which is higher than the expected level of 3% growth seen in Unit Dialysis year on year. Transplant activity has increased and continues to increase a testament to the work of the transplant team and the supporting services within C&V.

SBUHB region:
Based on Month 7 data, the trajectory for unit dialysis approximately nearing a 3% in line with the predicted year on year growth, with home dialysis continuing to be an area for some targeted intervention to increase patient transition.

What actions are WHSSC taking?	What are the main areas of risk?
BCUHB region: Funding agreement has been provided to the BCU Renal team for expanding Welshpool to a 6 day service provision and increasing capacity to a 17 station unit. Work will be ongoing in Qtr 4 of 23/24 with the team in BCU to determine the pan-wide capacity requirements to ensure that the commissioning requirements are defined in the rounds rather than on isolated asks. **C&VUHB region**: Funding release provided for increasing capacity within 3 sites in C&V region; Merthyr, Pontypool & Cardiff South. **SBUHB region:** Work is progressing within the regional team and the newly appointed Independent Service Provider on project plan for the new South West Wales contract both equipment replacement programme, refurbishment of existing units and the build of 2 new dialysis units within the Bridgend and Neath Port Talbot area. Recent updates has highlighted potential delays within the original dates for commissioning the new units, the WKN are working closely with the regions to understand the impact on programme and impact on services provided C&V UHB as patients will transfer between regional boundaries. **All regions:** Work is being undertaken on demand and capacity modelling for all 3 regions, to fully understand the commissioning requirements over the coming years. This will also be supported on the contracting and procurement pipeline for the services. ViHC projects are progressing across all 3 areas, staffing appointments are in progress with 1 out to recruitment stage. Progress being reported into the ViHC national team and WG.	**BCU region:** Increased pressure of staff working within a pan-BCU single service against a backdrop of a 3 sub-structured organisation. Insufficient funding mechanism within the existing BCU sub-structure does not provide the level of flexibility to manage the service provision pan BCU, compounded by the fact that BCU are within a block contract, current lack of visibility regarding funding flow. Capacity pressures across BCU footprint with particular hot spot in Welshpool site, due to increase demand for North Powys patients and SaTH. **C&VUHB region:** Increased pressure on workforce, which will be mitigated by rebasing activity and costings. Increase in cost within Independent Service Providers (ISPs) due to current market conditions and scarcity of labour. **SBUHB region:** Increase in demand within the Swansea Morriston region, mitigated by recently awarded contract for 2 additional ISP units to be located within the NPT and Bridgend areas, predicted to come on-line by end of 2024.

Report Title	**Financial Performance Report – Month 9 2023-2024**	**Agenda Item**	4.2
Meeting Title	**Joint Committee**	**Meeting Date**	30/01/2024
FOI Status	Open/Public		
Author (Job title)	Assistant Director of Finance		
Executive Lead (Job title)	Director of Finance		

Purpose of the Report	The purpose of this report is to set out the financial position for WHSSC for the 9th month of 2023-2024. The financial position is reported against the 2023-2024 baselines following approval of the 2023-2026 WHSSC Integrated Commissioning Plan by the Joint Committee in February 2023.				
Specific Action Required	RATIFY ☐	APPROVE ☐	SUPPORT ☐	ASSURE ☐	INFORM ☒

Recommendation(s)

Members are asked to:

- **Note** the contents of this report including the year to date financial position and forecast year-end position.

WHSSC FINANCIAL PERFORMANCE REPORT
MONTH 9 2023-2024

1.0 SITUATION

The purpose of this report is to provide narrative to the current financial position and forecast yearend position of WHSSC for the 2023-2024 financial year.

This report will be shared with WHSSC Management Group on 25th January 2024

2.0 BACKGROUND

The financial position is reported against the 2023/24 baselines following approval of the 2023-26 WHSSC Integrated Commissioning Plan by the Joint Committee of the 7 health boards in February 2023.

3.0 ASSESSMENT

The year to date financial position reported at Month 9 for WHSSC (excluding EASC) is an underspend against the ICP financial plan of (£5.018m), the forecast year-end position is an underspend of (£10.416m).
The current reported position includes significant non-recurrent reserve releases and performance savings. There remains a material recurrent underlying deficit, which will require funding through the 24/25 financial plan. The plan is currently in development and is being shared with commissioning HBs through the appropriate forums, the M9 indicative assessment is there is a recurrent funding deficit of approx. £15m which will require funding in the 24/25 plan before new unavoidable growth cost pressures are considered.

4.0 RECOMMENDATIONS

Members are asked to:

- **Note** the contents of this report including the year to date financial position and forecast year-end position.

Governance and Assurance	
Link to Strategic Objectives	
Strategic Objective(s)	Governance and Assurance Development of the Plan
Link to Integrated Commissioning Plan	This document reports on the ongoing financial performance against the agreed IMTP
Health and Care Standards	Governance, Leadership and Accountability Choose an item. Choose an item.
Principles of Prudent Healthcare	Only do what is needed Choose an item. Choose an item.
NHS Delivery Framework Quadruple Aim	People in Wales have improved health and well-being with better prevention and self-management Wales has a higher value health and social care system that has demonstrated rapid improvement and innovation, enabled by data and focused on outcome Choose an item. Choose an item.
Organisational Implications	
Quality, Safety & Patient Experience	
Finance/Resource Implications	This document reports on the ongoing financial performance against the agreed IMTP.
Population Health	
Legal Implications (including equality & diversity, socio economic duty etc)	
Long Term Implications (incl WBFG Act 2015)	
Report History (Meeting/Date/ Summary of Outcome	
Appendices	

FINANCE PERFORMANCE REPORT – MONTH 9

1.0 PURPOSE OF REPORT

The purpose of this report is to set out the financial position for WHSSC for 2023-2024 together with any corrective action required.

The narrative of this report excludes the financial position for EASC, which includes WAST & EMRTS provider contracts, EASC and the NCCU team running costs, which are covered in separate Finance Report that is tabled at the EAS Committee. For information purposes, the consolidated position is summarised in the table below:

Table 1 - WHSSC / EASC split

	Annual Budget	Budgeted to Date	Actual to Date	Variance to Date	Movement in Var to date	Current EOYF	Movement in EOYF position
	£'000	£'000	£'000	£'000	£'000	£'000	£'000
WHSSC	815,991	611,993	606,975	(5,018)	(1,670)	(10,416)	(693)
EASC (WAST, EMRTS, NCCU)	254,486	190,864	190,848	(16)	(2)	(21)	0
Total as per Risk-share tables	1,070,476	802,857	797,823	(5,034)	(1,672)	(10,437)	(693)

Please note that as LHB's cover any WHSSC variances, any over/under spends are adjusted back out to LHB's. Therefore, although this document reports on the effective position to date, this value is actually reported through the LHB monthly positions, and the WHSSC position as reported to Welsh Government is a nil variance.

2.0 BACKGROUND/INTRODUCTION

The financial position is reported against the 2023/24 baselines following approval of the 2023-26 ICP by the Joint Committee in February 2023. The remit of WHSSC is to deliver a plan for Health Boards within an overall financially balanced position. However, the composite individual positions are important and are dealt with in this financial report together with consideration of corrective actions as the need arises.

NHS England is reported on contract baselines agreed within the post pandemic NHSE framework of 'aligned payments and incentives'. These are reported against the current ICP provision. WHSSC continues to commission in line with

the contract intentions agreed as part of the ICP and historic standard PBR principles, and declines payment for activity that is not compliant with the business rules related to out of time activity.

3.0 GOVERNANCE & CONTRACTING

The Finance Sub Group has developed a risk sharing framework which has been agreed by Joint Committee and was implemented from April 2019. This is based predominantly on a 2 year average utilisation calculated on the latest available complete year's data. Due to the nature of highly specialist, high cost and low volume services, a number of areas will continue to be risk shared on a population basis to avoid volatility in individual commissioner's position.

Due to COVID and block contracting arrangements the current utilisation shares are based on a 2 year average of 2018/19 and 2019/20 activity. It was agreed by the Finance Sub group that to update utilisation for 2020/21 and 2021/22 activity would be too volatile given the downturn in activity.

NHS Wales Contracting Framework

The contracting framework for NHS Wales providers is reported as per the approved WHSSC ICP assumption of a return to pre COVID contracting terms, in that no provider tolerances are applied to contract underperformance and the extant marginal rates for performance are re-instated.

4.0 ACTUAL YEAR TO DATE AND FORECAST OVER / (UNDERSPEND) (SUMMARY)

The reported position is based on the following:

- NHS Wales activity – provider contract monitoring returned to the extant contracting framework for 2023/24 as an agreed financial assumption included in the ICP approved by Joint Committee
- NHS England activity – provider contract monitoring against agreed baselines based on the NHSE 'aligned payment and incentives' framework or bespoke local agreements with actual variances for drugs and devices applied and recognition of elective recovery where there is sustained recovery performance.
- Mental Health & IPFR – live patient data on agreed placements as at the end of the month, plus funding approvals and purchased block bed capacity.
- Developments – variety of bases, including agreed phasing of funding.

Table 2 - Expenditure variance analysis

Financial Summary (see Risk-sharing tables for further details)	Annual Budget £'000	Budgeted to Date £'000	Actual to Date £'000	Variance to Date £'000	Previous month Var to date £'000	Current EOYF Variance £'000	Previous month EOYF Var £'000
NHS Wales							
Cardiff & Vale University Health Board	291,470	218,602	222,852	4,250	3,217	5,859	5,304
Swansea Bay University Health Board	124,133	93,100	97,504	4,404	3,514	5,418	5,271
Cwm Taf Morgannwg University Health Board	11,246	8,434	8,434	0	0	0	0
Aneurin Bevan Health Board	11,773	8,830	9,377	547	486	729	729
Hywel Dda Health Board	2,110	1,583	1,583	0	0	0	0
Velindre NHS Trust	56,290	42,217	43,605	1,388	900	1,855	1,405
Sub-total NHS Wales	**545,139**	**408,854**	**419,904**	**11,050**	**8,662**	**14,477**	**13,526**
Non Welsh SLAs	132,236	99,177	103,916	4,739	3,818	5,560	4,312
IPFR	60,257	45,193	46,000	806	1,275	(659)	(697)
IVF	5,102	3,827	3,840	13	(55)	(91)	(173)
Mental Health	43,147	32,360	33,376	1,016	2,377	403	2,355
Renal	4,984	3,738	3,158	(581)	(552)	(744)	(729)
Plan Savings	(11,510)	(8,633)	(7,594)	1,039	528	1,291	698
Plan Developments & Provisions	31,593	23,695	12,153	(11,541)	(9,410)	(14,905)	(13,705)
Direct Running Costs	5,042	3,782	4,025	243	192	(12)	(36)
Reserves Releases 2022/23	0	0	(11,803)	(11,803)	(10,183)	(15,737)	(15,274)
Total Expenditure	**815,991**	**611,993**	**606,975**	**(5,018)**	**(3,348)**	**(10,416)**	**(9,722)**

5.0 FINANCIAL POSITION DETAIL

The **Welsh SLA** provider position at month 9 is an overspend of £11.1m, with a forecast year end variance of £14.5m

There continues to be significant pass through cost pressures on immunology and inherited bleeding disorder blood products of £3.7m to date, with a forecast variance of £4.8m.

We are currently reviewing expenditure growth in these areas, considering future pricing framework tenders and in house production potential to inform the ICP requirement.

There was material adverse reporting movement in the C&V provider prior year business case slippage forecast of £0.6m and Swansea Bay have sustained improved performance in Cardiology and TAVI activity.

The **NHS England SLAs** forecast overspend position of £5.6m is mainly driven by continued drug and device overspends, with elective activity absorbed within baselines and agreed block arrangements.

Material forecast overspends are emerging in Alder Hey and Walton, some of the Walton variance relates to growth in secondary care Neurology drugs which pass through the WHSSC contract which require provision in the 24-25 plan.

NHS England provider's activity and costs are impacted by industrial action in the year so far and are further disruption is anticipated. A number of providers have approached WHSSC to seek fixed financial support for loss of variable income in line with the latest NHSE guidance.

The **Mental Health** forecast position has improved by (£1.9m) in M9 due to improvements in the eating disorder and CAMHS forecast.

The over performance variances are offset by non-recurrent prior year releases of (£15.7m) and development slippage included in the forecast position.

The **WHSSC direct running costs** budget is forecasting an underspend of (£0.012m), after achieving the 5% budget reduction of (£0.175m) agreed through the WHSSC ICP.

6.0 FINANCIAL POSITION DETAIL – BY COMMISSIONERS

The financial arrangements for WHSSC do not allow WHSSC to over or underspend, therefore variances are distributed based on a defined risk sharing mechanism. The following table provides details of how the yearend variances are allocated by LHB and the movement from last month's forecast position.

Table 3 – Year to Date position by LHB

	Allocation of Variance							
	Total	Cardiff and Vale	SB	Cwm Taf Morgannwg	Aneurin Bevan	Hywel Dda	Powys	Betsi Cadwaladr
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Variance M9	(5,018)	(1,810)	(294)	(1,049)	(426)	(832)	211	(820)
Variance M8	(3,348)	(1,471)	(190)	(993)	(290)	(789)	261	124
Movement	(1,670)	(339)	(104)	(55)	(135)	(43)	(51)	(943)

Table 4 – End of Year Forecast by LHB

	Allocation of Variance							
	Total	Cardiff and Vale	SB	Cwm Taf Morgannwg	Aneurin Bevan	Hywel Dda	Powys	Betsi Cadwaladr
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
EOY forecast M9	(10,416)	(2,916)	(836)	(1,781)	(1,413)	(1,371)	(195)	(1,905)
EOY forecast M8	(9,722)	(2,610)	(774)	(1,770)	(1,294)	(1,385)	(217)	(1,673)
EOY movement	(693)	(306)	(62)	(10)	(119)	14	22	(232)

7.0 PLAN SAVINGS AND ADDITIONAL 1% PATHWAY SAVINGS

The 2023-26 WHSSC ICP included a 1.2% commissioning budget savings target of £9.160m in order to contain the uplift required by commissioning Health Boards to 3.11%.

This is in addition to prior year residual savings schemes rolled forward of £2.350m

At month 9 it is reported that there is a forecast shortfall against the planned savings of £1.291m.

Table 5 – Plan Savings Monitoring

Prior Year Plan Savings Targets	Annual Budget £'000	Expected to Date £'000	Actual To Date £'000	Variance £'000	Current EOYF £'000
Existing Medicines Management Optimisation Schemes	(1,600)	(1,200)	(900)	300	500
Referral Management Schemes	(250)	(188)	0	188	250
Neonatal Out of Area Capacity Reduction	(500)	(375)	(375)	-	-
Sub-total Prior Year Savings	**(2,350)**	**(1,763)**	**(1,275)**	**488**	**750**
.					
2023/24 ICP Re-commissioning Schemes	**Annual Budget £'000**	**Expected to Date £'000**	**Actual To Date £'000**	**Variance £'000**	**Current EOYF £'000**
23/24 Medicines Management Optimisation Schemes	(1,000)	(750)	(650)	100	240
Reduction in Neonatal OOA transfers due to SW capacity	(250)	(188)	(188)	-	-
Target Reduction in Forensic OOA Placements	(1,000)	(750)	(1,472)	(722)	(963)
Target Reduction in NW CAMHS OOA Placements	(250)	(188)	(188)	-	-
Target Reduction in SW CAMHS OOA Placements	(500)	(375)	(375)	-	-
Target Reduction in Eating Disorders OOA Placements	(500)	(375)	0	375	500
Paeds Contract Rebasing through Strategy Service Reviews	(250)	(188)	(188)	-	-
Device Optimisation C&V	(150)	(113)	(181)	(69)	(91)
Device Optimisation SB	(150)	(113)	(145)	(33)	(44)
Genetics - Repatriate send out tests to in house	(250)	(188)	(164)	24	31
WHSSC DRC Budget CRP 5%	(175)	(131)	(123)	9	-
Sub Total 2022/23 Re-commissioning Schemes	**(4,475)**	**(3,356)**	**(3,673)**	**(316)**	**(327)**
.					
2023/24 Disinvestments	**Annual Budget £'000**	**Expected to Date £'000**	**Actual To Date £'000**	**Variance £'000**	**Current EOYF £'000**
Cardiac Surgery disinvestment C&V	(1,875)	(1,406)	(946)	460	460
Cardiac Surgery disinvestment SB	(1,395)	(1,046)	(1,102)	(56)	(56)
Non Recurrent under performance (assume 50% recovery)					-
Paeds Surgery C&V	(150)	(113)	(113)	0	-
Plastics SB	(700)	(525)	(160)	365	365
Bariatrics SB	(90)	(68)	0	68	68
Thoracic SB	(125)	(94)	(213)	(119)	(119)
Thoracic C&V	(200)	(150)	0	150	150
Renal Activity	(150)	(113)	(113)	0	-
Sub Total Disinvestments	**(4,685)**	**(3,514)**	**(2,646)**	**868**	**868**
Total Savings	**(11,510)**	**(8,633)**	**(7,594)**	**1,039**	**1,291**

Table 6 – Schemes 1% Savings Target

	Aneurin Bevan UHB £m	Betsi Cadwaladr UHB £m	Cardiff & Vale UHB £m	Cwm Taf Morgannwg UHB £m	Hywel Dda UHB £m	Powys THB £m	Swansea Bay UHB £m	2023/24 Target / Forecast Achievement £m
WHSSC & HBs Shared 1% Savings Target	**(1.444)**	**(1.583)**	**(1.312)**	**(1.105)**	**(0.860)**	**(0.314)**	**(0.951)**	**(7.569)**
Cash releasing savings released through WHSSC								
Intestinal Failure - Beddays Reduction	(0.065)	0.000	(0.128)	(0.104)	(0.038)	(0.006)	(0.008)	**(0.350)**
Intestinal Failure - Nursing support	(0.057)	(0.033)	(0.073)	(0.050)	(0.018)	(0.007)	(0.012)	**(0.250)**
Intestinal Failure - Saline reduction	(0.023)	(0.013)	(0.029)	(0.020)	(0.007)	(0.003)	(0.005)	**(0.100)**
ALAS - Static Seating Contract	(0.008)	(0.010)	(0.007)	(0.006)	(0.005)	(0.002)	(0.005)	**(0.044)**
Cystic Fibrosis - Reduction in attendances NHSE	(0.000)	(0.144)	(0.000)	(0.000)	(0.000)	(0.006)	(0.000)	**(0.150)**
Cystic Fibrosis - Home IV Service	(0.066)	(0.078)	(0.055)	(0.050)	(0.043)	(0.015)	(0.043)	**(0.350)**
Cochlear Service review	(0.070)	(0.000)	(0.059)	(0.053)	(0.045)	(0.008)	(0.045)	**(0.280)**
Additional Medicines Management discounts	(0.030)	(0.036)	(0.025)	(0.023)	(0.020)	(0.007)	(0.020)	**(0.160)**
WBS IVD regulation efficiency	(0.051)	(0.034)	(0.041)	(0.039)	(0.035)	(0.012)	(0.033)	**(0.245)**
Pause of Uncommitted Expenditure	(0.749)	(0.268)	(0.743)	(0.559)	(0.326)	(0.072)	(0.370)	**(3.087)**
IPFR Policy Review - HIPEC	(0.041)	(0.048)	(0.034)	(0.031)	(0.027)	(0.009)	(0.027)	**(0.216)**
Total Schemes Identified through WHSSC	**(1.160)**	**(0.664)**	**(1.194)**	**(0.936)**	**(0.563)**	**(0.147)**	**(0.569)**	**(5.232)**

During the plan development process, the Joint Committee requested WHSSC to work with the HBs in year to identify additional pathway savings equivalent to 1% of the required plan uplift.

The forecast assessment of additional savings that will be realised through the WHSSC position is £5.232m.

There are a number of further identified non-cash releasing inferred system efficiencies within non-specialised pathways to be considered in the achievement towards the 1% pathway target.

These include growth hormone rationalisation within GP prescribing budgets, cost avoidance in stroke rehabilitation due to increased thrombectomy provision and released secondary care beddays from intestinal failure reduced lengths of stay.

It is difficult to quantify the inferred system efficiencies but using standard costing assessments these are estimated to be equivalent to a further £1m of savings and efficiency gains within secondary and primary care pathways.

8.0 INCOME/EXPENDITURE ASSUMPTIONS

8.1 Income from LHB's

There are no notified disputes regarding the income assumptions related to the WHSSC IMTP.

Invoices over 11 weeks in age detailed to aid LHB's in clearing them before arbitration dates:

- None

9.0 OVERVIEW OF KEY RISKS / OPPORTUNITIES

None

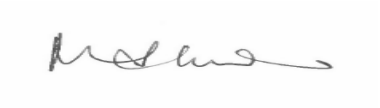
10.0 PUBLIC SECTOR PAYMENT COMPLIANCE Q3

As at the end of Q3 WHSSC has achieved 99.9% compliance for NHS invoices paid within 30 days by value and 98.2% by number.

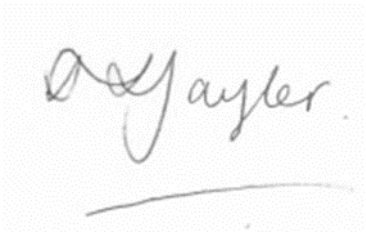
For non NHS invoices WHSSC has achieved 99.6% in value for invoices paid within 30 days and 99.9% by number.

This data is updated on a quarterly basis.

12.0 CONFIRMATION OF POSITION REPORT BY THE MD AND DOF



Sian Lewis,
Managing Director, WHSSC



Stacey Taylor,
Director of Finance, WHSSC

Report Title	**South Wales Trauma Network Delivery Assurance Group (DAG) Report (Quarter 2 2023/24)**	**Agenda Item**	4.3
Meeting Title	**Joint Committee**	**Meeting Date**	30/01/2024
FOI Status	Open		
Author (Job title)	Network Manager		
Executive Lead (Job title)	Director of Planning and Performance		

Purpose of the Report	The purpose of this report is to provide a summary of the Quarter 2 2023/24 Delivery Assurance Group (DAG) report of the South Wales Major Trauma Network (SWTN).				
Specific Action Required	RATIFY ☐	APPROVE ☐	SUPPORT ☐	ASSURE ☒	INFORM ☒

Recommendation(s):

Members are asked to:

- **Note** the report; and
- **Receive** assurance that the Major Trauma Network's delivery and outcomes are being scrutinised by the Delivery Assurance Group (DAG).

SOUTH WALES TRAUMA NETWORK DELIVERY ASSURANCE GROUP REPORT (QUARTER 2 2023/24)

1.0 SITUATION

The purpose of this report is to provide a summary of the Quarter 2 2023/24 Delivery Assurance Group (DAG) report of the South Wales Major Trauma Network (SWTN).

2.0 BACKGROUND

The WHSSC-commissioned South Wales Trauma Network was launched in September 2020 with Swansea Bay University Health Board (SBUHB) as the network host. The Network covers South Wales, West Wales and South Powys. Assurance on the Network's delivery, performance, evaluation and outcomes are provided by the DAG, whose function is to ensure that the SWTN's objectives are achieved, the WHSSC Service Specification is delivered, the benefits of the Programme Business Case are realised and that outcomes and experience are improved by working collaboratively.

3.0 ASSESSMENT

3.1 Highlights from the report

- For the period from go-live to the end of September 2023, the Major Trauma Centre (MTC) has seen 5016 patients, of whom 35% have been categorised as Silver Trauma. The Polytrauma Unit (PTU) has admitted/treated 1151 patients for the same period,
- **Network Clinical Director** – The Clinical Director role will be advertised for a permanent position in early March 2024, with the intention of ensuring robust leadership and strategic continuity moving forward,
- **Network Clinical Leads** – The Clinical Leads for Quality Improvement & Research and Training, Education & Rehabilitation have each completed their planned two year secondments; as a result of a number of Network senior leadership posts being taken forward on an interim basis, these contracts were extended. Interviews for permanent appointments were planned for December 2023 and Joint Committee will be further updated once any appointments have been confirmed,
- **Evaluation Programme** – The Major Trauma Network Gateway 5 Review is scheduled to take place in March 2024. The Network has received the associated paperwork; its ongoing preparations include a review of the Programme Business Case and the Benefits Realisation Plan, and an assessment of the lessons learnt since the Network's launch,

- **Peer Review** – The Network's next round of internal peer review is scheduled for July 2024, to which end the Network will identify peer review teams who will travel to each Health Board (HB),
- **MTN Annual Conference** – The Major Trauma Network annual conference was held at The Halliwell Conference Centre, Carmarthen, on Thursday 12 October 2023. The conference was well attended by stakeholders from across the Network's geographical footprint; the agenda (titled 'From Roadside to Recovery') sought to highlight the progress made against the Network's delivery plans whilst offering opportunities for shared learning,
- **Open Fractures** – The Network is working with the Welsh Ambulance Service Trust (WAST) and Morriston General Hospital to provide a direct access programme for open fractures at Morriston Hospital. It is intended that this programme will enable WAST to take patients to Orthoplastics in Morriston Hospital if they present with a lower limb open fracture. Prior to implementation, a review of Morriston Hospital's data is being undertaken to ensure that both Orthoplastics and WAST have capacity to support the planned programme; and
- **Training and Education** - A project to convert the Network's Level 1 learning portfolio into e-learning to link with ESR is in progress. The e-learning aspect has been subject to a first review by Trauma Network Matron and Emergency Department colleagues, and currently subject to revision and refinement. In addition, the first Major Trauma Life Support (MTLS) courses were launched October 2023, with two dates running consecutively.

3.2 TARN Data report

The DAG report contains data extracted from the Network's most recent TARN Clinical Report, intended to address the Joint Committee's need to see additional detail relating to evaluation, mortality and outcomes. As such, the DAG report now includes summaries of the data quality, excess rate of survival, the seniority of doctors in Emergency Departments and time to CT; further refinements to the DAG report will be incorporated into future iterations. The data included in report covers approximately the first two years of the Network (1 October 2020 to 30 September 2022).

3.3 Issues and Risks

- **TARN** – As noted in previous South Wales Trauma Network DAG updates, the University of Manchester was subject to a cyber-attack on 9 June 2023 that resulted in the Trauma Audit Research Network's National Major Trauma Database (TARN) being taken offline at midday on Thursday 15 June. It has since been agreed that the TARN system will not be re-established in its previous form and that NHS England (NHSE) will develop a new trauma data collection system that will be hosted by an NHS England data repository as part of NHSE National Outcomes Registries Programme. The Network has received regular updates from the TARN Transition Steering Group concerning the actions being taken, but the timescales for the launch of the new system are yet to be confirmed,

- Pending the launch of this new system – potentially in early 2024 – HBs and trauma networks nationwide will not receive the regular clinical reports and dashboards that have previously been issued as a matter of routine. The Major Trauma Network requires this data to evidence the realisation of the benefits identified in the programme business case, provide evidence for peer review, and to enable clinical governance and quality improvement,
- WHSSC therefore wrote to the National Clinical Director for Major Trauma and Burns and Chair of the NHS England Specialised Commissioning National Programme of Care (Trauma) in November 2023 to highlight concerns with:
  - The large and growing TARN submission backlog and the non-submission of data during the period that TARN is offline, culminating in a nation-wide loss of data for the affected quarter,
  - The unknown status of historical TARN data,
  - Delays to the availability of reporting, including quarterly dashboards, clinical reports and TARN analytics that drive the contracting frameworks,
  - The reimbursement of TARN fees during the downtime,
  - Inadequate communication,
- This letter advised that WHSSC was monitoring the TARN database as a serious commissioning risk, and to request detail of the plan and timescale for the implementation of a comprehensive TARN system, as well as assurance on delivery,
- In the meantime, the Network has developed its own interim spreadsheet in an attempt to capture some data, whilst the DAG has been advised that data that has not been submitted during the TARN downtime will be lost as there is no resource available to retrieve such a backlog, resulting in a period of time where metrics and comparisons will be lacking,
- **Other risks** – Of the 22 risks identified in the Network's Risk and Issue Register, two are currently highlighted as a red RAG rating:
  - Vulnerable Major Trauma Centre orthoplastic nursing workforce as a result of a split-site (CVUHB and SBUHB) working model and resultant siloes, compounded by the constraints of launching the SWTN during the Covid pandemic; and
  - Lack of a Clinical Lead for Trauma in Older People, received by WHSSC as a CIAG scheme in 2022 and 2023.

4.0 RECOMMENDATIONS

Members are asked to:

- **Note** the report; and
- **Receive** assurance that the Major Trauma Network's delivery and outcomes are being scrutinised by the Delivery Assurance Group (DAG).

Governance and Assurance	
Link to Strategic Objectives	
Strategic Objective(s)	Governance and Assurance
Link to Integrated Commissioning Plan	Major Trauma priorities and benefits realisation
Health and Care Standards	Safe Care Effective Care Individual Care
Principles of Prudent Healthcare	Reduce inappropriate variation Care for Those with the greatest health need first Only do what is needed
NHS Delivery Framework Quadruple Aim	Wales has a higher value health and social care system that has demonstrated rapid improvement and innovation, enabled by data and focused on outcome People in Wales have better quality and accessible health and social care services, enabled by digital and supported by engagement The health and social care workforce is motivated and sustainable Choose an item.
Organisational Implications	
Quality, Safety & Patient Experience	The DAG receives assurance reports which include indicators of quality, safety and experience.
Finance/Resource Implications	The DAG report includes a quarterly update on the major trauma expenditure and strategic priorities.
Population Health	The purpose of the SWTN is to improve access and equity to services to improve population health within South Wales.
Legal Implications	No legal implications have been identified.
Long Term Implications	The outcomes and benefits of the MTN are monitored and assured by the DAG.
Report History	CDGB - 16 January 2024
Appendices	-

Report Title	**Corporate Governance Report**	**Agenda Item**	4.4
Meeting Title	**Joint Committee**	**Meeting Date**	30/01/2024
FOI Status	Open		
Author (Job title)	Head of Corporate Governance		
Executive Lead (Job title)	Committee Secretary & Associate Director of Corporate Services		

Purpose of the Report	The purpose of this report is to provide an update on corporate governance matters that have arisen since the previous meeting.				
Specific Action Required	RATIFY ☐	APPROVE ☐	SUPPORT ☐	ASSURE ☒	INFORM ☒

Recommendation(s)

Members are asked to:

- **Note** the report.

CORPORATE GOVERNANCE REPORT

1.0 SITUATION

The purpose of this report is to provide an update on corporate governance matters that have arisen since the previous meeting.

2.0 BACKGROUND

There are a number of corporate governance matters that need to be reported as a regular item in-line with the governance and accountability framework for WHSSC. This report encompasses all such issues as one agenda item.

3.0 ASSESSMENT

3.1 Matters Considered In-Committee

In accordance with the WHSSC Standing Orders (SOs), the Joint Committee (JC) is required to report any decisions made in private "In-Committee" session, to the next available public meeting of the JC. An "In-Committee" meeting was held on 21 November 2023 and the following updates were received:

- Minutes of the In Committee Meeting held on 19 September 2023,
- Managing Directors Report,
- Financial Limits Assurance Report; and
- Any Other Business.

3.2 Welsh Health Circulars (WHCs)

Welsh Government (WG) issue Welsh Health Circulars (WHCs) around specific topics. The following WHCs have been received since the last meeting and are available via the WG website, where further details as to the risks and governance issues are available:

- WHC/2023/038 Healthy Start e-learning course
- WHC/2023/039 Independent authorization of blood component transfusion (IABT) – 2023 to 2026
- WHC/2023/040 The newborn and infant physical examination Cymru
- WHC/2023/043 Vaccination of healthcare staff to protect against measles
- WHC/2023/044 Change to the influenza (Flu) vaccination programme 2023 to 2024
- WHC/2023/046 All-Wales control framework for flexible workforce capacity
- WHC/2023/047 Influenza vaccines and eligible cohorts for the 2024 to 2025 season
- WHC/2023/48 - 2024-25 Health Board Allocations
- WHC/2024/001 - Changes to the way individuals who are at highest risk from Covid-19 access lateral flow tests

3.3 Forward Work Plan

The Joint Committee Forward Work Plan is presented at ***Appendix 1*** for information.

3.4 Virtual Committee Arrangements

Further to the Committee effectiveness exercise for 2021-2022 undertaken in April 2022, the feedback from individual members indicated that the majority of members would prefer to continue with the virtual meeting arrangements adopted during the COVID-19 pandemic and the recovery phase. The WHSSC IMs attended the Joint Committee on 16 May 2023 in person which was followed by an informal lunch as part of the inductions process. In addition, feedback received during the 2022-2023 exercise suggested twice yearly face to face meetings for the Joint Committee would be welcomed. Therefore, the majority of Joint Committee meetings will still be virtual with the exception of twice yearly in person meetings. An in person meeting took place in September 2023 and it was intended to hold the 19 March 2024 JC meeting in person. Unfortunately due to competing work pressures it has been decided that the March 2024 meeting will be held virtually. The sub-committee meetings will continue to be held virtually for the foreseeable future, and face to face meetings will be considered for any key decision making requirements as deemed appropriate by the Chair.

4.0 RECOMMENDATIONS

Members are asked to:

- **Note** the report.

Governance and Assurance	
Link to Strategic Objectives	
Strategic Objective(s)	Governance and Assurance
Link to Integrated Commissioning Plan	Approval process
Health and Care Standards	Governance, Leadership and Accountability
Principles of Prudent Healthcare	Public & professionals are equal partners through co-production
Institute for HealthCare Improvement Quadruple Aim	Improving Patient Experience (including quality and Satisfaction) Choose an item. Choose an item.
Organisational Implications	
Quality, Safety & Patient Experience	Ensuring the Integrated Governance Committee makes fully informed decisions is dependent upon the quality and accuracy of the information presented and considered by those making decisions. Informed decisions are more likely to impact favourably on the quality, safety and experience of patients and staff.
Finance/Resource Implications	Not applicable
Population Health	Not applicable
Legal Implications (including equality & diversity, socio economic duty etc.)	There are no direct legal implications. There are no adverse equality and diversity implications.
Long Term Implications (incl. WBFG Act 2015)	WHSSC is committed to considering the long-term impact of its decisions, to work better with people, communities and each other, and to prevent persistent problems such as poverty, health inequalities and climate change.
Report History (Meeting/Date/ Summary of Outcome	-
Appendices	Appendix 1- WHSSC Forward Work Plan

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

WHSSC JOINT COMMITTEE – 12 MONTH ROLLING FORWARD WORK PLAN 2023-2025

MEETING	STANDING ITEMS	FOR APPROVAL / ACTION	ROUTINE REPORTS	INFORMATION
30 January 2024	Chair's Report Managing Director's Report Declarations of Interest Minutes Action Log Forward Work Plan	WHSSC Integrated Commissioning Plan Corporate Risk Assurance Framework and Business Continuity Risks Related to the Establishment of the Joint Commissioning Committee Mental Health Strategy Delivering Mechanical Thrombectomy Capacity in South Wales (Phase 1).	WHSSC Integrated Performance Report – November 2023-2024 Financial Performance Report Month 9 Corporate Governance Matters Report Report from the Chair of the CTMUHB Audit & Risk Committee Reports from the Joint Sub-Committees - Management Group Briefings - Individual Patient Funding Request Panel - WKN	Commissioning of Advances Therapy Medicinal Products in Wales. WHSSC Cardiac Review – Outcomes of Phase 1 South Wales Trauma Network Delivery Assurance Group
19 March 2024	Chair's Report		WHSSC Integrated Performance Report	

MEETING	STANDING ITEMS	FOR APPROVAL / ACTION	ROUTINE REPORTS	INFORMATION
	Managing Director's Report Declarations of Interest Minutes Action Log Forward Work Plan		Financial Performance Report Financial Assurance Report Corporate Governance Matters Report Report from the Chair of the CTMUHB Audit & Risk Committee Reports from the Joint Sub-Committees - Management Group Briefings - Quality & Patient Safety Committee - Integrated Governance Committee - Individual Patient Funding Request Panel - WKN	
21 May 2024	Chair's Report		WHSSC Integrated Performance Report	

MEETING	STANDING ITEMS	FOR APPROVAL / ACTION	ROUTINE REPORTS	INFORMATION
	Managing Director's Report Declarations of Interest Minutes Action Log Forward Work Plan		Financial Performance Report Financial Assurance Report Corporate Governance Matters Report Report from the Chair of the CTMUHB Audit & Risk Committee Reports from the Joint Sub-Committees - Management Group Briefings - Quality & Patient Safety Committee - Integrated Governance Committee - Individual Patient Funding Request Panel - WKN	
16 July 2024	Chair's Report		WHSSC Integrated	

MEETING	STANDING ITEMS	FOR APPROVAL / ACTION	ROUTINE REPORTS	INFORMATION
	Managing Director's Report Declarations of Interest Minutes Action Log Forward Work Plan		Performance Report Financial Performance Report Financial Assurance Report Corporate Governance Matters Report Report from the Chair of the CTMUHB Audit & Risk Committee Reports from the Joint Sub-Committees - Management Group Briefings - Quality & Patient Safety Committee - Integrated Governance Committee - Individual Patient Funding Request Panel - WKN	

MEETING	STANDING ITEMS	FOR APPROVAL / ACTION	ROUTINE REPORTS	INFORMATION
17 September 2024	Chair's Report Managing Director's Report Declarations of Interest Minutes Action Log Forward Work Plan		WHSSC Integrated Performance Report Financial Performance Report Financial Assurance Report Corporate Governance Matters Report Report from the Chair of the CTMUHB Audit & Risk Committee Reports from the Joint Sub-Committees - Management Group Briefings - Quality & Patient Safety Committee - Integrated Governance Committee - Individual Patient Funding Request Panel - WKN	

MEETING	STANDING ITEMS	FOR APPROVAL / ACTION	ROUTINE REPORTS	INFORMATION
19 November 2024	Chair's Report Managing Director's Report Declarations of Interest Minutes Action Log Forward Work Plan		WHSSC Integrated Performance Report Financial Performance Report Financial Assurance Report Corporate Governance Matters Report Report from the Chair of the CTMUHB Audit & Risk Committee Reports from the Joint Sub-Committees - Management Group Briefings - Quality & Patient Safety Committee - Integrated Governance Committee - Individual Patient Funding Request Panel	

MEETING	STANDING ITEMS	FOR APPROVAL / ACTION	ROUTINE REPORTS	INFORMATION
			- WKN	
21 January 2025	Chair's Report Managing Director's Report Declarations of Interest Minutes Action Log Forward Work Plan		WHSSC Integrated Performance Report Financial Performance Report Financial Assurance Report Corporate Governance Matters Report Report from the Chair of the CTMUHB Audit & Risk Committee Reports from the Joint Sub-Committees - Management Group Briefings - Quality & Patient Safety Committee - Integrated Governance Committee - Individual Patient Funding Request	

MEETING	STANDING ITEMS	FOR APPROVAL / ACTION	ROUTINE REPORTS	INFORMATION
			Panel - WKN	
18 March 2025	Chair's Report Managing Director's Report Declarations of Interest Minutes Action Log Forward Work Plan		WHSSC Integrated Performance Report Financial Performance Report Financial Assurance Report Corporate Governance Matters Report Report from the Chair of the CTMUHB Audit & Risk Committee Reports from the Joint Sub-Committees - Management Group Briefings - Quality & Patient Safety Committee - Integrated Governance Committee - Individual Patient	

MEETING	STANDING ITEMS	FOR APPROVAL / ACTION	ROUTINE REPORTS	INFORMATION
			Funding Request Panel - WKN	

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

Joint Committee
30 January 2024
Agenda Item 4.5.1

CTMUHB Audit and Risk Committee – Part 2 Assurance Report

Reporting Committee	**CTMUHB Audit and Risk Committee – Part 2**
Chaired by	**Patsy Roseblade, Chair of the Audit & Risk Committee**
In attendance for WHSSC	**Stacey Taylor, Director of Finance** **Jacqui Maunder-Evans, Committee Secretary**
Date of Meeting	**19 December 2023**
Report Author	**Committee Secretary**

Summary of key matters considered by the Committee and any related decisions made

The CTMUHB Audit & Risk Committee (ARC) provide assurance to the Joint Committee of the effectiveness of its arrangements for handling reservations and delegations. The Memorandum of Agreement states that the Audit Lead will provide reports to the Joint Committee following the Host Audit & Risk Committee meetings. This assurance report sets out the key areas of discussion and decision.

1. EASC Update (including an update on Non-Emergency Patient Transport Services and the Integrated Commissioning Action Plan)

Gwenan Roberts (GR), Deputy Director Corporate and Committee Secretary, EASC gave an update on the EASC business including:

1. EASC Risk Register
2. EASC Assurance Framework
3. Investigation Welsh Language Commissioner
4. EASC Performance Report

The Committee **noted** the report.

2.WHSSC Corporate Risk Assurance Framework (CRAF)

Jacqui Maunder-Evans (JME) presented the Corporate Risk and Assurance Framework (CRAF). Members noted that:

- As at 31 October 2023, there were 23 risks on the CRAF with a risk score of 15 and above,
- There were 19 commissioning risks, which included three new commissioning risks; and
- There were 4 organisational risks.

The Committee **noted** the report.

3.WHSSC Internal and External Audit Recommendations Tracker
JME gave a progress report on the implementation of internal and external audit recommendations.

Members noted:

- the summary of internal audits undertaken during 2022-2023 and the assessment ratings,
- that two recommendations were outstanding in relation to the report on Risk Management, the due dates had been revised to March 2024 due to competing work pressures,
- That 2 recommendations were outstanding in relation to the report on the Welsh Kidney Network (WKN) and the due dates for both items had been revised,
- A new internal audit assessment report on the Development of the WHSSC integrated Commissioning Plan (ICP) was being presented for the first time. There are 3 recommendations in the report, none of which have reached the due date; and
- The progress made against the seven external audit recommendations outlined in the Audit Wales report "WHSSC Committee Governance Arrangements".

Members noted that a full progress report on the Audit Wales recommendations was presented to the WHSSC Joint Committee on 21 November 2023 and a further progress report will be shared with the NHS Wales Board Secretaries and Audit Wales in 2024.

The Committee **noted** the report.

4.WHSSC Internal Audit Report – Integrated Commissioning Plan (ICP) Process

Emma Samways presented the final internal audit report following an internal audit assessment of the WHSSC Integrated Commissioning Plan (ICP) process. Member noted that the report gave a substantial assurance assessment rating and that there were only very minor recommendations.

The Committee **noted** the report.

Matters referred to other Committees	
None	
Date of next scheduled meeting	22 February 2024

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

CORE BRIEF TO MANAGEMENT GROUP MEMBERS

MEETING HELD ON 23 NOVEMBER 2023

This briefing sets out the key areas of discussion and decision. It aims to ensure the Management Group members have a common core brief to disseminate within their organisation.

1. Welcome and Introductions

The Chair welcomed members to the meeting noting that, following on from the COVID-19 pandemic, meetings continued to be held via MS Teams.

2. Action Log

Members received an update on progress against the action log and **noted** the updates.

3. Managing Director's Report

Members received the Managing Director's Report and noted the update on:

- **Functional Neurosurgical Service for patients with complex movement disorders in South Wales (Including a Deep Brain Stimulation -** A letter has been sent to Bristol explaining our concerns about the Deep Brain Stimulation (DBS) Service. A letter inviting 'Expressions of interest' (EOI) to be the Designated provider for this service for the population of South Wales has been published on the WHSSC website with a closing date of 10 November 2023. The Designated Provider Process will follow once we have received the EOI responses from providers. There will be a requirement for potential designated providers to submit evidence to WHSSC that they can fulfil the service criteria to deliver a Functional Neurosurgery Service (including DBS) for the population of South Wales. The closing date for submissions is 15 December 2023 with the adjudication of potential providers scheduled for 20 December 2023. WHSSC will confirm with Bristol when the process is complete. WHSSC have met with the gatekeeper to request that those patients currently on the DBS pathway with Bristol will be reviewed by the Gatekeeper to establish whether we can send them to an alternative provider. A proforma has been completed to inform Llais of the urgent service change and the results of the process will be received by Management Group for scrutiny in January 2024,
- **Demand and Capacity Review Update -** In February 2023, the Joint Committee of Welsh Health Specialised Services Committee (WHSSC) commissioned a simulation-modelling led capacity and demand review of specialist mental health services. This report was

sent to WHSSC in October 2023. NICHE presented the report to representatives of the Welsh Government (WG), the NHS Wales Executive and to the WHSSC Corporate Directors Group Board (CDGB) on 30 October 2023. The report was also be presented to Joint Committee on 21 November 2023 and will provide a basis for the final Specialised Mental Health Strategy due for publication early in 2024.

Members **noted** the report.

4. Specialised Services Commissioning Strategy – Success Measures

Members received a report inform members of the progress made in developing a suite of meaningful success measures to support the Specialised Services Commissioning Strategy.

Members **noted** the progress made in developing a suite of meaningful success measures to support the Specialised Services Commissioning Strategy.

5. Integrated Performance Report – September 2023

Members received a report providing a summary of the performance of WHSSC commissioned services. Further detail by resident Health Board was provided in an accompanying Power Business Intelligence (BI) Dashboard report.

Members **noted** the report.

6. Financial Performance Report Month 7 2023-2024

Members received a report setting out the financial position for WHSSC for the 7th month of 2023-2024. The financial position was reported against the 2023-2024 baselines following approval of the 2023-2026 WHSSC Integrated Commissioning Plan by the Joint Committee in February 2023.

Members noted the year to date financial position reported at Month 7 for WHSSC (excluding EASC) is an underspend against the ICP financial plan of (£4.232m), the forecast year-end position is an underspend of (£9.287m).

Members **noted** the report.

7. Forward Work Plan

Members **noted** the forward work plan.

8. Any Other Business

- **Eating Disorder Unit at Ebbw Vale** - The Deputy Minister for Health opened Ty Glyn Ebwy, the new Eating Disorders unit in Ebbw Vale provided by Elysium Healthcare on 9 November 2023. WHSSC have secured the commissioning of 4 beds at the unit with 4 more coming on board in line with repatriation plans over the coming

weeks. Further beds may be commissioned at the unit if demand requires.

- **Cheshire and Wirral Partnership Mother and Baby Unit** - WHSSC have agreed to commission 2 beds at the Cheshire and Wirral Partnership Mother and Baby Unit for our north Wales and north Powys patients. We have been informed that enabling works commenced on 25th October 2023, main contracted works are commencing in January 2024, and completion and operational start of clinical services is scheduled for October 2024.
- **Internal Audit Report Integrated Commissioning Plan (ICP)** – An internal audit review of the processes that WHSSC has in place to develop its Integrated Commissioning Plan, with a focus on the financial planning element has taken place. The report concluded that the processes that are in place, including the engagement with the Management Group and the Joint Committee, allows timely feedback to the Health Boards (HBs) for inclusion in their Integrated Medium term Plans (IMTPs) and a substantial assurance rating was given for the work.
- **WHSSC Joint Committee Specialised Paediatric Services Workshop (Mid and South Wales)**
  There was a discussion on the recent JC Specialised Paediatric Services Workshop.

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

CORE BRIEF TO MANAGEMENT GROUP MEMBERS

MEETING HELD ON 14 DECEMBER 2023

This briefing sets out the key areas of discussion and decision. It aims to ensure the Management Group members have a common core brief to disseminate within their organisation.

1. Welcome and Introductions

The Chair welcomed members to the meeting noting that, following on from the COVID-19 pandemic, meetings continued to be held via MS Teams.

2. Action Log

Members received an update on progress against the action log and **noted** the updates.

3. Managing Director's Report

Members received the Managing Director's Report and noted the update.

Wales Fertility Institute Performance Concerns / Escalation

In July 2023, the Wales fertility Institute (WFI) was placed in stage 3 of the WHSSC Commissioning Assurance Framework (CAF). Since then, there have been a number of escalation meetings with the service, which did not provide assurance to WHSSC officers on the sustainability or the quality of the service. Due to the lack of assurance received during the escalation meetings the WFI have been placed at escalation level 4. Concerns relate to a Human Fertilisation & Embryology Authority (HFEA) inspection in January 2023 which identified a number of concerns including the statutory requirement for a person responsible (PR), the sustainability of the service, and a lack of assurance regarding the improvement plan. WHSSC and SBUHB continue to work together to address the issues of concern and the situation is fluid however there has been recent progress. Over recent weeks Swansea Bay University Health Board has been liaising with WHSSC and the Human Fertilisation and Embryology Authority (HFEA) and SBUHB have issued a joint statement providing assurance on the plans in place to strengthen and sustain the service.

Members **noted** the report.

4. Delivering Mechanical Thrombectomy Capacity in South Wales (Phase 1)

Members received a report seeking support to establish a regional Mechanical Thrombectomy (MT) centre in South Wales.

Members (1) **Noted** the report, (2) **Noted** the financial framework to support the development of a Mechanical Thrombectomy centre for South Wales, (3) **Noted** the benefits and risks associated with the investment, (4) **Supported** the funding to establish Phase 1 of a local Thrombectomy service for the South Wales region to present to Joint Committee to be considered as part on the wider ICP; and (5) **Supported** the proposal for a post-implementation commissioning evaluation for Phase 1 of the commissioned service.

5. WHSSC Cardiac Review – Outcomes of Phase 1

Members received a report summarising the outcomes of Phase 1 of the WHSSC Cardiac Review, which sought to re-baseline the South Wales Trans-catheter Aortic Valve Implantation (TAVI) and cardiac surgery contracts to ensure that they better reflected potential demand; and assessed the extent to which, in view of recent trends and differential valve costs, the TAVI policy remained both adhered to and apposite.

Members noted that in January 2023 the Joint Committee agreed that Phase 1 of the review would be completed by the end of Q3 2023/24, and that it would be followed by a second phase focussed on the future configuration of WHSSC-commissioned TAVI and cardiac surgery

Members (1) **Noted** the findings of Phase 1 of the WHSSC Cardiac Review**,** (2) **Approved** that the proposed revised TAVI and cardiac surgery contract baselines be used as the basis for negotiations with Cardiff and Vale University Health Board (CVUHB) and Swansea Bay University Health Board (SBUHB), (3) **Supported** the finding that the current WHSSC TAVI Commissioning Policy remains both adhered to and apposite; and (4) **Supported** the work ongoing to clarify and reduce TAVI valve costs.

6. ABUHB Obesity Surgery Business Case - Designated Provider Assessment

Members received a report summarising the outcomes of the ABUHB obesity surgery business case assessment through the WHSSC Designated Provider Framework.

Members noted that following the submission of a business case by Aneurin Bevan University Health Board (ABUHB) in support of the Health Board's (HBs) longstanding ambition of being a WHSSC-commissioned provider of obesity surgery had been made pertaining to the future commissioning of obesity surgery for the population of Wales and the actions in progress to address concerns with the activity levels and the waiting list position of the Salford Royal Hospital Obesity Surgery service.

Members (1) **Noted** the assessment of the ABUHB obesity surgery business case undertaken by means of the WHSSC Designated Provider Framework, (2) **Approved** that in view of the current financial climate, WHSSC advise ABUHB

that it was not able to fund an additional provider of obesity surgery and was not, therefore, able to support the recommendation contained in the business case that WHSSC commission an ABUHB obesity surgery service, (3) **Noted** that the submitted business case was of a high quality, but that potential interest from other Health Boards (HBs) in being a commissioned provider had necessitated the commencement of a new designated provider process in the event of changes to the funding climate and/or demand for obesity surgery; and (4) **Supported** the actions underway to communicate revisions to the obesity surgery access criteria, and to address concerns with access to obesity surgery for patients from Betsi Cadwaladr University Health Board (BCUHB) and North Powys.

7. Mental Health Specialised Services Strategy for Wales 2024/25 – 2028/29

Members received a report presenting the final WHSSC Mental Health Specialised Services Strategy for Wales 2024/25- 2028/29 and to outline the governance structure for the implementation programme.

Members (1) **Noted** the report; and (2) **Supported** the WHSSC Mental Health Specialised Services Strategy for Wales 2024/25- 2028/29 and submit to the Joint Committee for approval in January 2024.

8. Integrated Performance Report – October 2023

Members received a report providing a summary of the performance of WHSSC commissioned services. Further detail by resident Health Board was provided in an accompanying Power BI Dashboard report.

Members **noted** the report.

9. Financial Performance Report Month 8 2023-2024

Members received a report setting out the financial position for WHSSC for the 8th month of 2023-2024. The financial position was reported against the 2023-2024 baselines following approval of the 2023-2026 WHSSC Integrated Commissioning Plan by the Joint Committee in February 2023.

Members noted the year to date financial position reported at Month 8 for WHSSC (excluding EASC) was an underspend against the ICP financial plan of (£3.348m), the forecast year-end position is an underspend of (£9.722m).

Members **noted** the current financial position and forecast year-end position.

10. Forward Work Plan

Members **noted** the forward work plan.

11. Any Other Business

Shortage of Immunoglobulin – Members noted that due to increasing demand for immunoglobulins (year on year), there is a worldwide shortage that also affects the UK. WHSSC have been in discussion with Velindre University Hospital Trust (VUNT), and the Welsh Blood Service (WBS) to look at their proposal for future immunoglobulin production in line with Welsh Government discussions. It is likely that Management Group will receive a business case from VUNT in the new year, for support.

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

Agenda Item 4.5.3
Joint Committee
30 January 2024

Reporting Committee	**All Wales Individual Patient Funding Request (IPFR) Panel**
Chaired by	**Richard Hain – 15/11/2023** **Elizabeth Abderrahim since 22/11/2023**
Lead Executive Director	**Director of Nursing and Quality Assurance**
Date of last meeting	**WHSSC IPFR Panel meeting 19 January 2024 (Chairs Action)**

Summary of key matters considered by the Committee and any related decisions made.

The unavailability of Health Board representatives has meant that there have been a number of occasions when it has not been possible to achieve quoracy and funding decisions made during November and December 2023 have had to be made as Chair Actions.These decisions included both urgent and elective requests. Whilst unavoidable this represents a departure from the governance arrangements set out in the terms of reference and it is hoped that with the implementation of the new terms of reference this practice will be avoided in the future.

The following table demonstrates the number of requests considered at the Chair's Action Panel meetings and All Wales IPFR Panel meetings during this reporting period.

	Number of Requests discussed as Chair's Actions	Number of Requests discussed by WHSSC IPFR Panel
November	22	0
December	6	0

Key risks and issues/matters of concern and any mitigating actions

All Wales IPFR Policy Review
The final version of the All Wales IPFR policy, including the revised terms of reference for the All-Wales Panel, has been circulated to the Health Boards for approval by their respective boards.

Once all the Health Boards have agreed the policy, a date will be agreed to implement the Policy across NHS Wales but this unlikely to be before March 2024.

Induction and support of the Newly appointed All Wales IPFR Chair
Elizabeth (Lizzie) Abderrahim, took up the role from 1 November 2023. She has attended a full day in-house induction covering the process and function of IPFR

decision-making, overview of the extant policy and introduction to the revised policy. Her first Chair's Action meeting was held on 28 November 2023.

The role of the new Chair fits with the proposed revised terms of reference.

Change of meeting day
To meet the availability of the Chair, Panel meetings have now been scheduled from January 2024 for the first and third Wednesdays of each month.

The first full IPFR Panel meeting since 19 October 2023 was held on 3 January 2024. The meeting was quorate with 6 of the 7 Health Boards in attendance and provided an opportunity for the Chair to meet and receive introductions from Panel members.

IPFR Application form
An email detailing the issues related to completion of IPFR applications, especially section 9 of the IPFR form, and the need for clinician support and training in completing applications was sent to the Chair of the All-Wales Therapeutics and Toxicology Centre (AWTTC -the lead organisation for all Wales IPFR).

As a result, AWTTC in association with the All-Wales IPFR Network have commenced work on expanding existing and developing new training and guidance resources to assist clinicians.

- None

Matters referred to other Committees

- None

Confirmed Minutes for each of the meetings are available on request.

Date of next meeting	**7 February 2024**

Reporting Committee	**Welsh Kidney Network**
Chaired by	**Chair, Welsh Kidney Network**
Lead Executive Director	**Director of Programmes**
Date of last meeting	**6th December 2023**

Summary of key matters considered by the Committee and any related decisions made.

This report provides assurance to the Joint Committee in accordance with the Welsh Kidney Network Terms of Reference (ToR) which state that the Chair of the Welsh Kidney Network (the 'WKN') will provide reports to the Joint Committee following Welsh Kidney Network meetings, outlining the activities of the Network and bringing attention to any significant matters under consideration by the Network. Minutes are available on request from the Welsh Kidney Network Co-ordinator, Jonathan.Matthews@wales.nhs.uk.

1. STRATEGIC NETWORK ISSUES

1.1 Enhanced leadership capacity within the Welsh Kidney Network

Members noted that enhanced leadership capacity had been added to the central team of the Welsh Kidney Network recently by means of the following roles:

- The WHSSC Deputy Director of Planning and Networks (Claire Harding) joined the team from 06 November 2023 in order to offer senior oversight and leadership.
- The Clinical lead for Pharmacy (Robert Bradley)has been appointed within the quarter, additional pharmacy project leadership (Owain Brooks) has also been secured. Funding for both posts are within the current direct running costs of the Welsh Kidney Network.
- Interviews were held on 18/12/23 for the QPS clinical lead role, Rhodri Pyart, Consultant Nephrologist has been appointed – members offered their thanks to Dr Ashraf Mikhail who had led this role with great success for the past 13 years.

1.2 Strategic Framework and Delivery Plan

Having noted that the previous WKN delivery plan had a timescale of 2016-2020. Members agreed that it was now appropriate to revisit both the delivery plan and the high level strategic framework within the context of the Welsh Kidney Quality statement – a paper is being developed on this for the February Board meeting.

1.3 Financial Discussions re Welsh Kidney Network

Dr Sian Lewis attended the meeting on this occasion to share the National financial context, how this was impacting WHSSC generally, and to discuss the implications for the Welsh Kidney Network. Members were reminded of the £81m investment within Renal services in Wales, and asked to consider how they could contribute

to the savings required within NHS Wales. Members agreed to consider potential savings areas with all members commenting that this should not be at the detriment of patient care. All proposals to be with the interim Network Manager within 2 weeks. Following this, a proposal has been put together which equates to a potential near £0.5m savings within year, and a number of longer term savings targets linked to reducing unit dialysis and increasing both transplants and home therapy options.

1.4 Welsh Kidney Network Governance Review and action plan

Members were pleased to note that all aspects of the governance review had now been concluded and there was no need for further tracking of the action plan through the Board.

1.5 National Renal Audit Event

A report was received by the Welsh Kidney Network Board on the successful renal audit event held earlier in the year, in particular, the actions that arose as a result of the event (many of which will be the subject of forthcoming reports to Board) and the announcement that all presentations made on the day which demonstrated a number of areas of innovation and future developments are now available via this hyperlink (*may require being logged into Citrix session in order to view*).

1.6 Welsh Kidney Network - Peer Review Process

The Welsh Kidney Network has an established rolling programme of peer reviews. The focus within 2023/2024 was 'Unit dialysis'. This was the biggest peer review to date undertaken by the Network, and included peer review of 19 dialysis units across Wales. The programme commenced in January 2023, and concluded in November 2023. The findings of each review were conveyed to the visited units on the day of the visit and have been followed up with a Health Board specific formal written report. Common themes will be identified across the reports and these will assist future service and contract modelling. The findings will also be beneficial for shared learning amongst all units once the full suite of reports is released across the regions. A full report will be submitted into the next Welsh Kidney Network Board, February 2024.

1.7 Clinical Leads

The Network is lucky to be supported by a number of clinical lead roles. Approval was given in the December 2023 Board for a prevention clinical lead. This post is currently out for expression of interest, with an aim to appoint into the role by March 2024. A renewal process for the current Home Dialysis clinical lead role will run within a similar timescale.

1.8 Welsh Government Briefings (Home Dialysis & Housing)

Within the last reporting period, two briefings have been prepared for Welsh Government with regard the Networks approach to home dialysis and reporting on an innovative 'housing and health' scheme in North Wales.

2. ISSUES REPORTED FROM REGIONS

2.1 **South East Wales Region** – There were no issues of escalation from the South East Wales Region – previously reported pressures across Dialysis units has reduced

2.2 **South West Wales Region** – There appears to be slippage on the two new units in the South West Wales area (Bridgend and Neath Port Talbot) discussions following the WKNB resulted in the following timescales being confirmed:

- Bridgend revised date October 2024
- Neath Port Talbot revised date May 2025

It should be noted that these discussions are being managed at a regional level; as such only variance and assurance on mitigations are reported to Board.

Interventional radiology within the region remains fragile and proposals are being pursued within the region to address this.

There is a need to escalate actions with regard Peritoneal Dialysis fluids and associated procurement processes. The WKNB awaits update and need for any further action.

2.3 **North Wales Region** – BCUHB anticipate exceeding their agreed block contract activity numbers by the time they reach the end of the financial year. A number of the units are running at full capacity. Discussions to take place between the Welsh Kidney Network central team and BCUHB on this as well as potential to move capacity across units.

3. QUALITY AND PATIENT SAFETY

No new risks were reported to the WKN Board on this occasion. Three of the current risks on the Network register hold a residual risk score exceeding 15.

These risks are reported at QP&S committee however relate to:

3. Manpower within the team
4. Limited outpatient dialysis capacity in Swansea
5. Renal Dialysis capacity at BCU

There are mitigating actions in place for all risks.

4. HIGHLIGHT REPORTS

The following highlight reports were received during the Board meeting:

- Kidney Care UK Highlight Report
- Kidney Wales Highlight Report
- Popham Kidney Support Report

• Clinical Information Lead Highlight Report • Lead Nurse Work Programme update • Workforce Audit update • SBUHB Highlight Report • BCUHB Highlight Report • CVUHB Highlight Report • Transplant and Vascular Access Clinical Lead Highlight Report
Matters requiring Committee level consideration and/or approval
None.
Matters referred to other Committees
• None

Date of next meeting	**1st February 2024**