

Patient, Quality, Safety Outcomes Committee

Mon 02 September 2024, 14:00 - 17:00

Microsoft Teams



Agenda

1. PRELIMINARY MATTERS

1.1. Welcome and Introductions

Oral Chair

1.2. Apologies for Absence

Oral Chair

1.3. Declarations of Interest

Oral Chair

1.4. Draft Minutes of the last Meeting held on Tuesday 30th July 2024

Attached Chair

 1.4 PQSOC Minutes 30th July 2024 PB reviewed.pdf (12 pages)

1.5. Committee Action Log

Attached Chair

 1.5 Final Action Log September reviewed by RD.pdf (5 pages)

2. ITEMS FOR DISCUSSION

2.1. Committee Risk Report

Attached Director of Corporate Governance

-  2.1 Committee Risk Report.pdf (6 pages)
-  2.1 Appendix A Strategic Risk Register.pdf (1 pages)
-  2.1 Appendix B Strategic Risk Assessments..pdf (4 pages)

2.2. Quality Annual Report 2023/24

Attached Director of Nursing

-  2.2 Annual Quality Report 2023-24.pdf (5 pages)
-  2.2 Appendix 1 Quality Annual Report 2023-24.pdf (40 pages)
-  2.2 Appendix 2 PQSOC Quality Strategy - Implementation Plan Final July 2023.pdf (13 pages)
-  2.2 Appendix 3 - Reflections on STEEEP Aug 2024.pdf (23 pages)

2.3. Putting Things Right Annual Report 2023/24

Attached Director of Nursing

-  2.3 Putting Things Right Annual Report 23-24.pdf (11 pages)
-  2.3 Appendix 1 Putting Things Right Annual Report 2023-24.pdf (41 pages)

📄 3.2 NHS Wales Joint Commissioning Committee's Quality Report.pdf (6 pages)

📄 3.2 Appendix 1 - Services in Escalation Summary.pdf (8 pages)

3.3. Learning and Improvement Forum

Attached *Director of Nursing*

📄 3.3 Minutes 09.07..24 - Patient Quality Safety Learning Improvement Forum. (1).pdf (5 pages)

📄 3.3 Appendix 1 PQSLI Forum slide deck July.pdf (108 pages)

📄 3.3 Appendix 2 Sources of Learning and Approaches to Sharing and Improvement - DRAFT.pdf (9 pages)

4. OTHER MATTERS

4.1. Items to be Brought to the Attention of the Board and Other Committees

Oral *Chair*

4.2. Any Other Urgent Business

Oral *Chair*

4.3. Date of the Next Meeting: Tuesday 12th November 2024



**CYFARFOD BWRDD IECHYD PRIFYSGOLN
ANEURIN BEVAN/ANEURIN BEVAN UNIVERSITY
HEALTH BOARD MEETING**

**MINUTES OF THE PATIENT QUALITY, SAFETY AND OUTCOMES COMMITTEE
MEETING**

DATE OF MEETING	Tuesday 30th July 2024, 9:30am
VENUE	Microsoft Teams

PRESENT	Pippa Britton, Independent Member, Committee Chair Helen Sweetland, Vice Chair Paul Deneen, Independent Member Penny Jones, Independent Member
IN ATTENDANCE	Jennifer Winslade, Director of Nursing Rani Dash, Director of Corporate Governance Peter Carr, Director of Therapies & Health Science James Calvert, Medical Director Nicola Prygodzicz, Chief Executive Gemma Couch, Head of Quality, Patient Safety & Learning Kelly Downes, Deputy Director of Nursing Natalie Skyrme, Head of Nursing Ann Marie Matthews, Lead for Clinical Commissioning/IPFR Jonathan Simms, Clinical Director of Pharmacy Sarah Beuschel, Transfusion Practitioner Howard Stanley, Head of Safeguarding Kolade Gamel, Service Group Manager Linda Joseph, LLais Cymru Rhian Gard, Deputy Head of Internal Audit Sara Utley, External Audit Tracey Partridge-Wilson, Deputy Director of Nursing Jayne Beasley, Head of Midwifery & Gynaecology Moira Bevan, Head of Infection Prevention and Control Tanya Strange, Head of Nursing Person Centred Care Ceri Phillips, Consultant Pharmacist Thomas Jaynes, Committee Secretariat Megan Frampton, Committee Secretariat
APOLOGIES	Michelle Jones, Head of Board Business Leeanne Lewis, Assistant Director of Quality & Patient Safety

PQSOC 3007/01	Welcome and Introductions The Chair welcomed everyone to the meeting.
PQSOC 3007/02	Apologies for Absence Apologies for absence were noted.
PQSOC 0406/03	Declarations of Interest

PQSOC 3007/04	<p>There were no declarations of interest raised to record.</p> <p>Minutes of the previous meeting</p> <p>The minutes of the Patient Quality, Safety and Outcomes Committee held on 4th June 2024 were agreed as a true and accurate record subject to the inclusion of the following under minute PQSOC 0406/2.3:</p> <p>Paul Deneen (PD), Independent Member, queried the data presented on the Incident Reporting Module of DATIX Cymru, and in particular the process and criteria for determining “closed” and “rejected” incidents. It was agreed that the guidance for reporting and handling of incidents would be shared with Committee Members by email for information.</p> <p>Action: Director of Nursing/Director of Therapies and Health Science</p>
PQSOC 3007/05	<p>Committee Action Log</p> <p>The Committee received the action log and was content with the progress made in relation to completed actions and against any outstanding actions, as set out within the Action Log.</p>
PQSOC 3007/06	<p>Committee Risk Report</p> <p>Rani Dash (RD), Director of Corporate Governance, provided an overview of the Committee Risk Report, noting that the Committee Risk Register included three high-level risks, three sub-risks, and one corporate risk; all unchanged from the July Board report.</p> <p>RD explained that the corporate risk ‘catastrophic failure of the Pharmacy Robot’ would be eliminated with the implementation of a new robot scheduled between August and October 2024.</p> <p>Helen Sweetland (HS), Independent Member, asked if the Executive Team had scheduled a session to discuss corporate risks in detail. RD confirmed that a time-out session was planned for September, with a summary of corporate risks to be presented to the Board at the end of September 2024.</p> <p>The Committee:</p> <ul style="list-style-type: none"> • NOTED the delegated strategic risks; • NOTED the delegated corporate risk; • NOTED the work being undertaken to reduce the risks to within appetite level; and,

- **NOTED** the work being undertaken to ensure the Committee is sighted on all risks that have the potential to impact patient quality and safety.

PQSOC 3007/07**Quality Performance Report**

Jennifer Winslade (JW), Director of Nursing, supported by Peter Carr (PC), Director of Therapies & Health Science, Natalie Skyrme (NS), Head of Nursing – Urgent Care Division, Gareth Marr (GM), Improvement Programme Director for Mental Health and Learning Disabilities, and Tracey Partridge Wilson (TPW), Deputy Director of Nursing, presented the Committee with an overview of the patient quality and safety outcomes performance report for the period.

JW outlined key priorities for the next six months, including revising the Quality Outcomes Framework, strengthening divisional quality and safety structures, refreshing the Quality Improvement Plan, and enhancing assurance and reporting arrangements. JW mentioned a planned meeting with the Director of Corporate Governance to restructure the Quality Performance Report for greater assurance..

NS provided an update on patient experience within the Emergency Department (ED) at the Grange University Hospital, noting: -

- Monthly meetings were being held with CIVICA to look at ways to improve patient feedback capture.
- The establishment of a people participation panel had been initiated to enhance patient care.
- Collaboration with Cardiff & Vale University Health Board had been initiated to ensure best practices for caring for dementia patients in ED and
- Red Cross continued to support patients and staff.

The Committee raised a concern about potential abnormalities in recorded waiting times, and requested the data be re-examined. This was due to a statistic within the presentation to the Committee presenting a waiting time for one individual of 225 hours.

Action: Jennifer Winslade (JW), Director of Nursing, to review the data presented and provide confirmation to the Committee on its accuracy.

GM discussed ongoing improvements in the Mental Health and Learning Disabilities Division, which was under internal Special Measures, and reported progress towards achieving Welsh Government targets.

TPW updated on the 27 recommendations from Healthcare Inspectorate Wales (HIW), emphasising the use of the AMaT system for tracking actions, with regular progress reports planned.

NS reported improvements in the ED's triage times now down to 17 minutes, and a monthly decrease in the number of patients with chest pains waiting longer than 60 minutes.

Pippa Britton (PB), Committee Chair, inquired about the impact of E-Triage since implementation. NS confirmed this was positive, although the collection of data was still inconsistent.

Penny Jones (PJ), Independent Member, requested information on sepsis protocols. NS provided an overview of current arrangements which included immediate medical assessments and fortnightly sepsis protocol meetings. JW committed to presenting the outcome of a comprehensive sepsis management review to a future meeting.

Action: Jennifer Winslade (JW), Director of Nursing to present information regarding the protocol for patients presenting with Sepsis to the Committee.

JW reported that changes to Patient Safety Incident reporting had led to an increase in reported incidents due to new Welsh Government policy requiring the reporting of stillbirth, birth loss, uterine death, and infection prevention and control issues. JW noted that the Health Board had received feedback from the Welsh Government emphasising the need to improve the timely closure of patient safety incident reports. JW reported that tracked progress over the last three years showed significant improvement, with 8% of reports closed within the target timeframe in 2022, 13% in 2023, and 38% in 2024. JW committed to bringing a detailed report on the timeliness of closures to a future meeting for assurance.

Action: Jennifer Winslade (JW), Director of Nursing, to present a report on the timely closure of Patient Safety Incidents to the Committee.

TPW informed the Committee that in May 2024, Putting Things Right (PTR) established an acknowledgment team dedicated to making immediate contact with patients who had filed complaints. This initiative received positive feedback from the public and reaffirmed the commitment to a patient-centred approach. Despite a 40% increase in complaints compared to the same period last year the Committee observed that early resolution outcomes

managed through PTR had improved to 60%. It was noted that the Surgery Division accounted for a significant proportion, primarily concerning appointment issues and waiting times.

PC reported a decrease in the total number of falls and severity, with ongoing efforts to minimise harm. Part of the efforts would include collaboration with Divisions to identify any anomalies or areas needing targeted intervention. In addition, a comprehensive review of falls would be included in the annual report scheduled within the Committee’s forward workplan.

The Committee **NOTED** the contents of the report.

PQSOC 3007/08

Mortuary Incident Action Plan

Peter Carr (PC), Director of Therapies and Health Science, provided an update on the Pathology Directorate's progress regarding the action plans related to the Patient Safety Incident investigations at the Grange University Hospital (GUH).

PC reported that the investigations had been completed, chaired by Tracey Partridge-Wilson, and signed off by him as the Executive Lead. He noted that families, the Human Tissue Authority, Gwent Police, the Coroner, and the Welsh Government Quality team had been promptly informed of the incidents in compliance with legislation.

The investigation led to the development of an action plan, with most actions already implemented and two remained outstanding. PC noted that the incident investigation and action plan had been communicated to the affected families, with whom he met personally, keeping an open line for further questions. A media response was also provided to maintain public confidence.

The root causes were identified as failures in staff adherence to Health Board policies and procedures. While the policies were deemed appropriate, they have since been strengthened and simplified for clarity. PC mentioned that a recent unannounced visit by the Human Tissue Authority to the Mortuary at GUH yielded positive feedback on workplace culture and compliance.

Paul Deneen (PD), Independent Member, commended the thorough and transparent investigation. Helen Sweetland (HS), Independent Member, asked whether the revised policies would apply across all Health Board’s Mortuaries, to

which PC confirmed that they would. Nicola Prygodzicz (NP), Chief Executive, assured the Committee that she had met with the Coroner and Gwent Police, and all stakeholders were satisfied with the action plan. Pippa Britton (PB), Committee Chair, emphasised the importance of ongoing staff training on the revised policies.

The Committee **NOTED** the report.

PQSOC 3007/09

Commissioning Assurance Framework

Ann Marie Matthews (AMM), Lead for Clinical Commissioning / IPFR joined the meeting.

Jennifer Winslade (JW), Director of Nursing, informed the Committee that efforts were underway to create a standardised process for collecting quality information from commissioned services. This approach aimed to ensure consistent and rigorous data collection across the Health Board.

Pippa Britton (PB), Committee Chair, supported the move toward a standardised framework, noting that it would provide greater assurance. She inquired about lessons learned from WHSSC's escalation process and the inclusion of an independent member on the working group. Helen Sweetland (HS), Independent Member, asked for examples of commissioned services and the scope of the proposed framework.

JW clarified that the Health Board commissioned a wide range of services, with the new approach initially focusing on a smaller scope before expanding to cover all services. She acknowledged the suggestion for an independent member and noted that the working group had not yet been established but would consider the appropriateness of this inclusion at a future point.

The Committee **NOTED** the development and format of the Quality Commissioning Assurance Framework and the associated progress.

PQSOC 3007/10

Maternity Services: Organisational Improvement and Action Plan

Jayne Beasley (JB), Head of Midwifery and Gynaecology, joined the meeting.

JB provided an update on the Maternity Improvement Plan, aimed at improving outcomes for women and babies,

supporting staff, and fostering innovation. The plan focused on health promotion, choice, early intervention, and addressing strategic priorities. JB outlined the plan’s main themes: governance framework, training, labour and birth, workforce, bereavement care, infection prevention, and pathways of care, each with specific workstreams and measurable actions.

JB reported that the plan included 95 actions to be completed over three years, summarising progress in Quarters 1 and 2 and detailing ongoing and upcoming actions for Quarter 3.

Pippa Britton (PB), Committee Chair, inquired about measures for supporting Black and Minority Ethnic (BAME) mothers and babies. JB reassured the Committee that a voluntary service is in place to assist non-English speaking women in Gwent and guide them to appropriate services. There are plans to expand this service to reach more diverse communities. JB also noted efforts to pilot debrief sessions in Newport to better engage BAME women, as most current participants are white Welsh/British.

Helen Sweetland (HS), Independent Member, questioned the 2026 timeline for appointing a Lead Midwife for Diabetes and requested a glossary of acronyms for broader accessibility. JB clarified that a lead midwife is already in place, though the service is still under development. She also confirmed that future reports would include a glossary of acronyms.

Nicola Prygodzicz (NP), Chief Executive, commended the development and implementation of the benefits of the new digital system.

The Committee **NOTED** the ongoing work to implement and embed improvements within maternity services.

PQSOC 3007/11

Review of Committee Programme of Business 2024/25

Rani Dash (RD), Director of Corporate Governance, informed the Committee of amendments and updates to its Forward Work Programme.

The Committee **NOTED** the updated Forward Work Programme as presented.

PQSOC 3007/12

Pharmacy & Medicines Management Annual Report 2022/23

Jonathan Simms (JS), Clinical Director of Pharmacy, joined the meeting.

James Calvert (JC), Medical Director, highlighted that the annual report provided an overview of the critical role of pharmacy within the Health Board and emphasised the importance of proper prescribing practices.

JS reported on performance against key indicators and detailed clear actions taken to address these indicators. He noted significant improvements in the prescribing of Gabapentinoids.

Penny Jones (PJ), Independent Member, raised concerns about 30-50% of long-term medications not being taken by patients. JC reassured the Committee that both the Medical and Pharmacy Directorates were aware of this issue. He explained that ongoing efforts were in place to increase patient compliance through enhanced training and integration into clinical practice.

The Committee **NOTED** the contents of the Pharmacy and Medicines Management Annual Report.

PQSOC 3007/13

Hospital Transfusion Committee Annual Report

Sarah Beuschel (SB), Transfusion Practitioner, joined the meeting.

SB presented to the Committee an overview of the successes and challenges within the Hospital Transfusion programme. The update highlighted several achievements, including the successful integration of a Primary Care representative into the HPC (Health Professional Council) and the introduction of a new clinical Standard Operating Procedure (SOP) for the Haematological Management of Major Haemorrhage. Additionally, the programme had begun identifying staff who required essential transfusion practice training and continued to provide training on Blood Track Enquiry. The appointment of a Transfusion Support Officer also marked a significant advancement.

SB also noted some challenges; the all-Wales project to implement bedside blood collection had seen limited progress, and the development of the blood component transfusion policy remained outdated due to a small workforce.

The Committee was informed of the Quality Improvement (QI) projects in Transfusion, mentioning that the Patient Care Coordinator (PCC) was based in emergency care and that major haemorrhages were transferred to the Lab for further management.

The Committee **NOTED** the contents of the Hospital Transfusion Committee: Annual Assurance Report 2023-24.

Sarah Beuschel left the meeting

PQSOC 3007/14

Infection Prevention and Control and Cleaning Standards Annual Report 2023/24

Moira Bevan (MB), Head of Infection, Prevention & Control, Ceri Phillips (CP), Consultant Pharmacist, joined the meeting.

MB presented the Infection Prevention, Decontamination, and Antimicrobial Stewardship Annual Report for 2023/2024, noting key achievements and concerns. The report highlighted improvements in cleaning standards and the successful use of Regional Integration Funds to enhance care across Primary and Secondary Care. Despite being below the national average for reportable organisms, the Health Board experienced increases in certain infections due to factors like antimicrobial resistance and suboptimal prescribing.

MB reported a low respiratory infection rate, below the All-Wales average, and noted that the C-section rate had returned to pre-pandemic levels at 3.9%. Ongoing efforts include audits, quality improvement projects, and enhanced cleaning standards.

Ceri Phillips (CP), Consultant Pharmacist, discussed the Welsh Government targets for antimicrobial usage. The target to reduce antimicrobial prescribing by 25% in Primary Care was not met, achieving only a 14.8% reduction, partly due to challenges from Strep A outbreaks. However, Secondary Care met the target of using 55% or more of all antibiotics and is currently at 62-63%, with a new target of 72% forthcoming.

Pippa Britton (PB), Committee Chair, expressed concerns about the rise in cases of C. difficile. James Calvert (JC), Medical Director, explained that efforts to tackle C. difficile included enhanced antimicrobial prescribing practices and managing high bed occupancy.

MB emphasized that tackling C. difficile remained a top priority, with an updated action plan and enhanced governance. CP noted issues with suboptimal prescribing in Secondary Care and efforts to address this cultural challenge.

Paul Deneen (PD), Independent Member, requested an updated report and details on the action plan for proper prescribing at the next meeting.

Action: Director of Nursing to provide an update to the Committee on optimal prescribing in support of infection prevention and control measures

Helen Sweetland (HS), Independent Member, stressed the need for new medical staff to be inducted on proper antibiotic prescribing. This was acknowledged and the Committee was reassured that new staff received a comprehensive induction on Infection Prevention and Control, Pharmacy, and Microbiology.

Penny Jones (PJ), Independent Member, inquired about the training for all staff on infection control and antibiotic prescribing. MB confirmed that national training for infection and prevention was available, supplemented by eLearning modules and enhanced training for incidents.

The Committee **NOTED** the key achievements from 2023/2024 and support the priorities for 2024/2025.

Moira Bevan and Ceri Phillips left the meeting.

PQSOC 3007/15

Safeguarding Annual Report

Howard Stanley (HSt), Head of Safeguarding, joined the meeting.

HSt provided an overview of the Health Board's management of its safeguarding responsibilities for 2023/2024, detailing progress, performance, emerging trends, lessons learned, and the vision for 2024/2025.

HSt highlighted a significant increase in activity with an 85% rise in child cases and a 40% rise in adult, which is putting resources under pressure and delaying assurance and improvement work. Despite this, training success improved notably with levels 1 and 2 exceeding 80% compliance, although level 3 training remained low at 15%, falling short of the 50% target. HSt emphasised efforts to make training mandatory and ensure staff are released from duty to undertake it.

Pippa Britton (PB), Committee Chair, recognised the challenges and need for improved staff attendance. Penny Jones (PJ), Independent Member, noted the 92% rise in child

	<p>cases and a 90% increase in reports and questioned the cause. HSt attributed this to societal issues and improved safeguarding mechanisms, with complex cases requiring multiple reports. It was noted that the demand upon and the capacity of the Safeguarding team was being reviewed.</p> <p>Paul Deneen (PD), Independent Member, raised concerns about GPs in Monmouthshire not being updated on child protection issues, stressing the importance of GP involvement. He requested an update on this issue for the next meeting.</p> <p>Action: Director of Nursing to provide assurance on the effective sharing of safeguarding issues with GPs</p> <p>The Committee</p> <ul style="list-style-type: none"> • CONSIDERED the Safeguarding Annual Report 2023/2024 • NOTED the eight key priorities of the Safeguarding Annual Work Programme • NOTED the challenges associated with an increase in referral activity.
PQSOC 3007/16	<p>Overview of Internal & External Audit Recommendation Tracking</p> <p>Rani Dash (RD), Director of Corporate Governance, presented the report for information.</p> <p>The Committee NOTED the closing position of the 29 audit recommendations; and NOTED the approach being implemented by the Audit Risk and Assurance Committee to ensure a higher level of scrutiny for longstanding recommendations and high-rated recommendations that exceed the threshold for revised deadlines.</p>
PQSOC 3007/17	<p>Children's Rights & Participation Forum</p> <p>Jennifer Winslade (JW), Director of Nursing, noted the forum was supported by Paul Deneen, Independent Member and JW was the Executive Lead.</p> <p>JW noted the forum will report into the Children and Young People's Strategic Board that will be established in September.</p> <p>The Committee NOTED the contents of the report.</p>
PQSOC 3007/18	<p>Review of Neurodevelopmental Service for Under 18s</p> <p><i>Kolade Gamel (KG), Service Group Manger, joined the meeting</i></p>

Jennifer Winslade (JW), Director of Nursing, explained that the report was produced following an all-Wales review in collaboration with the Chief Operating Officer.

The Committee **NOTED** the report for information.

PQSOC 0406/21

Date of the Next Meeting:
Monday 02 September, 2024

DRAFT



Bwrdd Iechyd Prifysgol
Aneurin Bevan
University Health Board

**CYFARFOD BWRDD IECHYD PRIFYSGOLN ANEURIN BEVAN
ANEURIN BEVAN UNIVERSITY HEALTH BOARD
PATIENT QUALITY, SAFETY AND OUTCOMES COMMITTEE**

Outstanding	In Progress	Not Due	Completed	Transferred to another Committee
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Committee Meeting	Minute Reference	Agreed Action	Lead	Target Date	Progress/ Completed
4 th June 2024	PQSOC 0406/2.3	Quality Performance Report It was agreed that the guidance for reporting and handling of incidents within the Incident Reporting Module of DATIX Cymru would be shared with Committee Members by email for information	Director of Nursing/Director of Therapies and Health Science	September 2024	Completed DATIX guidance was shared by the Committee secretary on behalf of the Director of Therapies and Health Science on 23/08/24
30 th July 2024	PQSOC 3007/07	Quality Performance Report Update to be provided on the timely reporting of child safeguarding incidents to GP Practices.	Director of Nursing	November 2024	Not Due The first quarter of sharing this information has been completed and received well from GP practices within the Monmouthshire area. Process from a ABUHB Safeguarding Team has been reviewed and changed accordingly to streamline the process



Committee Meeting	Minute Reference	Agreed Action	Lead	Target Date	Progress/ Completed
					<p>for all agencies post first quarter. The next stage will incorporate these changes and be reviewed by the Corporate Safeguarding Team, Monmouthshire County Borough Council and the NCN to evaluate its impact prior to making recommendations regarding how a similar process can be applied in the other four LA areas.</p> <p>A detailed update will be included in the next Quality Performance Report to the Committee.</p>
30 th July 2024	PQSOC 3007/07	Quality Performance Report Information regarding the protocol for patients presenting	Director of Nursing	November 2024	Not Due



Committee Meeting	Minute Reference	Agreed Action	Lead	Target Date	Progress/ Completed
		with Sepsis to be presented to the Committee.			Protocol for patients presenting with Sepsis, has been added to the forward work plan and to be included on the agenda for November 2024 meeting.
30 th July 2024	PQSOC 3007/07	Quality Performance Report A report on the timely closure of Patient Safety Incidents to be presented to the Committee.	Director of Nursing	November 2024	Not Due Report on time closure of patient safety incidents, has been added to the forward work plan and to be included on the agenda for November 2024 meeting.



Committee Meeting	Minute Reference	Agreed Action	Lead	Target Date	Progress/ Completed
30 th July 2024	PQSOC 3007/07	Quality Performance Report A review of information presented to the Committee relating to an individual waiting 225 hours to be undertaken and an update provided to the Committee.	Director of Nursing	September 2024	Completed A review of the Symphony system data confirms that the longest duration of occupancy within the Emergency Department (ED) footprint for the period concerned was 6 days. The 10 days, which has been reported by a patient as experience feedback using the CIVICA system, is the personal perspective of the patient.
30 th July 2024	PQSOC 3007/14	Infection Prevention and Control and Cleaning Standards Annual Report 2023/24 An update on optimal prescribing in support of	Director of Nursing	November 2024	Not Due Update on optimal prescribing, has been added to the forward work plan and to be included on



Committee Meeting	Minute Reference	Agreed Action	Lead	Target Date	Progress/ Completed
		infection prevention and control measures to be provided to the Committee.			the agenda for November 2024 meeting.

All actions in this log are currently active and are either part of the Committee's forward work programme or require more immediate attention, such as an update on the action or confirmation that the item scheduled for the next Committee meeting will be ready.

Once the Committee is assured that an action is complete, it will be removed. This will be agreed at each Committee meeting.





CYFARFOD BWRDD IECHYD PRIFYSGOLN ANEURIN BEVAN
ANEURIN BEVAN UNIVERSITY HEALTH BOARD MEETING

DYDDIAD Y CYFARFOD: DATE OF MEETING:	02 September 2024
CYFARFOD O: MEETING OF:	Patient Quality, Safety and Outcomes Committee
TEITL YR ADRODDIAD: TITLE OF REPORT:	Committee Risk and Assurance Report
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Director of Corporate Governance
SWYDDOG ADRODD: REPORTING OFFICER:	Head of Corporate Risk and Assurance

**Pwrpas yr Adroddiad (dewiswch fel yn addas)
Purpose of the Report (select as appropriate)**

Ar Gyfer Trafodaeth/For Discussion

The purpose of this report is to provide a summary of the current strategic risks that have been delegated to the Patient Quality, Safety, and Outcomes Committee (the Committee) for monitoring, on behalf of the Board.

The report also informs the Committee of any significant operational risks identified by the Executive Committee through the Corporate Risk Register that have the potential to impact patient quality and safety.

**ADRODDIAD SCAA
SBAR REPORT**

Sefyllfa / Situation & Cefndir / Background

At the Committee meeting in July, it concluded that the Committee Risk Register contained **three** high-level risks with **three** sub-risks, and **one** corporate risk, for which the Board has delegated responsibility for receiving and scrutinising assurances.

Since July, the risk environment has remained relatively stable, with no changes in the risk score or exposure to the three strategic risks that this Committee monitors. However, changes with the corporate risk overseen by this Committee has resulted in a request to endorse the removal of CRR 004 from the Corporate



Risk Register prior to a formal request to the Executive Committee to remove the risk from the register.

Asesiad / Assessment

Strategic Risk Register (SRR)

Table 1 shows the current status of the three strategic sub-risks delegated to the Committee as at the end of August 2024. The three sub-risks have been reviewed and updated to ensure that the Committee has the most recent information on the internal control system and sources of assurance for each sub-risk.

The Committee Risk Register is included in **Appendix A** and the individual risk assessments for the **three** sub-risks are included in **Appendix B**.

Table 1

Risk Ref:	Risk Description	Sub-Risk	Risk Level	Within Appetite
SRR 005 Chief Operating Officer Theme Service Delivery Appetite Open Score 16 and below	There is a risk that the Health Board will be unable to deliver and maintain high-quality, safe services across the whole of the healthcare system.	Due to inadequate arrangements to support system-wide patient flow.	High 3 x 4 (12)	Y
SRR 008 Director of Nursing Theme Transformation & Partnership Working Appetite Open Score 16 and below	There is a risk that the Health Board fails to build positive relationships with patients, staff, and the public.	Due to inadequate arrangements to listen and learn from patient experience and enable patient involvement.	Moderate 2 x 4 (8)	Y
SRR 010 Director of Therapies & Health Science Theme Compliance & Safety Appetite	There is a risk that the Health Board will fail to protect the Health and Safety of staff, patients, and visitors in line with its duties under the Health and Safety at Work Act 1974.	Due to inadequate and ineffective systems, processes, governance, and assurance arrangements in place to implement, embed, and monitor the Health Board's compliance with the Act's	High 3 x 4 (12)	N



Minimal Score 8 and below		requirements, specifically, Manual Handling, RIDDOR Reporting, Fire Safety Risk Assessments, and Work-based Risk Assessments.		
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It should be noted that, while the risks have been updated to include improved control and assurances, the risk score and level for all **three** sub-risks have not changed. **SRR 005** and **SRR 008** remain within the Health Board's risk appetite for the risk domain, therefore the Committee can be assured that these risks are effectively mitigated.

Work will continue with risk owners to manage the risk and ensure that the controls and assurances in place prevent the potential risk from occurring.

SRR 010's risk score and exposure remain outside of the Health Board's agreed-upon risk appetite for the Compliance and Safety risk domain, as shown in Table 1. However, as the Improvement Plan has not been fully implemented, there is potential for the additional planned action to bring the level of risk down to within appetite.

Monitoring of **SRR 010** will remain a key focus of the Committee, and the findings of the scheduled Internal Audit of Health and Safety, planned for quarter 4 of the 2024/25 Plan, will provide the Board and Committee with the evidence needed to determine whether the Improvement Plan has delivered the necessary improvements.

Corporate Risk Register (CRR)

The Committee has been delegated responsibility for oversight of any corporate risk (significant operational risks) relevant to the agenda of the PQSOC.

Table 2 shows the one high-level operational risk that has been delegated to the PQSOC for oversight.

Table 2

Risk Ref:	Risk Description	Sub-Risk	Risk Level	Within Appetite
CRR 004 Theme Service Delivery Appetite Open Score 16 and below	There is a risk that the Health Board will be unable to deliver and maintain high-quality, safe services across the whole of the healthcare system.	Due to the current Pharmacy layout/robot at RGH being over 18 years old and not fit for purpose.	Extreme (20)	N



Since the last report to the Committee in July, which stated that work to improve the Royal Gwent Hospital's Pharmacy Dispensary Unit (PDU) would begin in August, the robot has been decommissioned, and renovations to the PDU and installation of the new Robotic Dispensing System have begun. The service has initiated business continuity plans, which will be maintained until the unit's improvements are completed and operational.

The Committee is therefore asked to endorse the removal of the risk from the corporate risk register, acknowledging that decommissioning of the robot means the risk has been eliminated.

All risks are being managed through the project management process; however, the Committee should be aware that there could be delays due to structural engineering remedial work needed to strengthen the floor so that the robot can be safely installed. The Executive Committee will be kept informed of progress and any challenges that may arise during the project's timeline.

Next Steps

Due to recent challenges, the Executive Team did not consider the draft corporate risk portfolio at its Exec Time Out Session scheduled for July. However, the Corporate Risk Register will be included as an item on the Executive Team weekly business meeting in the coming weeks, with a comprehensive report to the Board in November including the status of strategic and corporate risks. Following that, all risks relevant to the PQSOC's remit will be presented in subsequent reports to the Committee.

The closing position as at the end of August 2024, if accepted by the Committee, is that the Committee Risk Register includes **three** high-level risks and **three** sub risks.

Argymhelliad / Recommendation

The Committee is requested to:

- **NOTE** the delegated strategic risks;
- **ENDORSE** the termination of CRR 004 for formal approval by the Executive Committee;
- **NOTE** the work being undertaken to ensure the Committee is sighted on all risks that have the potential to impact patient quality and safety.

Amcanion: (rhaid cwblhau)
Objectives: (must be completed)

Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol:
 Datix Risk Register Reference and Score:

The Strategic Risk Register is informed by Datix, ensuring a bottom-up approach to risk escalation.



Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	Governance, Leadership and Accountability 2.1 Managing Risk and Promoting Health and Safety Choose an item. Choose an item.
Blaenoriaethau CTCI IMTP Priorities Link to IMTP	Choose an item. The Strategic Risk Register assesses risk that could impact achievement of all strategic priorities.
Galluogwyr allweddol o fewn y CTCI Key Enablers within the IMTP	Governance
Amcanion cydraddoldeb strategol Strategic Equality Objectives Strategic Equality Objectives 2020-24	Choose an item. Choose an item. Choose an item. Choose an item.

Gwybodaeth Ychwanegol: Further Information:

Ar sail tystiolaeth: Evidence Base:	N/A
Rhestr Termau: Glossary of Terms:	N/A
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol: Parties / Committees consulted prior to University Health Board:	The Board and respective Committees of the Board have considered risks contained within the Strategic Risk Register

Effaith: (rhaid cwblhau) Impact: (must be completed)

	Is EIA Required and included with this paper No does not meet requirements
Asesiad Effaith Cydraddoldeb Equality Impact Assessment (EIA) completed	An EQIA is required whenever we are developing a policy, strategy, strategic implementation plan or a proposal for a new service or service change. If you require advice on whether an EQIA is required contact ABB.EDI@wales.nhs.uk



**Deddf Llesiant
Cenedlaethau'r Dyfodol – 5
ffordd o weithio
Well Being of Future
Generations Act – 5 ways
of working**

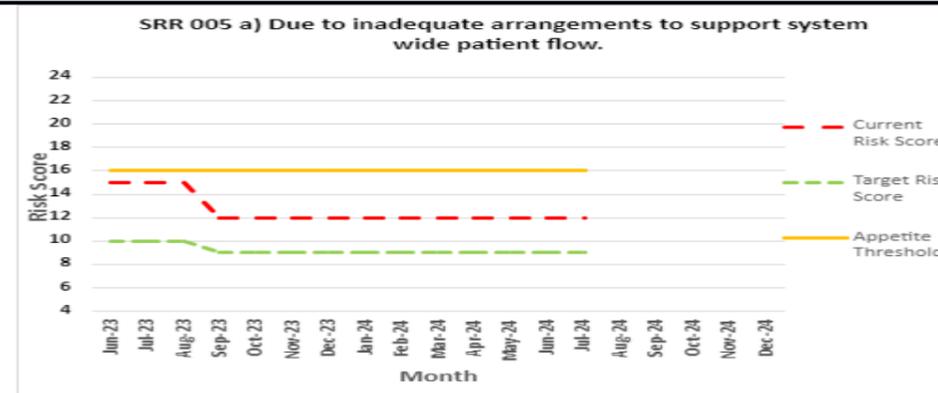
<https://futuregenerations.wales/about-us/future-generations-act/>

Choose an item.
Choose an item.
N/A



Risk ID	Monitoring Committee	Risk Theme	Risk Owner	Risk Description	Reason For The Risk	Impact	Current Risk Score				Risk Appetite		Assurance that the Risk is being managed effectively	Target Risk Score				Review of Risk		
							Likelihood Of The Risk Occurring	Impact Of Risk Occurring	Current Risk Score	Risk Level	Current Status Against Appetite	Risk Appetite and Threshold Explained		Actions to Reduce Risk to Target	Likelihood Of The Risk Occurring	Impact Of Risk Occurring	Target Risk Score	Risk Level	Last Reviewed	Next Review
SRR 005	Patient, Quality, Safety and Outcomes Committee	Service Delivery	Chief Operating Officer	There is a risk that the Health Board will be unable to deliver and maintain high-quality, safe services across the whole of the healthcare system	a) Due to inadequate arrangements to support system-wide patient flow	<ul style="list-style-type: none"> • Avoidable deaths or significant harm • Delays in releasing ambulances from hospital sites back into the community • Delayed discharges from acute and non-acute settings resulting in deteriorating patients • Litigation & Financial Penalties • Reputational damage and loss of public confidence 	3	4	12	High	Below Appetite Level	Open = 16 or below - Willing to consider all potential options subject to continued application and/or establishment of controls recognising that there could be a high-risk exposure.	<p>Escalation framework – evidence suggesting inconsistent escalation of ambulance position / long waits and rationale.</p> <p>Winter planning – Ahead of winter 23/24 there are a series of meetings which will ensure that tangible / practical plans are put in place to ensure:</p> <p>Focus</p> <ul style="list-style-type: none"> • Processing power • Capacity <p>Mental health-focussed flow meeting – implement a MH-focussed daily forum to ensure the flow requirements and risk profile is understood across all MH sites. Build in more impromptu, OoH and site visits to check on processes i.e., patient safety, risk, and performance across the Divisions.</p> <p>Regional flow processes not always supported with neighbouring HBs (Health Board)</p>	Medium	3	3	9	Moderate	01/07/2024	01/10/2024
SRR 008	Patient, Quality, Safety and Outcomes Committee	Transformation and Partnership Working	Director Of Nursing	There is a risk that the Health Board fails to build positive relationships with patients, staff, the public and partners	Due to inadequate arrangements to listen and learn from patient experience and enable patient involvement	<ul style="list-style-type: none"> • Adverse impact on patient experience • Failure to deliver health board priorities, required improvements and achieve longer-term sustainability • Reputational damage and loss of public confidence • Failure to deliver Duty of Quality 	2	4	8	Moderate	Below Appetite Level	Open = 16 or below - Willing to consider all potential options subject to continued application and/or establishment of controls recognising that there could be a high-risk exposure.	<ul style="list-style-type: none"> • Corporate Engagement Team • Patient Experience and Involvement Strategy- organisational ownership • Person Centred Care (PCC) Surveys via CIVICA • PCC KPI's (support PCC Quality pillar) • 'You said..... we did' public facing information for service areas. • PLO service at GUH • Introduction of PALS Service (Oct 23) • Volunteer Patient Experience Feedback • Collaboration to recruit community listeners to support Dementia Awareness • Digital patient stories to support listening and learning. • Patient Experience and Involvement Strategy • DATIX 	Medium	2	2	4	Low	01/07/2024	01/10/2024
SRR 010	Patient, Quality, Safety and Outcomes Committee	Compliance and Safety	Executive Director of Therapies and Health Science	The Health Board will fail to protect the Health and Safety of staff, patients and visitors in line with its duties under the Health and Safety at Work Act 1974	Due to inadequate and ineffective systems, processes, governance, and assurance arrangements in place to implement, embed and monitor the Health Board's compliance with the Act's requirements, specifically, Manual Handling, RIDDOR Reporting, Fire Safety Risk Assessments, and Work-based Risk Assessments.	<ul style="list-style-type: none"> • Unintended physical harm; • Punitive actions from the Health and Safety Executive (HSE); • Increased levels of staff sickness; • Loss of estate due to unsafe environments; • Financial implications; • Adverse publicity; and, • Reputational damage 	3	4	12	High	Above Appetite Level	Minimal = 8 or below - Ultra-Safe leading to only minimum risk exposure as far as practicably possible: a negligible/low likelihood of occurrence of the risk after application of controls.	<ul style="list-style-type: none"> • Attendance at Divisional Quality & Patient Safety meetings provides a forum to discuss Health and Safety concerns/best practices. • Health and Safety Policies and Procedures • Dedicated Health and Safety site on ABPULSE • Provision of dedicated health and safety expertise and advice to meet the requirements of the Management of Health and Safety at Work Regulations 1999, Regulation 7 'Health and Safety Assistance'. • Health and Safety training for all staff (include general H&S, fire safety, manual handling, violence & aggression) • Partial Programme of Health and Safety Monitoring (Active & Reactive) • Corporate and Directorate Health and Safety Risk Register established. 	Negative	2	3	6	Moderate	01/08/2024	01/09/2024

RISK THEME		SERVICE DELIVERY				
Strategic Risk: SRR 005		There is a risk that the Health Board will be unable to deliver and maintain high-quality, safe services across the whole of the healthcare system.			Publication Status	Public
Strategic Threat		Due to inadequate arrangements to support system-wide patient flow			Risk Appetite Level - Open Willing to consider all potential options, subject to continued application and/or establishment of controls: recognising that there could be a high-risk exposure.	
Impact		<ul style="list-style-type: none"> ➤ Avoidable deaths or significant harm ➤ Delays in releasing ambulances from hospital sites back into the community ➤ Delayed discharges from acute and non-acute settings resulting in deteriorating patients; ➤ Litigation & Financial Penalties ➤ Reputational damage and loss of public confidence 			Risk Appetite Threshold – Open SCORE 17 AND BELOW Risk related to all aspects of our ability to deliver, manage, and improve service quality and performance along with all risks relating to the current performance of our infrastructure such as IM&T and Estates including our ability to deliver associated strategy.	
					SUMMARY The current risk level is OUTSIDE of target level but WITHIN appetite threshold. The target level to be achieved is WITHIN the set appetite threshold.	
Lead Director		Chief Operating Officer	Risk Exposure	Current Level	Target Level	
Monitoring Committee		Patient Quality, Safety & Outcomes Committee	Likelihood	3 (Possible) X	3 (Possible) X	
Initial Date of Assessment		01 June 2023	Impact	4 (Catastrophic)	3 (Minor)	
Last Reviewed		01 July 2024	Risk rating	= 12 (High)	= 9 (High)	
Next Review Due (Quarterly based on current risk score)		01 October 2024				



Key Controls <i>(What controls/ systems & processes do we already have in place to assist us in managing the risk and reducing the likelihood/ impact of the threat)</i>	Plans to Improve Control <i>(Are further controls possible to reduce risk exposure within tolerable range?)</i>	Sources of Assurance <i>(Evidence that the controls/ systems which we are placing reliance on are effective)</i>	Gaps in Assurance/ Actions to Address Gaps <i>(Insufficient evidence as to the effectiveness of the controls or negative assurance)</i>	Assurance Rating <i>(Overall Assessment)</i>
<ul style="list-style-type: none"> Escalation Policy. Performance and Accountability Framework Major incident Procedures Daily X-site flow meetings - Twice daily flow calls to receive updates from all acute sites as well as community services. Allowing opportunity for escalation of risks. Escalation communications – ambulance focussed email escalation when congestion begins to build up on the GUH forecourt. Aim to escalate to senior management to aid in quick risk-based decision making. Includes members of the Executive team. fortnightly safety flow forum – Cross divisional focused forum to look at priority areas to improve flow from across the system. Action focussed and task driven. Enhanced monitoring in place for U&EC Range of performance measures/metrics in place Repatriation mechanism with neighbouring Health boards – Daily repatriation calls between head of operations and counterparts in south Wales to ensure regular dialogue to repeat patients between hospitals and health boards. Maximum Capacity Plan – Executive team agreed maximum capacity plan to ensure there is clear description and guide for where extra capacity can be accessed to ensure patient flow is maintained. Planned care recovery meetings with the NHS execs. Regular Dialogue with WAST regarding flow across the patch/regional and attending national calls. WG – IQPD meetings to review areas of focus. 	<p>Operational framework – Being revamped through operational framework ahead of next winter.</p> <p>Improve regional acceptance of flow processes with neighbouring Health Boards.</p> <p>Repatriation meetings established and new Wales-wide protocols due to come in regarding repatriation.</p>	<p>Level 1 Operational <i>(Implemented by the department that performs daily operation activities)</i></p> <p>The Escalation Framework has been enacted and is effective in mitigating threats and impact to services.</p> <p>Performance report against measures/metrics</p>	<p>Gaps in Assurance</p> <p>Evidence that the Escalation Framework is delivering improvements across all areas of patient flow e.g., ambulance handovers. Now working to KPI WG plan.</p> <p>The impact of the Performance and Accountability framework in improving patient flow</p>	Reasonable Assurance
		<p>Level 2 Organisational <i>(Executed by risk management and compliance functions.)</i></p> <p>Divisional Assurance reviews.</p> <p>Performance against measures/metrics reported to the Executive Committee</p>	<p>Action to Address Gaps in Assurance</p> <p>Close monitoring and reporting of the frameworks in practice to support learning and improvements.</p>	
		<p>Level 3 Independent <i>(Implemented by both auditors internal and external independent bodies.)</i></p>		
		<p>Internal Audit Reviews</p> <p>1. Intra-site Patient Transfers – Reasonable Assurance accepted by the ARAC on 9th July 2024.</p> <p>External inspections/visits.</p>		

RISK THEME	TRANSFORMATION AND PARTNERSHIP WORKING				
Strategic Risk: SRR 008	There is a risk that the Health Board fails to build positive relationships with patients, staff, and the public.			Publication Status	Public
Strategic Threat	Due to inadequate arrangements to listen and learn from patient experience and enable patient involvement.				
Impact	<ul style="list-style-type: none"> ➤ Adverse impact on patient experience ➤ Failure to deliver health board priorities, required improvements and achieve longer-term sustainability ➤ Reputational damage and loss of public confidence ➤ Failure to deliver Duty of Quality 				
Lead Director	Director of Nursing	Risk Exposure	Current Level	Target Level	
Monitoring Committee	Patient Quality, Safety & Outcomes Committee	Likelihood	2 (Unlikely) x	2 (Unlikely) x	
Initial Date of Assessment	01 June 2023	Impact	4 (Major)	2 (Minor)	
Last Reviewed	01 July 2024	Risk rating	= 8 (Moderate)	= 4 (Low)	
Next Review Due (Bi-annually based on current risk score)	01 October 2024				

Key Controls <i>(What controls/ systems & processes do we already have in place to assist us in managing the risk and reducing the likelihood/ impact of the threat)</i>	Plans to Improve Control <i>(Are further controls possible to reduce risk exposure within tolerable range?)</i>	Sources of Assurance <i>(Evidence that the controls/ systems which we are placing reliance on are effective)</i>	Gaps in Assurance/ Actions to Address Gaps <i>(Insufficient evidence as to the effectiveness of the controls or negative assurance)</i>	Assurance Rating <i>(Overall Assessment)</i>
<ul style="list-style-type: none"> Corporate Engagement Team Patient Experience and Involvement Strategy-organisational ownership Person Centred Care (PCC) Surveys via CIVICA PCC KPI's (support PCC Quality pillar) 'You said..... we did' public facing information for service areas. PLO service at GUH Introduction of PALS Service (Oct 23) Volunteer Patient Experience Feedback Collaboration to recruit community listeners to support Dementia Awareness Digital patient stories to support listening and learning. Patient Experience and Involvement Strategy DATIX Oversight of Medical Examiner reports to determine patient experience actions Public Engagement- Big Conversation Bereavement held 20th March 2024 People Participation Panel ED in Progress 	<ul style="list-style-type: none"> Structured graduated approach to roll out of Civica to ensure divisional teams can use and access data. This will ensure sustainable progress. PCCT staff training to support Civica data entry and retrieval. Programme Manager for Dementia working regionally to improve public engagement and promote the role of Community Listeners. Employment of dedicated PALS team who will have a key role in gaining feedback from patients, staff, and relatives. Monthly reporting in place and quarterly updates to QPSOG Completion of surveys limited to QR code access or physical presence of PCCT to manually ask and in-put data. No SMS provision. - Discussions with VBHC to pilot SMS in ED through DrDoctor National directives around new national surveys that need to be managed additional to internal roll out programme. Volunteer feedback to be reviewed to identify themes. 	<p>Level 1 Operational <i>(Implemented by the department that performs daily operation activities)</i></p> <ul style="list-style-type: none"> Patient Experience and Involvement Team oversee patient experience through dedicated work programme and link in with divisional teams. Concerns are fed back to divisional teams when identified. Outcome of the volunteer feedback to drive improvements. Patient Experience and Involvement Team undertaking Culturally Competent Accreditation Immediate feedback and escalation to clinical teams following PALS queries and concerns 	<p>Gaps in Assurance</p> <ul style="list-style-type: none"> No SMS provision to increase the number of PCC surveys. No single point of contact or 'drop in' provision for patients/families/staff to raise initial patient experience concerns. Need to develop bereavement model and improve bereavement offer to meet Bereavement Standards. Resources being scoped. Survey of bereaved people needs to be developed and rolled out to meet Bereavement Standards. 	Reasonable Assurance
		<p>Level 2 Organisational <i>(Executed by risk management and compliance functions)</i></p> <ul style="list-style-type: none"> Regular reporting to the Patient Quality, Safety & Outcomes Committee (PQSCO) Listening and Learning reported through QPSOG/ Outcomes Committee Implemented PALS DATIX Module 	<p>Action to Address Gaps in Assurance</p> <ul style="list-style-type: none"> Discussions with VBHC team to consider SMS through DrDoctor with pilot at ED PALS Single point of contact is established. PALS officers have key role in patient experience and involvement- including establishing 'drop in' clinics on hospital sites should patients/staff/relatives wish to discuss concerns. Ned to have discussions with facilities around rooms. Patient experience KPI's and common themes need to be identified and reported through the PCC Survey. These will be added to a template patient experience report and CIVICA surveys will be built into ward accreditation. 	
		<p>Level 3 Independent <i>(Implemented by both auditors internal and external independent bodies)</i></p> <ul style="list-style-type: none"> LLais Reports HIW inspections Advocacy reports 		

RISK THEME	COMPLIANCE & SAFETY				
Risk No: SRR 010	There is a risk that the Health Board will fail to protect the Health and Safety of staff, patients, and visitors in-line with its duties under the Health and Safety at Work Act 1974			Publication Status	Public
Strategic Threat	Due to inadequate and ineffective systems, processes, governance, and assurance arrangements in place to implement, embed and monitor the Health Board's compliance with the Act's requirements, specifically, Manual Handling, RIDDOR Reporting, Fire Safety Risk Assessments, and Work-based Risk Assessments.				
Impact	<ul style="list-style-type: none"> ➤ Unintended physical harm; ➤ Punitive actions from the Health and Safety Executive (HSE); ➤ Increased levels of staff sickness; ➤ Loss of estate due to unsafe environments; ➤ Financial implications; ➤ Adverse publicity; and, ➤ Reputational damage 				
Lead Director	Director of Therapies & Health Science	Risk Exposure	Current Level	Target Level	
Monitoring Committee	Patient Quality, Safety and Outcomes Committee	Likelihood	3 (Possible) X	2 (Unlikely) X	
Initial Date of Assessment	01 December 2023	Impact	4 (Major)	3 (Moderate)	
Date Reviewed	01 Aug 2024	Overall Risk Rating	= 12 (High)	= 6 (Moderate)	
Date of Next Review (Monthly based on current risk score)	01 Sept 2024				
<p>Risk Appetite Level - MINIMAL. Any risk that has a MINIMAL risk appetite level should be managed to a Score of 8 or below.</p> <p>Risk Appetite Threshold - Ultra-safe leading to only minimum risk exposure as far as practicably possible: a negligible / low likelihood of occurrence of the risk after application of controls.</p> <p>SUMMARY The current risk level is OUTSIDE of target level and OUTSIDE appetite threshold. The target level to be achieved is WITHIN the set appetite threshold.</p>					

Key Controls <i>(What controls/ systems & processes do we already have in place to assist us in managing the risk and reducing the likelihood/ impact of the threat)</i>	Plans to Improve Control <i>(Are further controls possible to reduce risk exposure within tolerable range?)</i>	Sources of Assurance <i>(Evidence that the controls/ systems which we are placing reliance on are effective)</i>	Gaps in Assurance/ Actions to Address Gaps <i>(Insufficient evidence as to the effectiveness of the controls or negative assurance)</i>	Assurance Rating <i>(Overall Assessment)</i>
<ul style="list-style-type: none"> • Attendance at Divisional Quality & Patient Safety meetings provides a forum to discuss Health and Safety concerns/best practices. • Health and Safety Policies and Procedures • Dedicated Health and Safety site on ABPULSE • Provision of dedicated health and safety expertise and advice to meet the requirements of the Management of Health and Safety at Work Regulations 1999, Regulation 7 'Health and Safety Assistance'. • Health and Safety training for all staff (include general H&S, fire safety, manual handling, violence & aggression) • Partial Programme of Health and Safety Monitoring (Active & Reactive) • Corporate and Directorate Health and Safety Risk Register established. 	<ul style="list-style-type: none"> • Develop and implement a 3-year health and safety culture plan, including the implementation of a new Health and Safety Management System • Suitable and Sufficient Risk assessments (including local risk assessments, specific fire risk assessments, and fire risk assessments) • Consultation and communication with the workforce regarding compliance with the Act • New ways of working with Divisions to ensure accountability for health and safety is recognised. • Implement key performance indicators to monitor health and safety compliance. • Review the governance arrangements for the Health & Safety Committee • Health and Safety Policies and Procedures to be reviewed. • Onboard further Manual Handling trainers across the organisation to improve compliance. • Scope for training non-Health Board staff 	<p>Level 1 Operational <i>(Implemented by the department that performs daily operation activities)</i></p> <ul style="list-style-type: none"> • Health and Safety compliance data extracted from ESR and Datix and reported 	<p>Gaps in Assurance</p> <ul style="list-style-type: none"> • Implementation of a health and safety performance report • Health and Safety Committee Membership and governance to be reviewed to ensure there is robust scrutiny and challenge on compliance with the Act. • Compliance on completion of risk assessments and mitigating actions 	Negative Assurance
		<p>Level 2 Organisational <i>(Executed by risk management and compliance functions)</i></p> <ul style="list-style-type: none"> • Established monitoring of H&S at the Executive Committee • Corporate H&S report risk and assurance to the Health and Safety Committee • Established monitoring of H&S at the PQSO Committee 	<p>Action to Address Gaps in Assurance</p> <ul style="list-style-type: none"> • Revise accountability arrangements for Health and Safety being progressed as part of the organisational Health & Safety Governance Framework. • Review the membership and ToRs of the Health and Safety Committee 	
		<p>Level 3 Independent <i>(Implemented by both auditors internal and external independent bodies)</i></p>		

<ul style="list-style-type: none"> • Board Training /development (Completed 24 April 2024) • Implementation of Health, Safety, and Fire Improvement Plan for 2023/24 to address 7 risk areas of concern. • Health and Safety Governance and reporting arrangements (Health and Safety Committee) 	<ul style="list-style-type: none"> • Learning from events to be documented and communicated to the organisation. 	<ul style="list-style-type: none"> • Performance reviews at All Wales Health and Safety Management Steering Group • Internal Audit – H&S processes Review to be included in 2024/25 Plan. • South Wales Fire & Rescue Service fire safety audit programme. • Health and Safety Executive reviews/inspections. 	<ul style="list-style-type: none"> • Risk assessments and mitigating actions to be documented and reported regularly to demonstrate progress against the Improvement Plan 	
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**CYFARFOD BWRDD IECHYD PRIFYSGOLN
ANEURIN BEVAN
ANEURIN BEVAN UNIVERSITY HEALTH BOARD
MEETING**

DYDDIAD Y CYFARFOD: DATE OF MEETING:	02 September 2024
CYFARFOD O: MEETING OF:	Patient Quality, Safety and Outcomes Committee
TEITL YR ADRODDIAD: TITLE OF REPORT:	Annual Quality Report
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Dr James Calvert, Executive Medical Director Jennifer Winslade, Executive Director of Nursing Peter Carr, Executive Director of Therapies & Health Science
SWYDDOG ADRODD: REPORTING OFFICER:	Leeanne Lewis, Assistant Director for Quality & Patient Safety Tracey Partridge-Wilson, Deputy Director of Nursing

Pwrpas yr Adroddiad (dewiswch fel yn addas)

Purpose of the Report (select as appropriate)

Er Sicrwydd/For Assurance

ADRODDIAD SCAA

SBAR REPORT

Sefyllfa / Situation

The Health Board presents the first Annual Quality Report for 2023/24, aligned to the reporting requirements in the Health and Social Care (Quality and Engagement) (Wales) Act (2020), which emphasised quality, transparency, and engagement through the Duty of Quality, Duty of Candour, and Citizen’s Voice; Llais.

This report provides a narrative on our quality journey throughout the year and reviews past objectives and sets new priorities for improving patient and staff safety, outcomes, and experiences.

We implemented two strategies aimed at improving services, clinical effectiveness, safety, and experiences, involving patients, families, carers, staff, and the community. Our Quality Strategy prioritises patient safety and staff wellbeing, guiding our plans and decisions. We developed a number of workstreams that impact on patient safety and have driven improvement considering a whole system

approach. There was a commitment and focus on developing our quality management system.

Heading into 2024/25, we carry forward our achievements and focus on continuous quality improvement and would wish to express our thanks to our teams, staff, volunteers, patients, partners, and stakeholders for your invaluable contributions.

The Health and Care Quality Standards provide a clear framework to help the planning, delivery and monitoring of healthcare services in Aneurin Bevan University Health Board. The Quality Report is mapped to the six domains of quality and the six quality enablers and structured under the Health Board's Six Pillars of Quality.

The outcomes and indicators reported here are a set of quality indicators that align with the Health Board's priorities and strategic goals. The indicators cover aspects of care, clinical outcomes, patient safety and patient experience.

This report is an interim quality report and the full Quarter 1 Quality Outcomes Framework will be reported at the next Board meeting.

Cefndir / Background

In April 2023, the Health Board implemented two strategies aimed at improving services, clinical effectiveness, safety, and experiences, involving patients, families, carers, staff, and the community. Our Quality Strategy prioritises patient safety and staff wellbeing, guiding our plans and decisions. We developed a number of workstreams that impact on patient safety and have driven improvement considering a whole system approach. There was a commitment and focus on developing our quality management system.

The Health and Care Quality Standards provide a clear framework to help the planning, delivery and monitoring of healthcare services in Aneurin Bevan University Health Board. The Quality Report is mapped to the six domains of quality and the six quality enablers and structured under the Health Board's Six Pillars of Quality.

Asesiad / Assessment

The Annual Quality Report provides information on our preparation programme to deliver the Duty of Quality and review our reporting and assurance framework. Key workstreams were identified as a priority for the first 12 months and key actions and initiatives can be found in the report to demonstrate the impact on patient safety.

The Health Board adopted a reporting structure which mapped progress on quality and patient safety as mapped against the Pillars of quality:

- Patient and staff experience and stories
- Incident reporting – falls, pressure ulcers, medicines management and mortality
- Complaints, concerns and compliments
- Health, safety and security
- Infection Control and Prevention
- Safeguarding

These 'pillars of quality' run through our organisation, ensuring that we deliver the highest standards of care under these domains.

As part of our statutory reporting under the Duty of Quality the report aimed to focus on a report that can be read by members of the public. Our first report reviews past achievements, identifies challenges, and outlines future priorities and monitoring methods. It showcases our efforts to embed quality across the Health Board, using continuous 'Always on' reporting throughout 2023/24.

As part of the Quality Strategy an Implementation Plan was produced for the Health Board to enhance the quality of healthcare throughout 2023. In order to deliver the Health and Care Quality Standards, the plan was mapped with quarterly objectives aligned to the six key quality domains. Highlights of the achievements for 2023/24 can be seen in the Appendix. This plan was built on existing achievements, emphasising continuous improvement and embedding quality, safety, and learning in daily operations.

The report details the work on embedded learning and improvement which has developed over the year. Heading into 2024/25, we carry forward our achievements and focus on continuous quality improvement. The Health Board is refining the workplan for year two and the quality enablers to support the delivery. As ongoing work, we will continue to strengthen our governance structures through Board-to-Floor connections that promote cross directorate and multi-professional working. We have initiated work to ensure that the implementation, measurement and monitoring of our strategy is hardwired through our governance and integrated performance reporting.

Key priorities for the next six months include automation and revision to the Quality Outcomes Framework, development of Integrated reporting with Finance, Workforce and Planning, strengthening of Quality Patient Safety structures within Divisions, refreshing the Quality Improvement Plan and strengthening assurance and reporting.

Argymhelliad / Recommendation

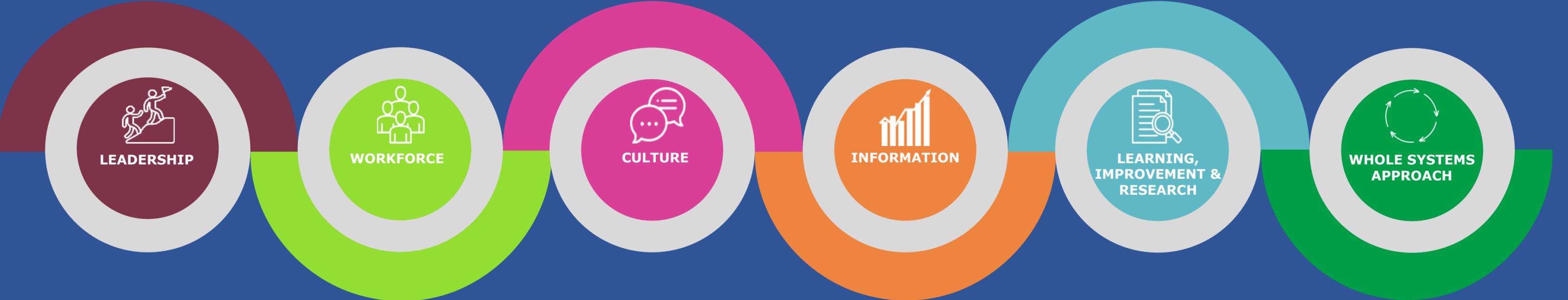
The Board is requested to note the progress of work over the past 12 months as reflected in the annual quality report and to take assurance from this report.

Amcanion: (rhaid cwblhau) Objectives: (must be completed)	
Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol: Datix Risk Register Reference and Score:	
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	3. Effective Care 3.1 Safe and Clinically Effective Care 3.3 Quality Improvement, Research and Innovation Choose an item.
Blaenoriaethau CTCI IMTP Priorities Link to IMTP	Getting it right for children and young adults
Galluogwyr allweddol o fewn y CTCI Key Enablers within the IMTP	Experience Quality and Safety
Amcanion cydraddoldeb strategol Strategic Equality Objectives Strategic Equality Objectives 2020-24	Improve patient experience by ensuring services are sensitive to the needs of all and prioritise areas where evidence shows take up of services is lower or outcomes are worse Improve patient experience by ensuring services are sensitive to the needs of all and prioritise areas where evidence shows take up of services is lower or outcomes are worse Choose an item. Choose an item.

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	
Rhestr Termiau: Glossary of Terms:	
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol: Parties / Committees consulted prior to University Health Board:	

Effaith: (rhaid cwblhau)

Impact: (must be completed)	
	Is EIA Required and included with this paper
<p>Asesiad Effaith Cydraddoldeb Equality Impact Assessment (EIA) completed</p>	<p>Choose an item.</p> <p>An EQIA is required whenever we are developing a policy, strategy, strategic implementation plan or a proposal for a new service or service change. If you require advice on whether an EQIA is required contact ABB.EDI@wales.nhs.uk</p>
<p>Deddf Llesiant Cenedlaethau'r Dyfodol – 5 ffordd o weithio Well Being of Future Generations Act – 5 ways of working</p> <p>https://futuregenerations.wales/about-us/future-generations-act/</p>	<p>Collaboration - Acting in collaboration with any other person (or different parts of the body itself) that could help the body to meet its well-being objectives</p> <p>Prevention - How acting to prevent problems occurring or getting worse may help public bodies meet their objectives</p>



GIG
CYMRU
NHS
WALES

Bwrdd Iechyd Prifysgol
Aneurin Bevan
University Health Board

Quality Annual Report 2023 / 24



Executive Summary

Welcome to the Aneurin Bevan University Health Board's Quality report for 2023/24.

The Health Board presents the 2023/24 Annual Quality Report, reviewing past objectives and setting priorities for improving patient and staff safety, outcomes, and experiences. This report provides a narrative on our quality journey throughout the year.

This year was busy with many challenges, met by the hard work and commitment of our staff, leading to progress in our improvement priorities.

In 2023/24, Aneurin Bevan University Health Board focused on quality and safety, aiming to deliver high-quality healthcare. This focus was bolstered by the Health and Social Care (Quality and Engagement) (Wales) Act (2020), which emphasised quality, transparency, and engagement through the Duty of Quality, Duty of Candour, and the creation of the Citizen's Voice through Llais.

We have implemented two strategies aimed at improving the quality of our clinical services, the clinical effectiveness of care, improving safety and reducing avoidable harm and improving the experience patients, their families and their carers. These strategies have also increased the involvement of patients, families, carers, staff, and the community in planning delivering and assessing the quality of care.

Heading into 2024/25, we carry forward our achievements and focus on continuous quality improvement. Thank you to our team, staff, volunteers, patients, partners, and stakeholders for your invaluable contributions.



Jennifer Winslade
Executive Director of Nursing



Dr James Calvert
Executive Medical Director



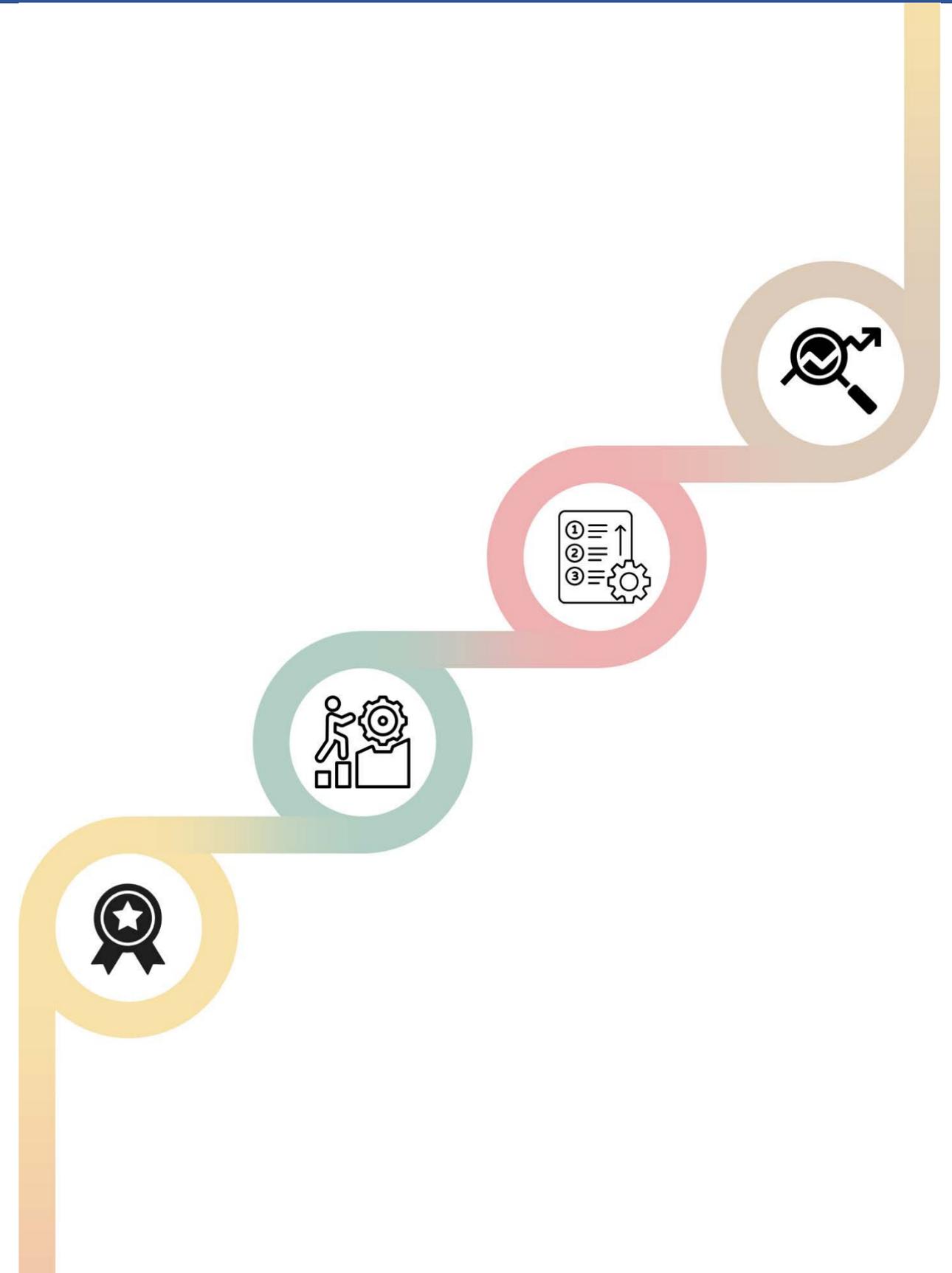
Peter Carr
Executive Director of Therapies
and Health Science

Introduction

NHS bodies must publish an annual quality report detailing steps taken to comply with the duty of quality. Our first report reviews past achievements, identifies challenges, and outlines future priorities and monitoring methods.

Quality standards are guided by the Health and Social Care (Quality and Engagement) (Wales) Act 2020, A Healthier Wales and Core Commissioning Requirements.

This report showcases our efforts to embed quality across the Health Board, using continuous 'Always on' reporting throughout 2023/24. This is reflected in our reporting to the [Patient Quality, Safety and Outcomes Committee \(PQSOC\)](#) and the forward work plan.



Preparation Programme

The Health Board initiated a comprehensive program to prepare for the Health and Engagement Act, including a readiness assessment to identify key leadership roles for quality and candour duties.

Workshops and sessions were conducted with stakeholders to develop a Quality Strategy with input from healthcare partners, patients, and staff, ensuring readiness for April 2023. The strategy was launched through engagement sessions, a Board developmental session, and updates to the intranet, along with public-facing videos and staff information provided by the NHS Executive. Information was also disseminated via memorandums and dedicated webpages with details and training resources.

The Health Board's Quality Strategy is underpinned by "A Healthier Wales," focusing on quality and safety through our 'pillars of quality' program. These pillars help review performance and reporting to the Board and PQSOC, ensuring high standards of care in:

- Patient and staff experience
- Incident reporting (falls, pressure ulcers, medicines management, mortality)
- Complaints, concerns, and compliments
- Health, safety, and security
- Infection control and prevention
- Safeguarding



Reporting and Assurance

The Health Board developed a Quality Outcomes Framework (QOF) as part of its Quality Management System in quarter two 2023/24. This framework tracks outcomes to systematically measure, monitor, and enhance healthcare quality.

The QOF aimed to enable continuous improvement with key goals to:

- Identify improvement areas and patient safety risks
- Establish benchmarks and quality indicators
- Promote evidence-based practices
- Enhance patient satisfaction and experience
- Ensure compliance with standards and regulations
- Enable data-driven decisions and resource allocation
- Foster a culture of accountability, transparency, and learning

The QOF has enhanced **reporting requirements** to the Board and Executive Committee, and providing assurance to PQSOC. Benefits of the QOF have included:

- Improved patient outcomes and safety
- Enhanced patient experience and satisfaction
- Increased adherence to evidence-based practices
- Efficient resource utilisation
- Regulatory compliance
- Improved staff engagement and professional development
- Accountability and transparency in care delivery

The Health Board has developed a Governance and Assurance Framework for Quality to support the Quality Management System (QMS) at all levels. This work will continue into 2024/25, reviewing reporting arrangements via Groups and Committees, aiming to implement a new oversight and reporting structure for transparency and performance monitoring. Objectives of the quality governance framework includes:

- Define and shape quality governance across the organisation
- Support the Board in achieving quality governance
- Clarify reporting lines
- Increase assurance, public trust, and confidence

A multi-professional Clinical Forum will be developed with Clinical Executives in 2024/25. This will form a Clinical Advisory Committee, which will support Quality and Professional Strategies, provide independent strategic advice and maintain a strategic overview.

Progress on 2023/24 Priorities

Our quality ambitions for the first three years focused on prioritising quality and safety, acknowledging that challenges evolve. Over the past year, our key commitments were:

- **Learning Organisation:** We strive to be a learning organisation where staff deliver high-quality clinical care daily.
- **System Understanding and Capability Building:** We aim to understand our care systems, build capability through an all-teach/all-learn philosophy, encourage innovation, and engage patients, relatives, carers, staff, and communities in improvement efforts while learning from mistakes.
- **Embedded Quality and Supportive Culture:** Quality is embedded throughout the Health Board, fostering a culture of openness and transparency where concerns can be raised.
- **Collaborating and Partnership:** Patients, relatives, carers, staff, and communities will partner with us to achieve our vision.

Our strategies have been shaped by the experiences of patients, relatives, carers, staff, and communities, focusing on improvement, planning, and assurance in alignment with the Duty of Quality and Duty of Candour.

Quality Strategy

This provided a:

- **Blueprint for Patient Safety and Quality:** Outlines patient safety and quality for the next three years.
- **Focus on Quality and Safety:** Prioritises quality and safety while addressing emerging challenges.
- **Improvement Objectives:** Sets improvement goals and a supporting framework for the next three years.
- **Commitment to Continuous Improvement:** Embeds a culture valuing quality and continuous improvement.



Patient Experience & Involvement Strategy

This provided a

- **Feedback-Driven Culture:** Created & based on feedback from staff, patients, families, and carers, focusing on what matters to them.
- **Passion for Improvement:** Acknowledges staff's dedication to improving service experiences.
- **Learning from Experience:** Places learning from experiences at the Health Board's core.



These strategies ensure that quality, safety, and continuous improvement are central to all our activities, fostering a culture of excellence and collaboration.

Progress against 2023/24 Objectives

- Delivery of an approved strategy for Quality, Framework and Delivery Plan with a clear understanding of priorities.

Quality Strategy Implementation Plan developed and approved, supporting our reporting structure through a quality outcome framework.

- Through the launch of the new system for patient experience and the Health and Well-being survey, put in place mechanisms to learn from the insight gained.

Civica Platform Launch: Enhanced real-time patient experience feedback, enabling ongoing partnerships with patients, families, carers, staff, and communities.

- Establish a framework for learning and skills at all levels and the capacity and capability to grow and develop our skills and learning networks.

Listening and Learning Framework: Held meetings to engage and inform this nearly completed framework.

Developing Best Practices: Through listening and learning, supporting staff to deliver excellent person-centred care.

- Deliver the Safe Care Partnership, Faculty workstreams and the outcomes as set by each team.

Quality Improvement Capability: Expanded through the Safe Care Partnership, building capacity, conditions, and connections for staff to use QI methodology to solve complex problems consistently.

Just Culture: Continuously working to correct mistakes, encouraging experience sharing, and restoring confidence.

- Agree and implement the measures and reporting structures.

Reporting Structures: Huge progress on developing our reporting structure, reporting via a quality outcomes framework has enabled clear indicators reported aligned to the Health and Care Quality Standards. We have made this a priority to refine reporting for 2024/25.

- Review the capability of our data capture systems for resilience and suitability.

Quality Management System: working collaboratively with the Divisions of planning and digital, data and technology has enabled data capture to be developed through existing systems.

- Implement new systems to provide insight and support for delivery.

Quality Management System: developing the quality outcomes framework provided quantitative data that can be reported. We have enriched this data with narrative and included patient stories and staff feedback.

- Review our quality and safety structures and teams along with the reporting structures to ensure learning at every level and appropriate assurance and governance.

Reviewed Structures: Aligned resources within Quality and Patient Safety. A review of the reporting and assurance via current governance structures and Groups and Committees will continue through 2024/25.

PILLAR 1

Patient and staff experience and stories

Civica

Bereavement
Collaboratives

Patient
Stories

IPAC
Dashboards

Volunteer to
Career

Chaplaincy

Volunteering

Patient Advice
and Liaison
Service (PALS)

Leadership,
Accountability
and Culture

Deprivation of
Liberty Safeguards/
Mental Capacity Act

Cultural
Competence
Accreditation
Scheme

Dementia
Standards

Listening
Meetings

Key Achievements

Patient Experience - Launch of the Citizen Feedback System:

- **Total Responses:** 1,343 (Person-Centred Care Survey: 1,137).
- **Satisfaction Score:** 86% for Person-Centred Care Survey.
- **Surveys:** 10 live surveys, including 3 national surveys (Emergency Department, Palliative Care, National Nosocomial Investigation).
- **Active Areas:** 190 areas.
- **Staff Training:** 229 Health Board staff trained.
- **Promotion:** Development of a promotional poster, improved uptake.
- **Engagement:** Enhanced engagement with Teams/Divisions and QPS Teams.
- **Collaboration:** Strong collaboration across Wales on patient experience.

Patient Advice and Liaison Service (PALS):

- **Launch:** November 2023.
- **Contacts:** 3,978 contacts, including enquiries and complaints.
- **Complaints:** 162 complaints received, 155 managed by PALS, 7 escalated to PTR (4.3%).
- **Compliments:** 49 received.
- **Champion Roles:** Developed roles in Equality, Diversity & Inclusion, Dementia, Bereavement, and CIVICA.
- **Recognition:** Nominations are being written in the Patient Experience category at the staff recognition awards for 2024.
- **Surveys:** Planned launch for PALS Patient and Relative Feedback survey will be launched in May 2024.
- **Engagement:** Met with families and clinical teams to avoid escalation to PTR; attended Caerphilly Deaf club following a formal complaint for positive actions.
- **Outreach:** Met with teams, directorates, and divisions to highlight PALS benefits.

Areas for Improvement

- Ensuring all 'live' areas are collecting feedback.
- Timely access to feedback by some areas.
- High volume of feedback from paper surveys, concerns about the method and cost.
- Delays with paper surveys might lead to missed or untimely feedback.
- Lack of SMS feedback usage possibly affecting response rates.
- Slower rollout due to training demands and limited staff (one dedicated member for CIVICA).

Challenges for 2024/25

- National progress; the Health Board is the only one in Wales not using CIVICA SMS.
- Limited resources, with only one Administrator affecting rollout speed.
- Need to demonstrate evidence of feedback collection and learning.
- Possible implementation of new Core Questions.
- Unable to offer bespoke PREM surveys due to resource constraints.
- Costs associated with implementing CIVICA SMS (currently piloting in the Emergency Department).

PALS Challenges for 2024/25:

- Achieving absolute early resolution is difficult due to complex enquiries.
- Developing a role for a Patient and Family Support Officer for end-of-life and bereavement support.
- Lack of dedicated PALS hubs across the Health Board; hubs would offer 'drop-in' opportunities.
- Current staffing limits capacity for face-to-face support, prioritising urgent cases.

PILLAR 2

Incident Reporting Falls Pressure Ulcers Medicines Management Mortality

Leadership, Accountability and Culture	Never Events	Deteriorating Patient	Patient Safety Incident process	QPSE Dashboards
Pressure Ulcers / Medicines Management	Staff Training	Datix (validation)	Falls Panel	Duty of Candour
Learning, Monitoring & Assurance	Just Culture/ Psychological Safety	Mortality	Risk Registers	Human Factors

Falls

Key Achievements

- Significant effort in tracking and analysing falls within the Health Board.
- Comprehensive data collection system through RLDatix.
- Notable reductions in falls incidents observed in February 2024, following a peak in January 2024.
- See falls improvement programme for additional information.

Challenges for 2024/25

- Managing a high volume of falls incidents, with 44 patients experiencing more than two falls within a short period.
- Continued improvement needed in falls prevention strategies, particularly among high-risk patients.

Pressure Ulcers

Key Achievements

- Establishment of the Pressure Ulcer Faculty in 2023.
- Implementation of educational initiatives and pilot projects, including a PDSA cycle.
- Downward trend in HAPU incidences from January to April 2024.

Challenges for 2024/25

- Meeting the Welsh Government standard of 0% avoidable HAPUs.
- Sustained efforts needed to maintain focus on prevention and address contributing factors.

Medicines Management

Key Achievements

- Enhanced monitoring and review processes, focusing on antibiotic prescribing and compliance.
- Utilization of whole genome sequencing (WGS) for Clostridioides difficile infection identification.
- Root cause analyses provided insights into sub-optimal antibiotic use, leading to targeted actions.

Challenges for 2024/25

- Addressing sub-optimal prescribing of antibiotics.
- Ensuring consistent compliance with hand hygiene and environmental cleanliness.

Mortality

Key Achievements

- Development of a governance process for mortality outliers.
- Implementation of the Risk Adjusted Mortality Index (RAMI) tool.
- Ongoing efforts to align mortality review processes with quality improvement frameworks.

Challenges for 2024/25

- Need for a standardized framework to review and learn from mortality cases.
- Ensuring reliability and consistency of mortality data across reporting mechanisms.

Incidents Learning and Improvement

- A review of the Health Board's Patient Safety Incident Policy in November 2023 to align with the All-Wales Directive and to reflect patient and family feedback on the Safety Incident process. This Policy also more explicitly outlines expectations and procedures. A further update is planned to be approved by the Board in September following a further strengthening of the approach;
- Bespoke development of Chair, Investigating Officer and staff responsibilities for Patient Safety Incidents has been established;
- Bespoke rather than generalised training is being provided for Investigating Officers on a 1- 2-1 basis to guide them through the investigation process supported by a member of the Corporate Patient Safety Incident team;
- All moderate and above harm incidents are presented to the weekly Executive Huddle for an investigation level decision, identification of an appropriate Chair and allocation of Executive Sign off lead;
- There is now a focused review of open incidents with Divisional Quality and Patient Safety teams and escalation to Triumvirates (then Executives) where delays occur; and
- There has been an increase in the number of Executive Chairs to address delays in the initiation of investigation meetings.

Falls Improvement Programme

Key Achievements

- **Data Improvement:** Enhanced availability and analysis of falls data across the Health Board have informed key quality improvement initiatives, leading to better monitoring and reduction of falls.
- **SWARM Methodology Implementation:** Rolled out in April 2023 within the Medicine Division, this multi-disciplinary team (MDT) approach is being expanded across the wards.
- **Digital Integration:** Successful rollout of the Welsh Nursing Care Record Multi-Factorial Risk Assessment (MFRA) to wards, with completion anticipated in October 2024. Additionally, a modified MFRA has been developed for use in Emergency Departments.
- **National Contributions:** Contributed to the development of the Falls National Head Injuries pathway and the National Inpatient Falls Network's work on sensor use, setting a national standard.
- **Ward Accreditation:** Falls prevention and management have been incorporated into the ward accreditation initiative, further embedding these practices into daily routines.
- **Falls Awareness:** A highly successful Falls Awareness Week in 2023 saw significant patient and staff engagement across the Health Board.
- **RIDDOR Compliance:** Established a Standard Operating Procedure (SOP) and developed a compliance dashboard within the Datix system to improve reporting and monitoring.
- **Training:** Continued delivery of falls prevention and management training, adapted for the digital format of the Welsh Nursing Care Record.

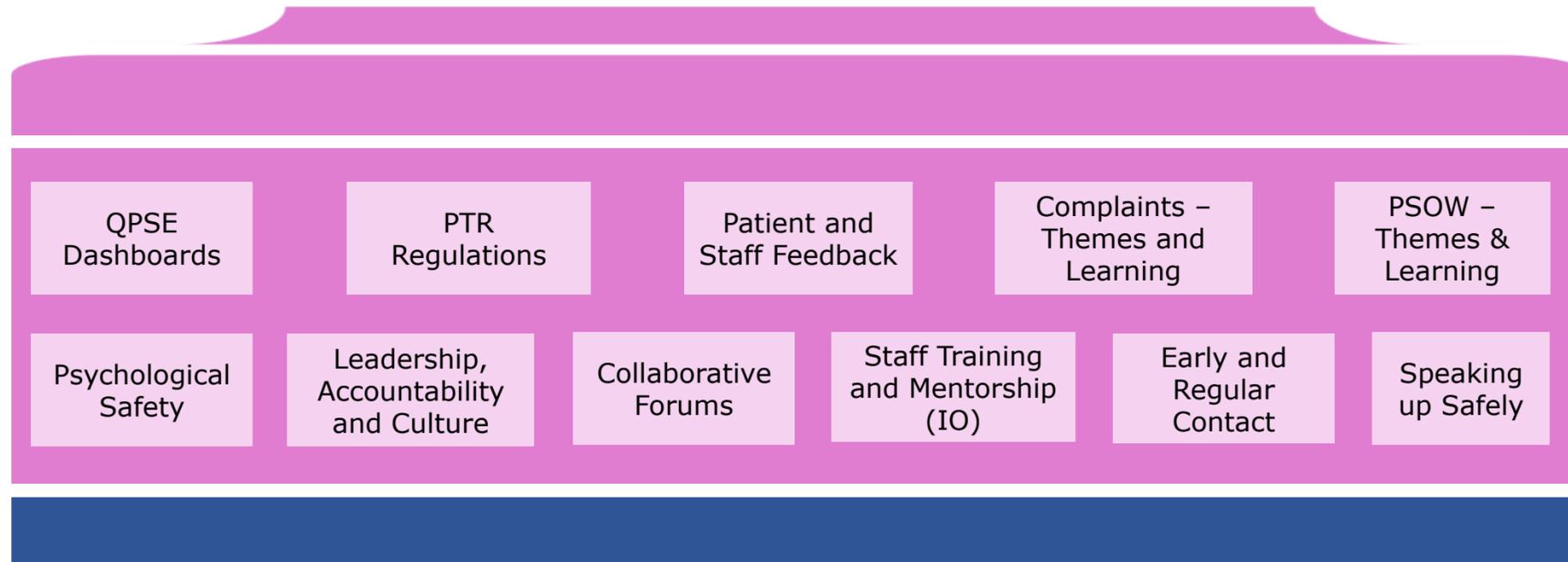
Challenges for 2024/25

- **Consistency in Practice:** Ensuring consistent application of the SWARM methodology and MFRA across all wards and specialties remains a challenge.
- **Data Utilisation:** While data availability has improved, fully leveraging this data to drive sustained reductions in fall rates and severity of harm requires ongoing effort.
- **Staff Engagement:** Maintaining high levels of staff engagement in falls prevention initiatives, especially in the face of evolving clinical environments and pressures, is a continuing challenge.
- **Technological Integration:** The successful digital integration of falls management tools like MFRA needs continuous support to ensure all staff are proficient and the tools are used effectively.
- **Resource Allocation:** Ensuring that adequate resources, including appropriate flat lifting equipment and trained personnel, are available across all units to effectively manage falls.
- **RIDDOR Reporting:** Despite progress, achieving full compliance with RIDDOR reporting protocols across the Health Board requires ongoing monitoring and training efforts.

These achievements and challenges reflect the Health Board's commitment to reducing falls and improving patient safety across its facilities. The next steps focus on building upon these successes through enhanced training, data utilization, and multi-disciplinary collaboration.

PILLAR 3

Complaints, Concerns and Compliments



Key Achievements

- **PTR Regulations:** Active engagement in the review and public consultation.
- **Early Resolution and Meaningful Engagement:** Implementation of PALS.
- **Planned Initiatives:** Introduction of an "Acknowledgement Team" and development of Communication Standards.
- **Collaboration and Learning:** Working closely with various oversight bodies and commitment to an open culture.

Common Complaint Themes

- Clinical treatment/ assessment
- Appointments
- Communication issues.
- Concerns about wait times and the impact of Covid on clinical treatment and assessment.

2023/24 Statistics

- **Formal Complaints:** 1,596 received.
- **Resolved via Early Resolution:** 1,555.
- **Compliance Target:** Striving to meet the Welsh Government's 75% compliance target for 30-working day response times.

Key Focus for 2024/25

- Prioritise timely and appropriate management of concerns.
- Achieve compliance with the Welsh Government Targets
- Collaborate with colleagues, communities, and partners to ensure quality and safety.

PILLAR 4

Health, Safety and Security



Key Achievements

- **Health, Safety & Fire Improvement Plan:** Implemented a 30, 60, 90-day plan, resulting in improved compliance and risk reduction.
- **Health & Safety Monitoring:** Conducted 51 workplace inspections with an average compliance score of 88.2%.
- **RIDDOR Reporting:** Established a RIDDOR Compliance Dashboard and new awareness training sessions.
- **Training and Development:** Conducted various safety training sessions.
- **Safety Procedures and Protocols:** Introduced new or updated procedures.
- **Fire Risk Assessments:** Completed 96% of programmed assessments.
- **Support for New Developments:** Assisted with planning and opening of new facilities.
- **Fire Alarm System Projects:** Replaced outdated systems and planned further upgrades.

Areas for Improvement

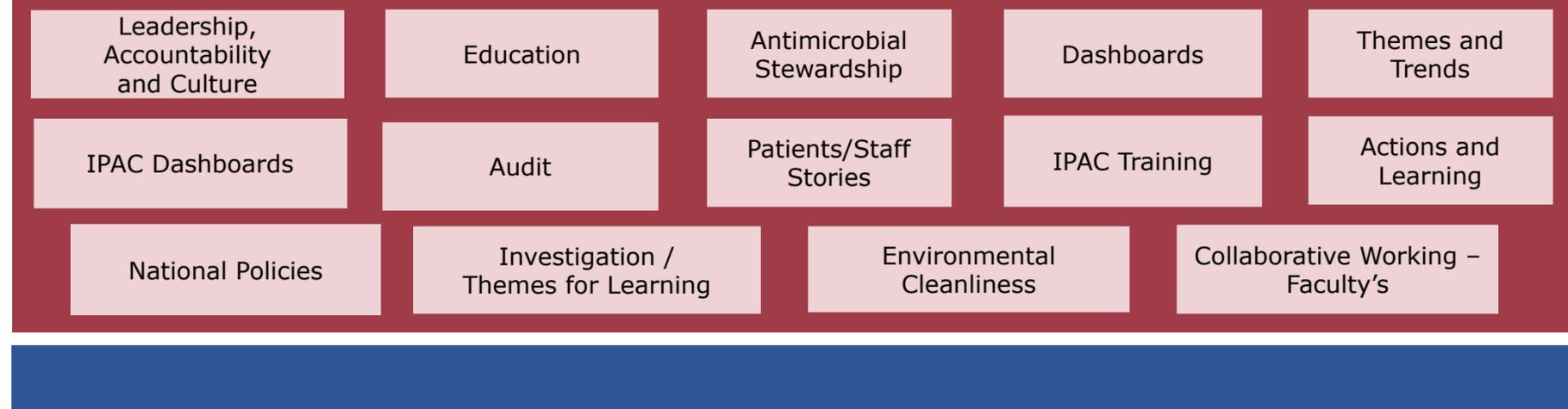
- Ensuring timely action completion by local managers following inspections.
- Enhanced engagement in Health & Safety to reduce reliance on Corporate Health & Safety.

Challenges for 2024/25

- Balancing resources to enhance current safety measures and implement new initiatives.

PILLAR 5

Infection Control and Prevention



Key Achievements

- **Welsh Government Reduction Goals:** Reduction in infection rates.
- **C-Section Surgical Site Infections:** Reduced to pre-pandemic levels.
- **Audit & Education:** Conducted 1,538 audits and trained 1,294 staff.
- **Respiratory Infections:** Managed Covid-19, Influenza, and RSV rates effectively.
- **COVID Investigation:** Reviewed 2,883 nosocomial infection cases with no cases referred to Legal and Risk.

Key Strategies and Interventions

- Focus on Gram-Negative Bloodstream Infections through various initiatives.
- Enhanced cleaning strategy and prudent antimicrobial prescribing

Areas for Improvement

- Addressing increase in healthcare-associated infections, particularly Klebsiella bloodstream infections.

Challenges for 2024/25

- Developing a robust cleaning program to reduce healthcare-associated infections.
- Managing patient flow and infection prevention.
- Ensuring ongoing support for infection prevention best practices.

PILLAR 6

Safeguarding

Policy/SOP

Leadership,
Accountability and
Culture

Level 1, 2 and 3
Training

Safeguarding
Supervision

Practitioner
Concerns

Partnership
Working

Domestic Abuse
and Sexual Safety

Statutory Reviews

Key Achievements

- Improved Safeguarding Maturity Matrix outcomes.
- Delivered Level 3 Safeguarding Training.
- Expanded scope for safeguarding supervision.
- Achieved reasonable assurance in Safeguarding Audit.
- Sustained Independent Domestic Violence Advocate role in urgent care.
- Established a productive Safeguarding Committee.
- Actively supported MARAC process.
- Increased volume of Safeguarding Children and Adult referrals.

Areas for Improvement

- Addressing delays in quality assurance and service improvement due to increased operational activity.
- Mandating Level 3 Training for specific staff via ESR limitations.
- Securing funding for the IRIS program to support domestic abuse survivors.

Challenges for 2024/25

- Ensuring primary care staff receive necessary training and resources.
- Providing appropriate Safeguarding Adult Supervision.
- Developing and launching sexual safety documents.
- Revising delivery and monitoring model for Level 3 Safeguarding training.
- Launching the DATIX Safeguarding Module for better case management.
- Updating internal processes and achieving objectives despite operational demands.

Workstream Priorities

2023/24

Deteriorating Patients

Addressing Deteriorating Patients: 2023/24 Key Actions

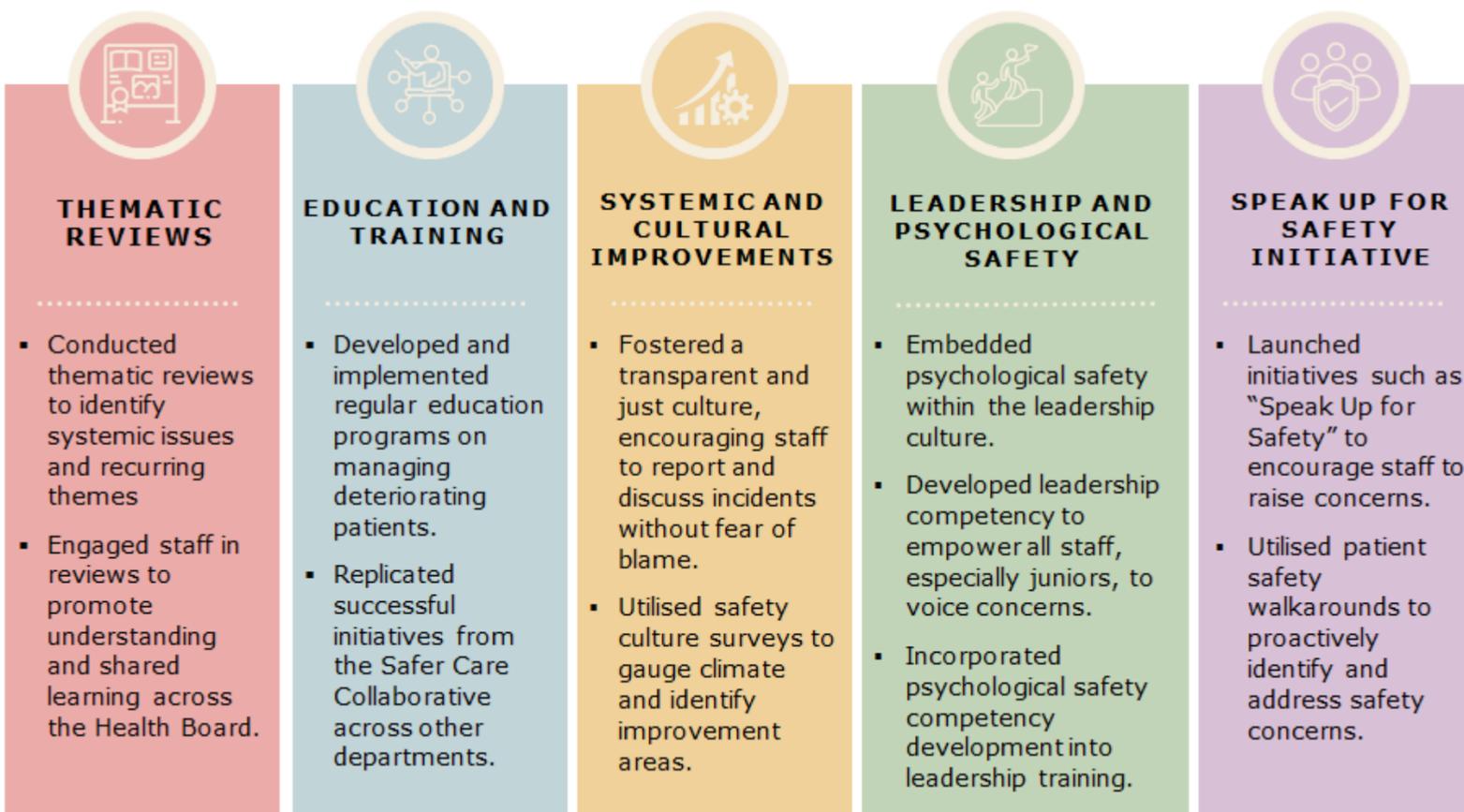
Background

Deteriorating patients are a significant issue due to basic care and observation failures and presents a multifaceted problem across the Health Board. Oversight by the Executive Director for Nursing emphasised returning to fundamental nursing, therapy, and medical care practices. A thematic review of serious incidents highlighted issues such as incomplete observations and failures to escalate concerns, underscoring the need for comprehensive reviews.

Objectives

The Health Board aimed to address systemic issues and improve patient safety through the following strategies:

Actions and Steps



Safer Care Collaborative

Overview:

A two-year national collaboration aiming to develop systems for safe, reliable, and effective care. It focused on strengthening leadership, supporting quality improvement, working across the system, and reducing patient health deterioration.

Achievements

Surgical Ward CO	Reduced cardiac arrests by 75%.
Monmouthshire Team	Improved patient experience during discharge through personalised care.
Older Adult Mental Health Services	Increased access to home-based memory services.
Acute Medical Unit	Introduced standardised observations every four hours.
Operating Theatres Team	Focused on reducing Never Events and building a safety culture.
Executive Safety Walkarounds	Facilitated direct communication between staff and executives to address concerns and support improvements.

Theatre Never Events

Definition of Never Events

- **Never Events:** Serious, largely preventable patient safety incidents that should not occur if the available preventative measures are implemented.
- The national list of never events evolves, but all such events are avoidable adverse incidents.

Background

This programme, led by the theatre's safety team with support from the Executive Medical Director and ABCi, addressed a series of never events that occurred in theatres. Despite prior efforts in quality assurance and system redesign, the lack of an overarching approach led to siloed learning and inefficiencies. This workstream emphasised the need for a more integrated system to enhance learning and improve outcomes.

Challenges included a lack of a universally understood process for preventing never events and contribution of multiple system, personal, and environmental factors to these events. There appeared to be an increased in reporting which indicated a transparent culture but also highlights recurring themes and systemic issues.

A thematic review of never events was undertaken in theatres and included:

- **Retained Foreign Bodies:** Such as retained swabs.
- **Wrong-Sided Nerve Blocks:** Involving teams like Anaesthetics, Radiology, OBS, Gynae, Trauma, and Orthopaedics.

Actions and Insights Over 2023/24

Existing Actions:

- Some teams adopted "stop before you block" protocols but faced implementation challenges.
- A test on wrong-site nerve blocks highlighted the need for systemic and multifactorial solutions.

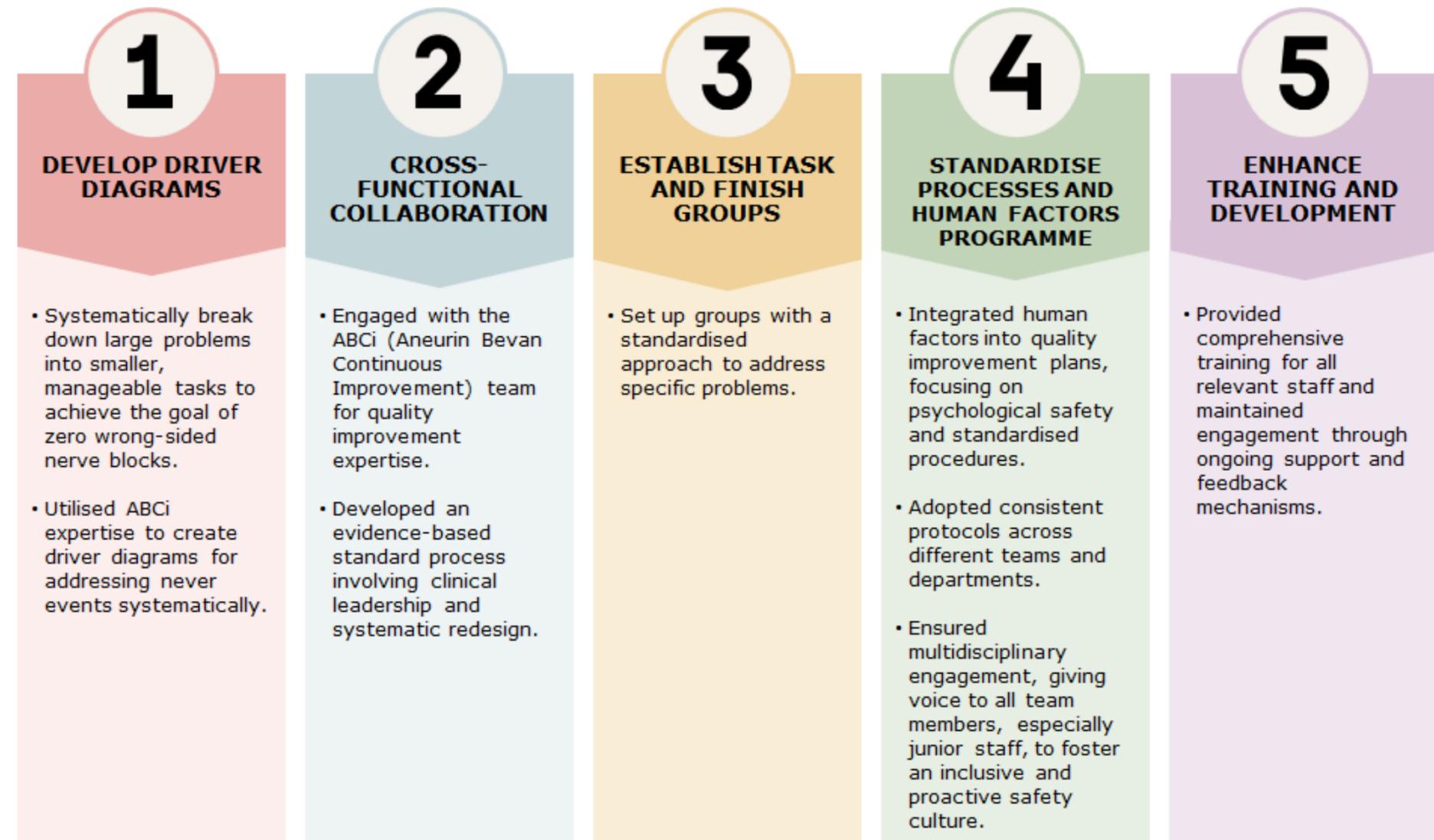
Human Factors Approach:

- **Simulation-Based Training:** Conducted fortnightly simulations in emergency theatres to test systems and generate actionable insights.
- **Team Training and Psychological Safety:** Focused on creating a just and safe culture, improving team dynamics, and fostering situational awareness.

Conclusion

The integration of these actions and strategies has led to a reduction in never events throughout 2023/24. This program has created a more cohesive, transparent, and safety-focused culture within the Health Board, significantly improving patient safety and care quality in theatres.

Key Steps Undertaken in 2023/24



Theatre Quality & Safety Programme

Aim

The aim of the Aneurin Bevan University Health Board Theatre Quality and Safety Programme was to reduce the number of Serious Incidents (SI), National Reportable Incidents, and Never Events across theatre sites. By integrating quality improvement practices into the daily routine of all theatre staff, the programme contributes to a stronger safety culture as a crucial component of the Health Board's Quality Strategy.

Appointment of a Quality Improvement Advisor for Theatres (started January 2024) to support primary safety objectives in theatres, ensuring that lessons from never events and incidents contribute to a stronger safety culture.

Key Actions and Initiatives

Introduction of National Safety Standards for Invasive Procedures (NatSSIPs) 2

- Work began to introduce NatSSIPs 2 across Theatres.
- Current workstreams focus on updating the World Health Organisation Surgical Safety checklist, using Quality Improvement (QI) principles and co-design with staff to include the 'NatSSIPs 8' sequential steps.
- The scope of work involves both organisational and sequential steps, with the wider teams exploring ideas for change, including patient engagement and creating a NatSSIPs network for the health board, linking all areas that undertake invasive procedures.
- Theatre Safety and Compliance workstreams are being reviewed and realigned to the new Theatre Safety Agenda.

Building a Safety Culture Using Human Factors

- Regular protected space for the established human factors in theatres programme.
- Use of simulation as a tool to test the system and identify improvement opportunities through 'listen to learn' debrief sessions.
- Consideration of system, team, and individual factors at play.
- Safety culture surveys for staff are used as a listening tool, facilitating debriefing sessions and identifying topics for future workshops to address potential safety concerns and share improvement ideas.

'Quiet for the Count' Project: Started in November 2023.

- **Purpose:** Develop a safety culture and understanding among all theatre team members about the importance of reducing distractions during surgical counts.
- **Testing and Spread:** Initially tested at Grange University Hospital (GUH) and eventually spread across all theatre sites.

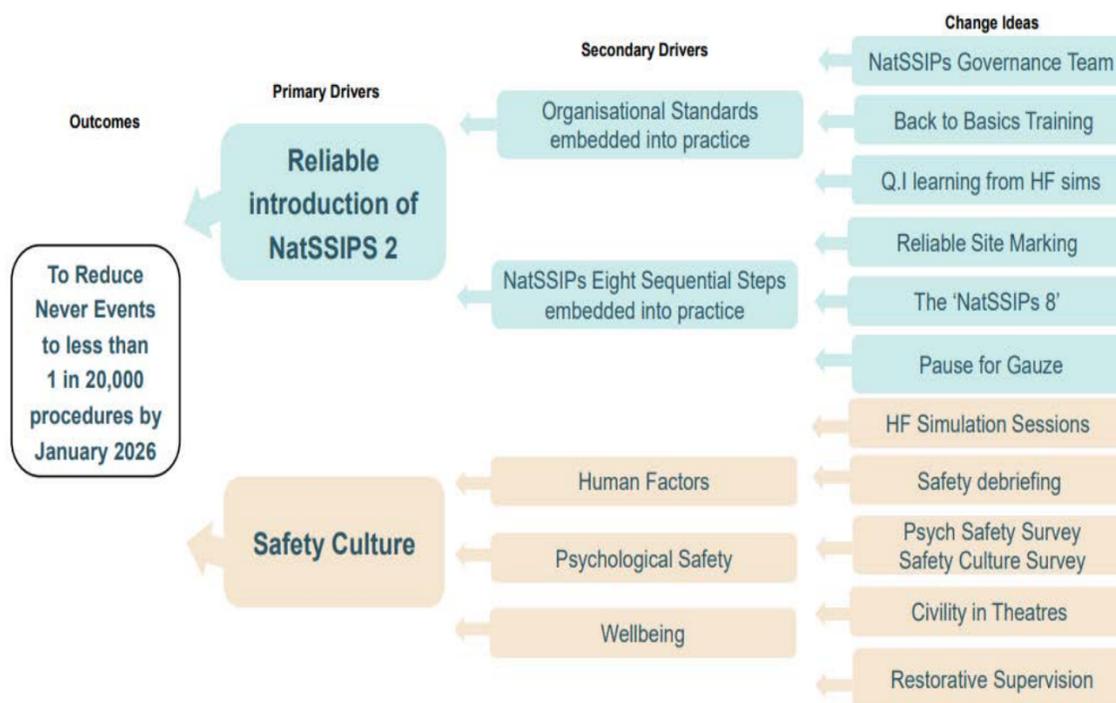
Monthly 'Back to Basics' Training Sessions: Started January 2024

- **Content:** Safety education package focusing on different subjects each month to refresh key knowledge and provide updates on essential topics.
- **Effectiveness:** Pre- and post-training surveys demonstrated improvement in understanding and confidence across these areas.

Psychological Surveys: Regular Surveys

- Conducted across all theatre sites to capture qualitative data on potential future improvement projects and quantitative measures of psychological safety.

The Theatre Quality and Safety Programme scope of work is visually displayed in a driver diagram to support the reduction of never events in theatres. The diagram breaks down large goals into smaller, actionable tasks, aligning with the systematic approach suggested by the Aneurin Bevan Continuous Improvement (ABCi) team.



Summary

By implementing these comprehensive actions and initiatives, the Theatre Quality and Safety Programme aimed to create an integrated, safety-focused environment in the Health Board's theatres. The programme has emphasised the importance of a strong safety culture, continuous learning, and systematic improvements to reduce never events and enhance patient care quality.

Radiological Serious Incidents

Background

A number of missed diagnostic findings and failures to follow up on radiological exams were identified as critical issues. These incidents dated back to 2019. Undertaking a thematic review of these incidents illustrated failures and found the root causes were identified as both human and system factors, with assumptions playing a significant role in that radiological results were received and acted upon. This work programme was led by the Executive Director of Therapies and Health Science.

Objectives

The Health Board aimed to mitigate these issues by standardising communication protocols, improving IT systems, and addressing human factors to enhance overall patient safety and care quality.

Key Themes and Issues

Systemic and Human Factors:	<ul style="list-style-type: none"> Human assumptions are made that no incidental findings exist if none are expected and that someone else is following up on unexpected findings. Failures in IT systems to capture or record results lead to missed follow-ups. Inconsistent communication methods within the Health Board exacerbate these failures.
Standardising Communication:	<ul style="list-style-type: none"> Communication of findings has been inconsistent. The development of the STOP protocol aims to standardise alert communication following significant findings, improving understanding and reducing errors. The STOP protocol is nearing finalisation and will be shared across the Health Board.
IT System Improvements:	<ul style="list-style-type: none"> A new Picture Archiving and Communication System (PACS) provider has been selected, with implementation expected next year. This should enhance result communication clarity and accuracy, reducing errors.
Personal and Professional Responsibility:	<ul style="list-style-type: none"> Emphasis on the responsibility and accountability of requesting clinicians (Referrer: IR(ME)R 2017) to act on results. Complexities, especially in emergency departments (ED), where imaging may be requested in the name of a consultant who hasn't seen the patient.
Cross-Sector and IT Interface Issues:	<ul style="list-style-type: none"> Assumptions are driven by the interface between primary and secondary care and differing IT systems. Errors often occur due to dropdown lists and ambiguous messages in electronic discharge summaries. Ensuring radiology reports are sent to the correct recipient is critical, requiring correct identification of the referrer, specialty, and location.

Actions Undertaken in 2023/24

01

Standardising Communication Protocols

- Implementing the STOP protocol to clarify alert communication for significant findings.
- Sharing the standardised communication process across the organisation to reduce errors.

02

Improving IT Systems

- Transitioning to a new PACS provider to enhance result communication clarity and accuracy.
- Monitoring the correct identification of referrers and specialties to ensure accurate report delivery.

03

Addressing Human Factors

- Conducting thematic reviews to understand systemic issues.
- Engaging staff in reviews to promote understanding and shared learning.

04

Enhancing Policies and Promoting Personal Responsibility

- Reiterating the accountability of clinicians to act on results.
- Providing training to ensure clinicians understand their responsibilities and the processes involved.

05

Cross-Sector Collaboration

- Addressing interface issues between primary and secondary care.
- Ensuring clear and unambiguous communication in electronic discharge summaries.

Conclusion

By implementing these steps, the Health Board aims to reduce errors related to missed diagnostic findings and follow-up failures, thereby improving patient safety and care quality.

Health and Care Quality Standards

As part of the Quality Strategy an Implementation Plan was produced for the Health Board to enhance the quality of healthcare throughout 2023.

In order to deliver the Health and Care Quality Standards, the plan was mapped with quarterly objectives aligned to the six key quality domains. Highlights of the achievements for 2023/24 can be seen in the Appendix.

This plan was built on existing achievements, emphasising continuous improvement and embedding quality, safety, and learning in daily operations.



Duty of Candour

The Duty of Candour, effective from 1 April 2023, mandates all NHS bodies to openly and promptly report, manage, and investigate notifiable adverse patient safety events as stipulated by the Health and Social Care (Quality and Engagement) (Wales) Act 2020. This includes compliance with the Concerns, Complaints, and Redress Arrangements (Wales) Regulations 2011.

Healthcare professionals who are subject to a professional Duty of Candour have to be open and honest with service users, colleagues, their employers and relevant organisations.

The statutory duty of candour and the professional Duty of Candour have the same aim: To be open and honest with people who receive care and treatment. The strong links between the statutory and professional duties of candour will empower staff to speak openly about concerns and will encourage learning to improve quality of care.

Operational since April 2023, through the Duty of Candour, the Health Board must be honest in informing patients and their families when things go wrong in providing care or our services fail to meet expectations or the standards that they should. There is an obligation to find out what went wrong; and, to make sure the same mistake does not happen again. A culture of openness, transparency and candour is widely associated with good quality care. It encourages learning and is achieved without apportionment of blame. The Duty of Candour applies if the care the Health Board provides has or may have contributed to unexpected or unintended moderate or severe harm, or death. This duty builds on the Putting Things Right process for raising concerns or complaints.

The Health Board has provided information and guidance for all staff. It has shared the national programme of education and publicity to help ensure that colleagues across the Health Board were aware of the new Duty and the steps needed to comply with the Duty. The Duty of Candour integrates into incident reporting via Datix.

This included:

- Education materials are due to be available soon.
 - Staff awareness video
- Staff information leaflet (pdf) explaining what the new Duty means for all staff working in the NHS.
- A dedicated intranet page was also established
- New tools in DATIX that will help us have Candour conversations with patients and their family.
- Standardised templates and letters ensure consistent communication with patients.
- Meetings with Primary Care and community divisions support comprehensive reporting, and staff receive ongoing guidance on applying the Duty of Candour criteria consistently.

Duty of Candour

Achievements for 2023/24:

Trigger:	Initiated when an adverse event review reveals unexpected or unintended harm (moderate, severe, or death) related to NHS-funded care.
Preparation:	The Health Board aligned incident management systems and processes to meet Duty of Candour requirements.
Training:	Duty of Candour training is available on the Health Board's electronic training platform (ESR), and staff are encouraged to complete it.
Implementation:	Centralised Quality, Patient Safety (QPS) teams and designated Duty of Candour leads ensure consistent training and compliance.
Reporting Tool:	A new Duty of Candour reporting tool supports continuous monitoring and data validation within incident and complaint systems.
Support:	The Patient Safety Incident team assists divisions in implementing the Duty.

Challenges and Improvements:

Harm Categorisation:	Initial confusion in distinguishing between actual and healthcare-related harm in lower harm incidents led to additional education. Increased understanding is being achieved through education and support across multiple forums.
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NEXT STEPS FOR 2024/25

Encourage all staff to complete Duty of Candour training on ESR.

Conduct further training sessions by Quality, Patient Safety leads.

Use incident reports to identify trends and areas for improvement.

Implement changes based on lessons learned.

Foster a culture of continuous learning and improvement.

Produce quarterly data for divisional review at QPS Learning and Improving meetings.

Discuss learning and improvements at the Patient Quality and Safety Learning and Improvement Forum.

Learning and Improvement

Organisational Learning for Continuous Healthcare Improvement

In 2023/24, the Health Board placed a significant emphasis on organisational learning to drive continuous improvement in healthcare. By engaging staff and key stakeholders, we began to develop a comprehensive **Listening and Learning Framework**, demonstrating our commitment to embedding lessons learned to enhance patient care, safety, quality, and experience. This framework is set to be approved in April 2024.

Key Focus Areas for 2023/24:

- **Identifying Learning:** Actively seeking insights and lessons from various sources, including patient feedback, incident reports, and staff experiences.
- **Triangulating Learning:** Cross-referencing information from different sources to gain a holistic understanding of issues and ensure accuracy in learning.
- **Disseminating Learning:** Sharing insights and lessons learned across the organisation to ensure they are accessible to all staff and stakeholders.
- **Implementing Learning:** Applying the lessons learned to practical strategies and interventions to foster a culture of continuous improvement.
- **Just Culture:** Promoting a fair and open environment where staff feel safe to report incidents and share insights without fear of blame or retribution.
- **Triangulated Approach:** Integrating quality, patient safety, and experience data to create a comprehensive understanding and drive informed decision-making.

Initiatives and Developments for 2024/25:

- **Bi-Monthly Learning and Improvement Forum:** Establishing a regular forum dedicated to learning and improvement, allowing staff to share knowledge, discuss insights, and drive change.
- **Learning Repository:** Creating a central repository to store and share knowledge, ensuring that valuable lessons and best practices are easily accessible.
- **Transformation of the Quality and Patient Safety Operational Group:** Evolving this group into a learning and improvement forum to reinforce a culture of continuous improvement.
- **Quality Improvement Strategy:** Developing a strategy over the next 6-9 months to provide a structured approach to quality improvement across the Health Board.

Commitment to Continuous Improvement:

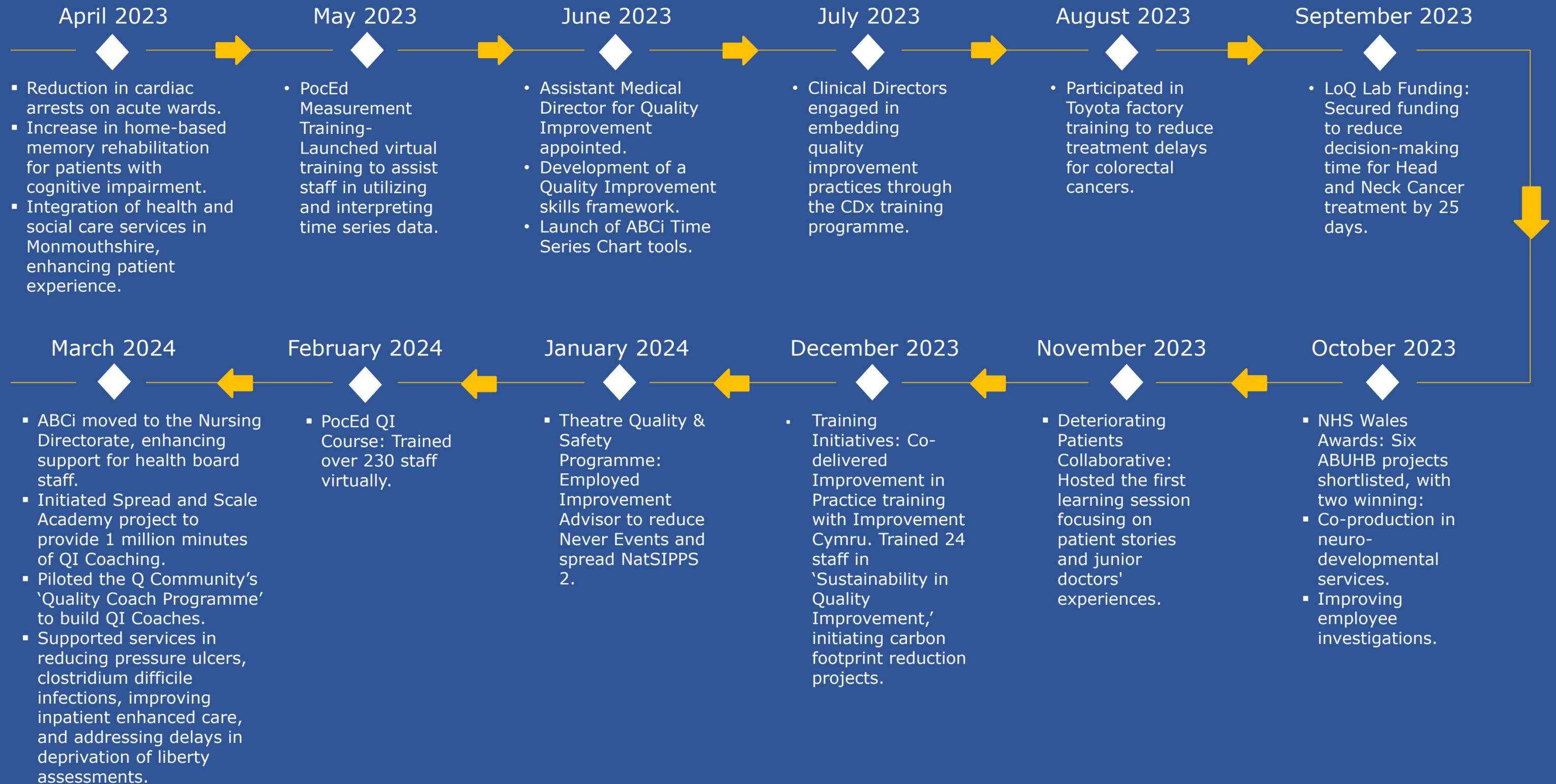
The Health Board is committed to fostering a culture of continuous improvement, learning from every opportunity to enhance patient care, safety, quality, and experience. By embedding a Just culture and triangulated approach, we aim to create an environment where learning is a fundamental part of our operations, driving excellence in practice and improving outcomes for our patients.

ABCi (Aneurin Bevan Continuous Improvement) / Quality Improvement Timeline of Achievements

In 2023/24, the Health Board made significant strides in quality improvement across various domains, with notable achievements in patient care, training, and operational enhancements. Despite the successes, challenges such as staff limitations, financial constraints, and the effective adoption of new tools remain. Moving forward, the Health Board is committed to addressing these challenges, fostering a culture of continuous improvement, and maintaining high standards of care for all patients.

April 2023	<ul style="list-style-type: none"> Continued support of All-Wales Safe Care Collaborative & local teams throughout 2023-24 to: <ul style="list-style-type: none"> Reduce cardiac arrests on acute wards Provide home based memory rehabilitation to a greater number of patients diagnosed with cognitive impairment to enable independence Integrate health and social care services in Monmouthshire to re-able patients both before and after discharge leading to better patient experience
May 2023	<ul style="list-style-type: none"> New PocEd Measurement virtual training launched helping staff to use and interpret time series data
June 2023	<ul style="list-style-type: none"> New role: Assistant Medical Director for Quality Improvement Quality Improvement skills framework developed to train staff around QI methods ABCi Time Series Chart tools launched
July 2023	<ul style="list-style-type: none"> Connecting with Clinical Directors around embedding quality improvement practice via 3 cohorts of CDx training programme
August 2023	<ul style="list-style-type: none"> ABCi team attended training at Toyota factory, and skills gained were used to reduce delays, particularly in making decision around treatment for colorectal cancers
September 2023	<ul style="list-style-type: none"> Q Lab funding obtained to support a project which has reduced the time to make decisions around treatment for Head and Neck Cancer patients by around 25 days
October 2023	<ul style="list-style-type: none"> NHS Wales Awards – 6 projects from ABUHB of 24 across Wales were shortlisted, with two winners across eight categories. Winners were: <ul style="list-style-type: none"> Co-production to support neuro-developmental services in Gwent (ABUHB) Improving our Employee Investigations
November 2023	<ul style="list-style-type: none"> First ABUHB Deteriorating Patients Collaborative learning session took place focussing on listening to unheard voices including patient stories of bereavement and a junior doctor's experience
December 2023	<ul style="list-style-type: none"> ABCi team worked with Improvement Cymru to co-deliver Improvement in Practice training for ABUHB staff 24 staff successfully attended 'Sustainability in Quality Improvement' training, leading to several projects being initiated to reduce the carbon footprint
January 2024	<ul style="list-style-type: none"> Improvement Advisor employed to support Theatre Quality & Safety Programme aiming to reduce Never Events in Operating Theatres through building a culture of safety within theatres and spreading NatSIPPS 2
February 2024	<ul style="list-style-type: none"> PocEd QI, our bi-monthly QI fundamentals live virtual course, which is open to all staff in the organisation, has now over 230 staff successfully completing the training
March 2024	<ul style="list-style-type: none"> The ABCi QI Unit continues to support quality improvement across clinical professions. ABCi has moved to sit within the Nursing Directorate which will free up additional support to work with staff across the health board The ABCi team with support from colleagues in nursing, have initiated a Spread and Scale Academy project which aims to, 'Unleash 1 million minutes of Quality Improvement Coaching to enable our staff to improve what matters to them and their patients' The ABCi team have led work in conjunction with Improvement Cymru colleagues to deliver a pilot of the Q Community, 'Quality Coach Programme' to build QI Coaches within clinical areas to support improvement work ABCi continue to support services across different areas such as: <ul style="list-style-type: none"> Reducing pressure ulcers Reducing clostridium difficile infections Improving enhanced care for inpatients Improving effectiveness and patient experience around continence for patients living with dementia Reducing delays around deprivation of liberty assessments

Year in Review: Quality Improvement Milestones and Challenges in 2023/24



Quality Improvement

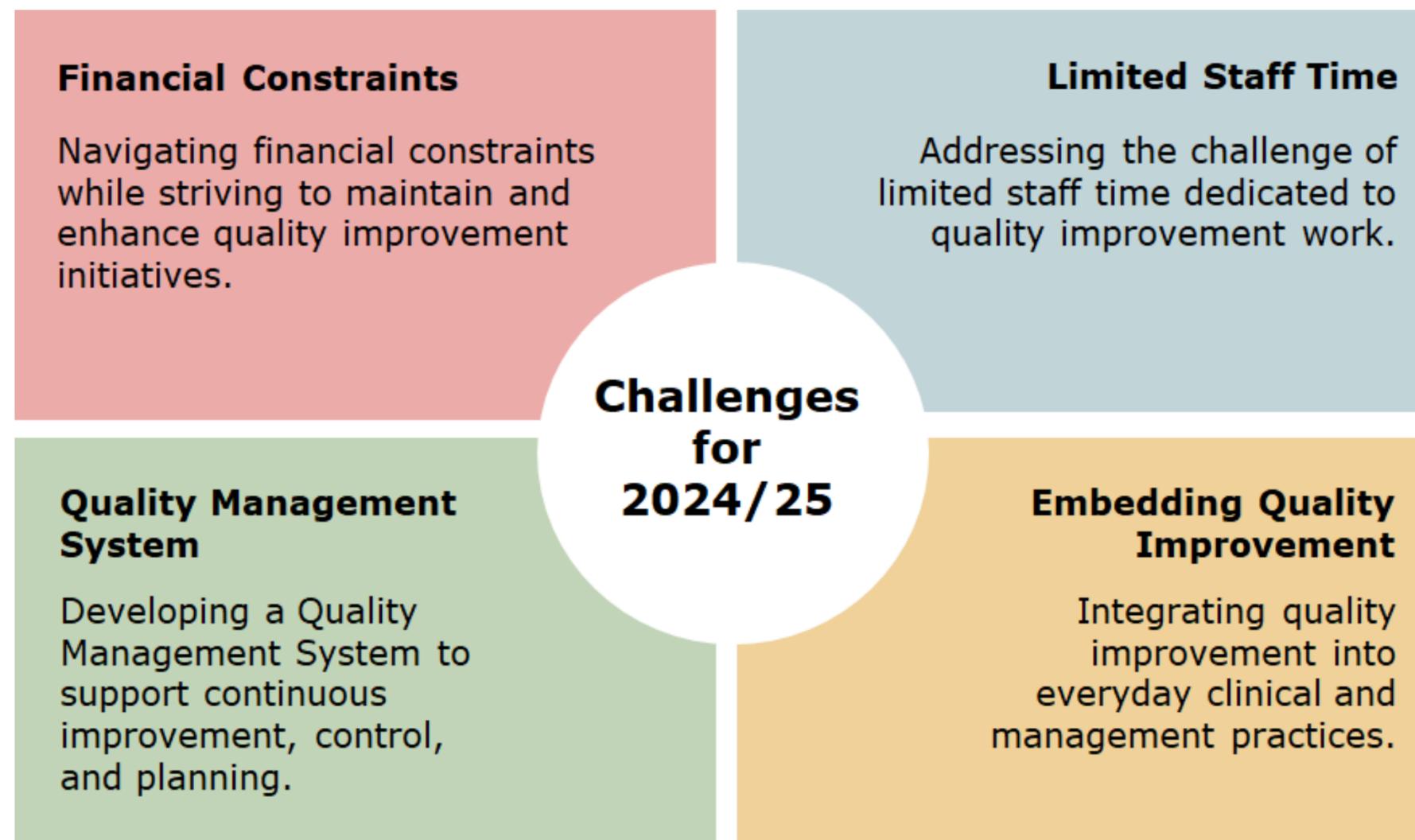
Areas for Improvement:

Team Withdrawals:

Three teams withdrew from the Safe Care Collaborative due to service pressures.

LifeQI Tool Adoption:

The adoption of the LifeQI tool was less effective than anticipated.



Learning from Deaths

The Health Board aimed to complete Mortality Reviews to learn and identify improvement. This has been aligned with the development of a learning from deaths framework (similar to NHS England) that will support an approach of systematic ward to Board reporting and monitoring of mortality, this will be launched in April 2024.

The objective is to ensure systematic ward-to-board mortality reporting and monitoring. Key indicators will include risk adjusted mortality. The Risk Adjusted Mortality Index (RAMI) adjusts for individual patient risk factors and co morbidities and therefore allows comparison between organisations. The accuracy of RAMI is dependent on the completion and accuracy of clinical coding. This has increased to 108 in December 2023 from 103 in 2021. The Health Board has also been reporting crude Mortality as part of the QOF. The mortality rate has remained flat and consistent, necessitating individual mortality reports for deep dives into high mortality specialties.

The role of the Medical Examiner (ME) Service is to provide independent death scrutiny, quality death certification, and reducing the stress of the bereaved. The service began in January 2021 and expanded to all sites in April 2023 (currently excluding maternity, paediatric, and neonatal). Approximately 25% of deaths are referred back to the Health Board for further action or learning. The learning from death framework will allow triangulation of accurate mortality data and Medical Examiner (ME) information for trend identification and condition-specific analysis.

There have been a number of achievements in 2023/24, this includes: Welsh Government mandated ME scrutiny of all deaths (excluding coronial cases) in April 2023, development of a mortality review screening panel to discuss the cases referred by the ME service and assess learning and improvement. The release of biannual newsletters highlighting ME referral themes and learning.

Future Goals for 2024/25 include: -

- Expansion of the ME service to include community deaths, increasing referrals.
- Continued communication of the biannual newsletters for shared learning.
- Sharing positive feedback and compliments from bereaved families with clinical areas.

Implement Robust Audit Processes and Plans

In 2023/24, the Health Board continued its Clinical Audit Strategy, presenting the strategy and new Audit Management and Tracking platform (AMaT) at Divisional meetings. AMaT training was provided, and all National Audits are now managed using this platform. The standardised reporting tool in AMaT facilitates the reporting of successes, concerns, risks, and assurance levels.

A SMART action plan is developed for each audit and monitored by the Quality and Patient Safety Clinical Audit team. Local audits are also being reported on AMaT. The platforms used in the Clinical Standards and Effectiveness Group (CSEG) to discuss each national report and ensure risks identified are acted upon accordingly. This process enables ensuring full participation in the Programme for [NCAORP 2023/2024](#). Continuous management of NCEPOD studies by the Audit team ensures full participation.

Despite resource issues delaying the Corporate Audit project and staff training, progress has been made. Challenges include obtaining engagement for multi-specialty audits and outdated information requests. For 2024-25, the focus will be on improving audit participation and data accuracy amidst busy clinical environments, while addressing resource constraints.

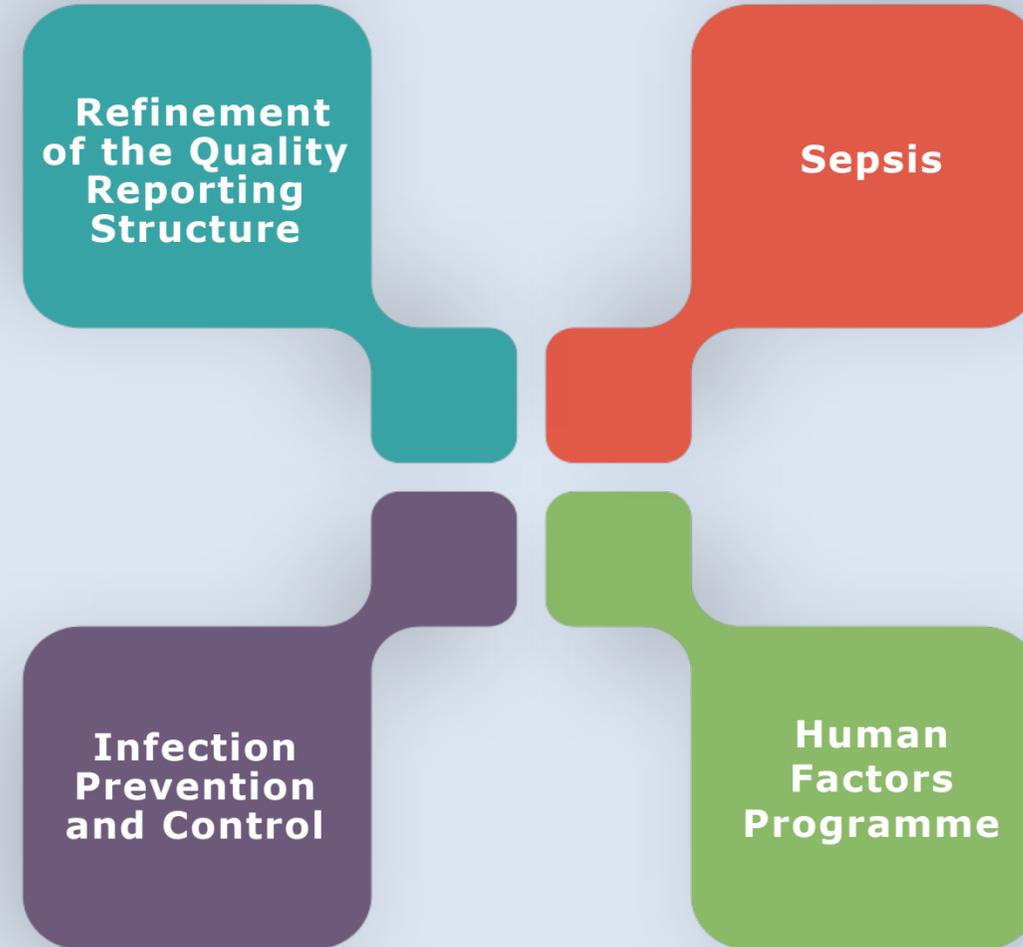
The Health Board [Clinical Audit Plan 2023/2024](#) has been published as well as the [Clinical Audit Activity Report 2023/2024](#) evidencing Health Successes and Concerns within each audit and detailing actions plans moving forward.

Key Workstreams for 2024/25

Commitment to Quality, Safety, and Patient Experience:

The Health Board remains steadfast in its commitment to quality, safety, and patient experience. By enhancing systems of care, promoting continuous learning, fostering innovation, and maintaining a culture of openness and transparency, we aim to create a healthcare environment that consistently delivers high-quality care and positive patient outcomes. Through the strategic initiatives outlined above, we are building a robust foundation for continuous improvement and excellence in healthcare delivery.

Key workstreams for 2024/25 include:



A workstream will be produced for each of these for 2024/25 with SMART action plans. A brief description is provided:

Infection Prevention and Control

With the routine reporting of infection rates, the Infection Prevention and Control pillar of our quality strategy will include a workstream to focus on improving antibiotic prescribing. Work going into 2024/25 already includes:

- **Enhanced Cleaning Programme:**
 - Need for a robust cleaning programme to reduce healthcare-associated infections.
 - Balancing the safety of patients with bed availability and ward reconfiguration.
 - Proposal submitted to Executives for a more focused approach.
- **Patient Flow and Infection Prevention:**
 - Daily challenge of protecting patients from infection while managing bed availability.
 - Attendance at Patient Flow Meetings to support patient placement.
- **Reporting and Root Cause Analysis:**
 - Use of Datix for reporting and analysing healthcare-associated infections.
 - Reinstated virtual root cause analysis meetings to identify themes and learning.
- **Supporting Divisions:**
 - Ongoing promotion of best practices in infection prevention.
 - Financial support from Regional Integration Funds (RIF), with potential risk to service provision if not funded in 2025.
- **Antimicrobial prescribing, stewardship and resistance:**
 - Work closely with Divisions to reinforce start smart and focus guidelines.

Refinement of the Reporting Structure

Ensure clear, evidence-based reporting across all committee and group levels to assure Health and Care Standards delivery. A workstream will include the following workplan:

- **Health Board Corporate Clinical Audit Plan:** Complete and refine the Clinical Audit Plan to ensure systematic evaluation and improvement of clinical practices.
- **Annual Health and Care Standards Reports:** Develop and regularly update these reports to track compliance with health and care standards, identifying areas for improvement.
- **Implementation of Standardisation Efforts:** Standardise processes and procedures across the Health Board to ensure consistency in care delivery.
- **Establishment of Corporate Support Roles:** Create roles dedicated to providing corporate support and integrating decision frameworks to streamline operations and improve decision-making.
- **Enhancement of Assurance Mechanisms:** Improve mechanisms for assurance to ensure that quality and safety standards are consistently met across all areas of care.
- **Utilise Existing Resources:** Leverage the Health Board's existing resources and support systems to effectively implement key initiatives. This includes using available tools, staff expertise, and technological solutions to drive improvements.
- **Alignment with Health Board Commitments:** Ensure all initiatives and actions are aligned with the Health Board's overarching commitment to quality, safety, and patient experience. This alignment ensures that every effort contributes to the broader goals of enhancing patient care and operational excellence.

Sepsis

The Health Board will focus on implementing the updated **National Institute for Health and Care Excellence (NICE) sepsis guideline (NG51)**. The updated guidance aligns with the [Academy of Medical Royal Colleges \(AoMRC\) statement](#) on the initial antimicrobial treatment of sepsis. This will build on improving patient safety by addressing systemic issues related to deteriorating patients. A workstream will be dedicated to sepsis recognition and early assessment from primary care to acute care. A full improvement plan will be developed and ensure the Health Board is delivering the Sepsis 6, focusing on the following:

- Initial treatment
- Including prescribing/admin of antibiotics
- Finding the source of infection
- Early monitoring
- Escalating care (Call for Concern / Martha's law)
- Information and support, - sepsis awareness and safety netting, patient information
- Training and education
- Audit strategy – develop an implementation plan for the Health Board on audit and assurance for sepsis organisation

We will look to work with the UK Sepsis Trust to embed best practice and to mirror any work undertaken nationally and UK wide to enable early recognition of sepsis and improve sepsis awareness.

Human Factors Programme

Implement Human Factors as a Health Board wide approach. Developed with medical, nursing, admin, and managerial staff, the programme at Grange University Hospital (GUH) promotes patient safety, team performance, and staff wellbeing. It embeds human factors by designing better systems and listening to staff. Stakeholders collaborate in protected spaces to identify solutions and actions.

Initially, the Health Board introduced human factors concepts through half-day workshops for multidisciplinary teams. The programme's core involves "safe listening spaces" and simulations to generate discussions for meaningful change. Originally focused on GUH Emergency theatres, it has expanded to other areas and includes a Human Factors training page on the Health Board's intranet.

With the success of the work on never events, this workstream aims to integrate human factors training and methodologies across the Health Board to improve patient safety and staff well-being. This involves implementing human factors training and establishing "safe listening spaces." The human factors programme currently uses existing training programs and resources to enhance overall patient safety and staff well-being.

1

A Learning Organisation

Foster a culture of continuous learning and improvement throughout the organisation.

- Q1: Embed our quality patient safety and quality improvement teams within our divisions
- Q2: Develop a learning repository for all our staff which will allow us to review how learning will be identified, stored, triangulated, shared, disseminated and implemented
- Q2: Develop a learning bulletin to share learning across the organisation
- Q2: Review mortality data and improve clinical outcomes by implementing a Learning from Death Framework and report
- Q2: Scope our Deteriorating Patients Collaborative
- Q3: Review quality and safety structures and reporting structures ensuring learning at every level.

2

Culture

Establish a supportive and proactive culture focused on quality improvement and patient safety.

- Q1: Engage to identify new quality improvers and support existing Quality Improvers
- Q1: Increase Quality Coaching capacity
- Q1: Develop our methodology to learn from incidents and establish a listening and learning framework, enabling us to deliver an learning forum
- Q3: Establish bespoke Patient Experience Collaboratives and use feedback for learning and improvement
- Q3: Formalise an approach to supporting staff involved in patient safety incidents
- Q4: Support a data informed experience (CIVICA) quality and patient safety agenda organisation wide
- Q4: Introduce an electronic patient feedback system to capture real time patient experience feedback

3

Quality Management System

Integrate quality management systems to ensure continuous improvement and compliance with health standards.

- Q1: Support the ward accreditation programme with quality and patient safety measures
- Q2: Utilise and triangulate patient experience data listening and learning from lived experience to provide qualitative data
- Q3: Improve the quality of incident reporting
- Q4: Identify specific areas within national clinical audits that require improvement

4

Quality Improvement

Use data-driven approaches to inform quality improvement initiatives and enhance patient safety.

- Q2: Produce an annual quality report outlining achievements and areas for strengthening
- Q2: Scope the theatre safety programme
- Q3: Strengthen the link between learning from direct and indirect feedback, investigations, and improvement work.
- Q3: Strengthen and embed 'Human Factors' to examine why incidents occur
- Q3: Utilise Clinical Audit expertise to provide the evidence-base and measurement function which drives quality improvement initiatives
- Q3: Initiate Leaders Skills Development Programme
- Q4: Data informed approach to learning from patient feedback and patient safety incidents

Conclusion

This report highlights the continued commitment of Aneurin Bevan University Health Board in providing high-quality care for everyone. Over the past year, we have made significant progress in enhancing patient safety, improving access to services, and ensuring that our care is compassionate, effective, and centered on the needs of those we serve.

The report presents a balanced picture of the Health Board's commitment to delivering the Health and Social Care (Quality and Engagement) (Wales) Act (2020) over the first 12 months. The Health Board has agreed the priorities clearly set out in the report and developed a robust methodology for improving clinical effectiveness, reducing harm, improving outcomes and embedding and measuring quality. We have collected a large amount of information on the quality of the services we provide aligned to the Health and Care Quality Standards, with a focus on patient safety, clinical effectiveness and patient experience.

We have deliberately focused on learning and connecting that learning into tangible improvements ensuring that we listen to our patients, their families and our communities drawing in a deep understanding of their experience to ensure that this becomes our moral compass for quality. Understanding the themes from the experience of our patients and their service users is critical to the quality management system delivery and therefore quality assurance but the value of individual stories is important to triangulate and understand whether improvements translate to real change. The experience of our staff is also of importance and how we listen to their experiences and understand how we can support them to continuously improve the quality of the care they provide, that safety concerns are responded to swiftly and decisively and that the experience of our patients and their families is improved.

We acknowledge the challenges faced by our healthcare system, including the ongoing pressures on our staff and resources. However, these challenges have only strengthened our resolve to innovate, collaborate, and adapt. Our dedicated teams have worked tirelessly to deliver services that meet the highest standards, and we are proud of the strides made in improving patient outcomes.

It was a year of challenge and change but, amidst this, we are proud that our culture for delivering high quality care and commitment to continuous improvement remains strong. This will be key to our ongoing work in 2024/25. As we look to the future, the Health Board remains focused on further improving the quality of care. We are committed to listening to our patients, supporting our staff, and working together with our partners to build a healthcare system that is resilient, responsive, and ready to meet the needs of our communities. Together, we will continue to work towards a healthier, more equitable future for all.



GIG
CYMRU
NHS
WALES

Bwrdd Iechyd Prifysgol
Aneurin Bevan
University Health Board

Quality Strategy Implementation Plan



PERSON
CENTRED



SAFE



TIMELY



EFFECTIVE



EFFICIENT



EQUITABLE

Introduction

This implementation plan for the new Quality Strategy will be delivered throughout Aneurin Bevan University Health Board throughout 2023.

A key focus in the development of this Strategy is progressing on what we have already accomplished and building on existing structures throughout the organisation. Quality is embedded in our culture, and we are committed to continually improving. Delivering the highest quality healthcare to our local communities and putting Quality, Safety and Learning at the heart of everything we do. We have fantastic teams delivering safe, timely, effective, efficient, and person-centred care. Every day we hear positive stories about how they go above and beyond.

Our commitment to Care Aims Principles (integrated decision making) underpins our ambition to embed a person-centred approach to service provision. The Health Board will adopt, at scale, the 'Care Aims' model across multi-disciplinary teams by truly embedding 'what matters' principles, improving patient experience, voice, value, and choice. This will provide us with improved metrics for patient experience and evidence of feedback influencing service plans, delivery, and improvement.

Our Strategy and this implementation plan was developed in collaboration with a diverse group of people, ranging from healthcare partners to patients and colleagues, and we are grateful for the feedback and insights provided by everyone involved. This collaborative approach is critical to our journey of improvement. We are committed to delivering an open, learning organisation with a 'Just Culture'. We all have the same common goal of improving quality, and by working together, we can enable the organisation to accomplish much more.

This Implementation Plan for the Quality Strategy will be delivered over the next three years, we are in an excellent position to implement it.

We will continue to review the strategy and plan annually as we know this is a ten-year ambition to evolve and sustain its development by our teams. Ultimately, it is about people, and the measure of its success will be determined by the experiences of our patients and staff.

Our Quality Strategy Commitment

- Aneurin Bevan University Health Board will be a learning organisation where staff members work towards delivering high quality clinical care every day.
- We will strive to better understand our systems of care, build capability through an all teach/all learn philosophy, encourage innovation and engage patients, relatives, carers, staff and communities in improvement endeavours, whilst learning from mistakes.
- We will ensure that quality is embedded throughout the organisation creating a culture of openness and transparency where people are supported to raise concerns
- Our patients, relatives, carers, staff and communities will partner with us to achieve this vision.

Six Domains of Quality

The Quality vision of Aneurin Bevan University Hospital Board (ABUHB) is to be "widely recognised for delivering safe, timely, effective, efficient, equitable and person-centred care." Our first and most important commitment to our patients is to keep them safe. Over the next three years, this Quality Strategy will improve the delivery within these six domains of quality, while continuing to improve patient and staff experience and outcomes.

The experiences of our patients, relatives, carers, staff and communities will continue to be the most important measure of our progress. It is the delivery of this Strategy, together with the supporting strategies of patient experience, risk management, clinical effectiveness and employee wellbeing to deliver high quality care, person centred and effective health and care services for our local population.

Provide **SAFE** care – we aim to reduce harm, prevent errors, and deliver consistently safe care through increased visibility and insight from multiple sources of patient safety information. Care will be delivered by capable and competent staff. Maximising the things that go right and learning from when things that go wrong to prevent reoccurrence. We will work to identify, monitor and minimise risk.

Provide **EFFECTIVE** care – Deliver consistently effective and reliable care, based on evidence-based best practice which is delivered in a culture that encourages and enables innovation to **Improve** outcomes.

Provide **EQUITABLE** care, ensuring equal opportunities for individuals to attain their full potential for a healthy life which does not vary in quality and is non-discriminatory. We will embed equality and human rights and promote and protect the welfare and safety of children and adults who become vulnerable or at risk at any time.



Deliver **PERSON CENTRED** care which involves patients, relatives, families, carers, and system partners in the planning delivery of care and opportunities to improve patient safety. We care about the wellbeing of individuals, families, carers and staff, ensuring everyone is treated with compassion, kindness, dignity and respect.

Provide **TIMELY** care, ensuring people have access to the high-quality advice, guidance and care they need quickly and easily, in the right place, first time. We will care for those with the greatest health need first, and where treatment is identified as necessary, we treat people based on their identified and agreed clinical priority.

Provide care that is **EFFICIENT** by taking a value-based approach to improve outcomes that matter most to people in a way that is as sustainable as possible and avoids waste. We will make the most effective use of resources to achieve best value, doing only what is needed, ensuring any interventions represent the best value that will improve outcomes for people.

Deliverables - The goals of the implementation plan include:

1. Enabling staff to improve quality

The aim of the delivery plan is to enable staff to improve the services they provide for our patients and staff. This plan will ensure that we can answer the 'who', 'what', 'when', 'how', and 'why' we have focused on key projects and areas and how this will deliver our strategy. Improve patient and staff experience and embedding improvement into daily practice.

Collectively the measures and actions will help us to move forward towards the integration and sustainability aspirations for the Health Board. Ensuring we are putting quality and safety above all else, driving improvements in health and social care and leading to better outcomes that matter most to the people of Gwent.

2. Implement the Duty of Quality

The duty requires the Health Board to develop leadership and management systems with a view to securing improvement in the quality of services. Through continuous improvement of our services over time, ensuring that quality challenges are improved upon, we will report our learning through our annual quality report.

3. Meet the requirements of the Duty of Candour

This duty will support the Health Board when things go wrong in providing care or our services fail to meet expectations or the standards that they should.

Through this Duty, the Health Board must be honest in informing patients and their families when things do not go right. We will be obligated to find out what went wrong; and, to make sure the same mistake does not happen again.

A culture of openness, transparency and candour is widely associated with good quality care. This must encourage learning and be achieved without apportionment of blame.

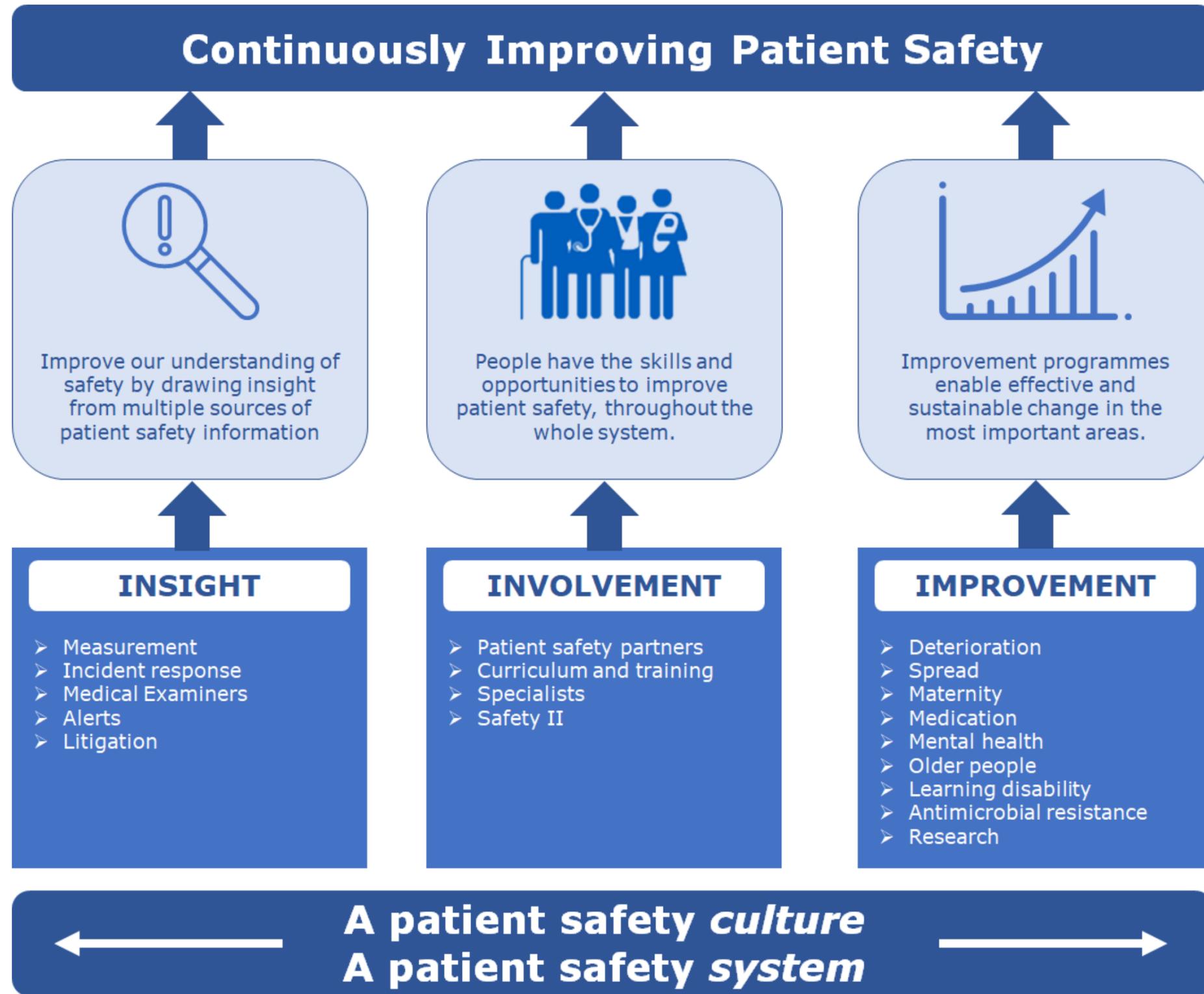
Quality Strategy Performance Monitoring

To successfully implement our Quality Strategy, the implementation plan will form a cohesive approach. This is grounded in a commitment to develop the underpinning foundations of quality through the six domains which can be mapped to our 'pillars of quality' programme.

This means that the way in which we report our quality performance is under development and will be periodically reviewed as a matter of course.

A Quality Outcomes Framework will be used and a report will cover all the performance indicators. This will be available through monthly summary data, more detailed quarterly data and insight, and annual performance review data.

These quality outcome indicators will be the foundations of our Quality Management System and transforming services which will assist in improving quality learning and reducing inequality and risk across the system.



Key objectives for the next year

- Delivery of an approved strategy for Quality, Framework and Delivery Plan with a clear understanding of priorities.
- Through the launch of the new system for patient experience and the Health and Well-being survey, put in place mechanisms to learn from the insight gained.
- Establish a framework for learning and skills at all levels and the capacity and capability to grow and develop our skills and learning networks.
- Deliver the Safe Care Partnership, Faculty workstreams and the outcomes as set by each team.
- Agree and implement the measures and reporting structures.
- Review the capability of our data capture systems for resilience and suitability.
- Implement new systems to provide insight and support for delivery.
- Review our quality and safety structures and teams along with the reporting structures to ensure learning at every level and appropriate assurance and governance.

QUALITY PRIORITY 1: Deliver PERSON CENTRED care which involves patients, relatives, families, carers, and system partners in the planning delivery of care and opportunities to improve patient safety.

Objective	Actions for each Quarter for 2023				Delivering (so what)	Indicators
	Q1	Q2	Q3	Q4		
Patient and Staff Experience						
Launch a system to capture Patient Experience across the Health Board (CIVICA)	<ul style="list-style-type: none"> Launch the CIVICA system in Community Hospitals. Divisional awareness campaign commences. Training and user programme commences. Define measures 	<ul style="list-style-type: none"> Generate and review first reports and insight 	<ul style="list-style-type: none"> Define and redesign the questions if required 	<ul style="list-style-type: none"> CIVICA available in all acute and community areas 	<ul style="list-style-type: none"> Opportunities to receive direct patient feedback to inform learning 	<ul style="list-style-type: none"> General experience rating of episode of care Increase in number of responses in Civica
To respond and learn from complaints	<ul style="list-style-type: none"> Review of resources and processes available to respond to complaints 	<ul style="list-style-type: none"> Recommendations finalised for approval, and implementation complete by the end of the quarter. Reduction in complaints backlog 	<ul style="list-style-type: none"> Reduction in complaints backlog 	<ul style="list-style-type: none"> Backlog of complaints resolved 	<ul style="list-style-type: none"> Timely feedback and response to concerns Opportunities to learn and focus improvement 	<ul style="list-style-type: none"> Compliments - themes identified for improvement Reduction in the complaints backlog Qualitative feedback use of the learning section in Datix Increase in the number of actions plans completed
To listen to feedback from staff	<ul style="list-style-type: none"> Employee wellbeing survey undertaken by workforce 	<ul style="list-style-type: none"> Results available from survey Capture ideas for improvement generated by staff 	<ul style="list-style-type: none"> Analyse results 	<ul style="list-style-type: none"> Themes for improvement You said, we did approach for ideas 	<ul style="list-style-type: none"> Timely feedback to ideas for staff Enhance staff wellbeing 	<ul style="list-style-type: none"> Triangulate staff experience with data
To ensure that the "Voice of the Child" and the principles of "Making Safeguarding Personal" are integral to safeguarding practices within the Health Board	<ul style="list-style-type: none"> Develop key messages to be delivered via Safeguarding Level 3 Training 	<ul style="list-style-type: none"> Develop key messages to be delivered via Safeguarding Level 3 Training 	<ul style="list-style-type: none"> Develop mechanisms for feedback from patients on their experience of safeguarding processes 	<ul style="list-style-type: none"> Undertake case file audit to determine if principles are embedded in process and provide formal feedback to clinical teams 	<ul style="list-style-type: none"> Care is planned and delivered respecting the views of the individual 	<ul style="list-style-type: none"> Evidence of person centred care in safeguarding care plans

QUALITY PRIORITY 2: Provide SAFE care – we aim to reduce harm, prevent errors, and deliver consistently safe care through increased visibility and insight from multiple sources of patient safety information

Objective	Actions for each Quarter for 2023				Delivering (so what)	Measure
	Q1	Q2	Q3	Q4		
Theatre Quality and Safety Programme	<ul style="list-style-type: none"> Scope, define and design improvement role and objectives with QPS and Division 	<ul style="list-style-type: none"> Advertise and appoint Define work programme to include: <ul style="list-style-type: none"> Reducing never events Building quality improvement capability Human Factors in Safety programme Safe Care Collaborative – Acute Workstream 	<ul style="list-style-type: none"> Progress reporting commences 		<ul style="list-style-type: none"> Dedicated time for improvement and accountability from within the Division 	<ul style="list-style-type: none"> Reduction in the number of SI's, by harm category, National Reportable Incidents and Never Events
Implement Human Factors as a HB wide approach	<ul style="list-style-type: none"> Define programme of work and scope of the simulation programme 	<ul style="list-style-type: none"> Schedule sessions and design of QI programme 	<ul style="list-style-type: none"> Training and wider team engagement Reporting the QI action plan established 	<ul style="list-style-type: none"> Publication of case studies 	<ul style="list-style-type: none"> Training and simulation programme in place with improvement programme of work 	<ul style="list-style-type: none"> Reduction in the number of SI's, by harm category, National Reportable Incidents and Never Events
To implement Datix as the main method of reporting	<ul style="list-style-type: none"> Awareness campaign to Divisions about the reporting requirements 	<ul style="list-style-type: none"> Review of reports and incidents rolling action plan in place Review of informatics requirements 	<ul style="list-style-type: none"> Implementation of informatics infrastructure as required 	<ul style="list-style-type: none"> Include learning in the Annual Learning festival 	<ul style="list-style-type: none"> The ability to report and highlight incidents to improve patient safety 	<ul style="list-style-type: none"> Reduction in the number of SI's, by harm category, National Reportable Incidents and Never Events
Reporting – redesign the reports and implement an outcome framework	<ul style="list-style-type: none"> Scope and define the outcomes and measures Align with the Assurance Governance Framework 	<ul style="list-style-type: none"> Approval at Exec and Board First report produced Realign the PQSOC reporting 	<ul style="list-style-type: none"> Refine and design the report Implement the new reporting processes 	<ul style="list-style-type: none"> Review and revise Action Plan as a result of learning from the indicators 	<ul style="list-style-type: none"> Improved oversight governance and assurance to provide learning and insight to be able to make improvements 	<ul style="list-style-type: none"> QOF Updated Board and PQSOC paper format
Review the QPS infrastructure to drive and spread improvement and learning	<ul style="list-style-type: none"> QPS resource being mapped within Divisions Working with HR to devise the OCP 	<ul style="list-style-type: none"> Draft proposal Undertake OCP for staff with HR 	<ul style="list-style-type: none"> Review structure and interdependencies with Divisions and QPS 		<ul style="list-style-type: none"> An infrastructure designed for improvement 	<ul style="list-style-type: none"> Standardised agenda for Divisions on Patients Safety, Quality and risk
To complete a Mortality Review to learn and identify improvement	<ul style="list-style-type: none"> Through morbidity and mortality reviews and findings from the Medical Examiner Mortality Reviews Mortality framework being developed 	<ul style="list-style-type: none"> Action Plan and reporting in place Validate mortality measures Work collaboratively with All Wales Mortality group and NHS Exec to define measures 	<ul style="list-style-type: none"> Devise a report for Board and Divisions on mortality data Drill into CHKS data for improvements and deteriorating data 	<ul style="list-style-type: none"> Refine mortality report and measures 	<ul style="list-style-type: none"> Identification and learning opportunities used to focus improvements 	<ul style="list-style-type: none"> RAMI Crude mortality rare
Pressure Ulcers Improvement Programme		<ul style="list-style-type: none"> Revisit and refresh the learning from the collaborative Redesign the information extracted from Datix 	<ul style="list-style-type: none"> Datix learning report established 		<ul style="list-style-type: none"> Improvement in the numbers of HA pressure ulcers and a reduction in harm. 	<ul style="list-style-type: none"> Decrease in the number of HA pressure ulcers by grade Decrease in the number of HA pressure ulcers Decrease in the severity of medicines incidents Decrease in the number of incidents under Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
Falls Improvement Programme	<ul style="list-style-type: none"> Embed the multifactorial risk assessment Falls prevention training Falls review panel in place 	<ul style="list-style-type: none"> From the Fall Review Panel, Themes identified to inform an improvement action plan Review the Community Falls action plan and revise and update improvement action plan 	<ul style="list-style-type: none"> Hold a learning and design event for Community and Inpatient falls 		<ul style="list-style-type: none"> Reduced risk and prevalence of falls Prevention of risk for those vulnerable to fall 	<ul style="list-style-type: none"> Decrease in the number of falls treated in ED which have had a previous admission – reattendance Improvement in the severity of harm following a fall in hospital Decrease in the number of Falls by 10,000 occupied IP Bed days

QUALITY PRIORITY 3: Provide TIMELY care, ensuring people have access to the high-quality advice, guidance and care they need quickly and easily, in the right place first time

Objective	Actions for each Quarter for 2023				Delivering (so what)	Indicators
	Q1	Q2	Q3	Q4		
Discharge Programme Board programme	<ul style="list-style-type: none"> • Delivery of Move it May campaign. • Visit to Swansea to view Signal IT system • Short term digital solution – design and analysis 	<ul style="list-style-type: none"> • Away Day RGH Hub • Trusted Assessor workshop • Short term digital solution – development • Prepare operational process for capturing D2RA/Red to Green • Roll out of Nurse Led Discharge 	<ul style="list-style-type: none"> • Short term digital solution – development • Continue to prepare operational process for D2RA/Red to Green • Implement Trusted Assessor model • Full role out of Optimising Patient Flow Framework 	<ul style="list-style-type: none"> • Implement Trusted Assessor model • Short term digital solution – test and run • Continue to develop and review the RGH Discharge Hub 	<ul style="list-style-type: none"> • Optimal hospital care and discharge practice at the point of admission • A Home First approach to reduce re-admission 	<ul style="list-style-type: none"> • Reduce time from surgery to discharge • Reduce Time spent on a waiting list • Reduction of handovers >1 hour • Reduction in time for patients to be seen by first clinician
Support individuals to stay at home or close to home	<ul style="list-style-type: none"> • Pilot for extended hours • Start OCP 	<ul style="list-style-type: none"> • Conclude OCP • Publish navigable pathway for ambulatory care offer • Produce strategy and action plan for Community Hospitals 	<ul style="list-style-type: none"> • Service transition to extended hours • Develop the professional hub • Changes to ambulatory care model 	<ul style="list-style-type: none"> • Continuation of existing workstreams • Commence Phase 2 	<ul style="list-style-type: none"> • To support individuals to stay at home or close to home, where this is both safe and appropriate. To support all health care professionals to engage with what is right for individuals, first time. 	<ul style="list-style-type: none"> • Reduction in time for bed allocation from request • Decrease in ED waits >12hrs • Increase in discharges before midday; • Decrease in LoS OVER 21 DAYS • Time from Flow Centre call to discharge/ admission from assessment?
Improve Ambulance handovers	<ul style="list-style-type: none"> • Review Q4 APP pilot and whether permanent roll out beneficial or justifiable • Implement outcome of PRU winter service activity • Complete recruitment process and on-board remaining therapy practitioners, OT and Physio • Identify and recruit Care of the elderly (COTE) locum for duration of the pilot 	<ul style="list-style-type: none"> • System wide engagement on risk stratification and subsequent effect of regular patient flow from ED utilizing eLGH and community sites • Recruitment of locum resilience to enable Frailty assessment • Feasibility assessment of GP resilience to eLGH and GUH front door, possibly utilizing SDEC space 	<ul style="list-style-type: none"> • Procure e-Triage solution and focus on the long lead time aspect (relating to technical integration with Welsh Patient Administration System (WPAS)) • Agree mechanism to be used (i.e. CWS watchlist) and risk management approach for a pilot of a new ED referral process 	<ul style="list-style-type: none"> • Utilize lessons learned from Same Day Emergency Care (SDEC), Integrated Assessment Centre (IAC) and early e-Triage experience to shape new ways of working • Continuous Data and PREM Review 	<ul style="list-style-type: none"> • Maximising and individuals time and outcomes and improving system safety 	<ul style="list-style-type: none"> • Number of emergency admissions in hospital over 7 days • Decrease in the time from request to step up/down to a different site • Decrease Overnight bed moves and patient transfers
Improved Cancer outcomes	<ul style="list-style-type: none"> • Programme priorities agreed • Programme structure agreed 	<ul style="list-style-type: none"> • Prehabilitation Business Case • Establishment of NHH working groups 	<ul style="list-style-type: none"> • WG approval of NHH Cancer Centre • Patient Group initiated 	<ul style="list-style-type: none"> • Acute Oncology Regional model rolled out • ABUHB Cancer 'Blueprint' agreed 	<ul style="list-style-type: none"> • Maximising cancer outcomes 	<ul style="list-style-type: none"> • Increased compliance of the number of patients starting their first definitive cancer treatment within 62 days from point of suspicion • Increase in 5 year cancer survival rates
Timely completion of Duty to Report	<ul style="list-style-type: none"> • Meet with Local Authorities to understand the prevalence of delayed referrals 	<ul style="list-style-type: none"> • Work with clinical teams to understand the barriers to timely referral 	<ul style="list-style-type: none"> • Review of pathways for referral with Safeguarding committee and Partnership Boards 	<ul style="list-style-type: none"> • Update clinical teams with changes to referral process to strengthen practice 	<ul style="list-style-type: none"> • Referrals will be made via the appropriate route in a timely way, to ensure appropriate and suitable responses 	<ul style="list-style-type: none"> • Reduction in complaints from local authorities in regard of delay in reporting

QUALITY PRIORITY 4: Provide EFFECTIVE care – Deliver consistently effective and reliable care, based on evidence-based best practice which is delivered in a culture that encourages and enables innovation to Improve outcome

Objective	Actions for each Quarter for 2023				Delivering (So what)	Indicators
	Q1	Q2	Q3	Q4		
Increased Get It Right First Time (GIRFT) implementation by area		<ul style="list-style-type: none"> Establish a reporting mechanism with Ops to track the progress and implementation 			<ul style="list-style-type: none"> Clear programme by specialty designed to improve the treatment and care of patients 	<ul style="list-style-type: none"> Increased Get It Right First Time (GIRFT) implementation actions by area Number of INNUS's being completed
Implement robust Audit processes and plans	<ul style="list-style-type: none"> Develop action plan and agreed forward work plan for audit Implement AMAT as a reporting and analysis tool 	<ul style="list-style-type: none"> Compliance with the audit plan 	<ul style="list-style-type: none"> Compliance with the audit plan 	<ul style="list-style-type: none"> Compliance with the audit plan 	<ul style="list-style-type: none"> Reduced variation in Care Increased understanding of variation to focus Improvements 	<ul style="list-style-type: none"> Increase in the SMART action plans with accountability in National Clinical Audit Increase in the numbers of wards participating in accreditation (Audits via AMaT) Increase in the actionable audit recommendations by National Clinical Audits
Implement Duty of Candor reporting	<ul style="list-style-type: none"> Awareness campaign to Divisions about the reporting requirements 	<ul style="list-style-type: none"> Review the DoC reports and effectiveness of the process 	<ul style="list-style-type: none"> Compliance with DoC audit requirements 	<ul style="list-style-type: none"> Compliance with DoC audit requirements 	<ul style="list-style-type: none"> Increased understanding of variation to focus Improvements 	<ul style="list-style-type: none"> Implement Duty of Candour reporting Compliance the number of incidents triggering Duty of Candour within 5 days
Ward accreditation	<ul style="list-style-type: none"> Test the ward accreditation programme 	<ul style="list-style-type: none"> Increase in the numbers of wards participating in accreditation 	<ul style="list-style-type: none"> Reporting against the implementation of the accreditation 	<ul style="list-style-type: none"> Roll out to clinical areas 	<ul style="list-style-type: none"> Reduced variation in Care Increased understanding of variation to focus Improvements 	<ul style="list-style-type: none"> Audit report available via AMaT to include quality measures and organisational measures
Safe Care Collaborative (also Safe Care)	<ul style="list-style-type: none"> Driver diagrams completed for teams Leadership work plan agreed Training programme agreed 	<ul style="list-style-type: none"> Charter complete Attend action calls and learning session Monthly reporting Measurement of progress Project score 	<ul style="list-style-type: none"> Leaders for Safety Improvement starting training programme Safety Coaches starting coaching training 		<ul style="list-style-type: none"> Reduced variation in Care Increased understanding of variation to focus Improvements 	
Implement a Quality Training Programme to drive and spread improvement	<ul style="list-style-type: none"> Define and share the programmes available. 	<ul style="list-style-type: none"> Safety Coaches starting coaching training 	<ul style="list-style-type: none"> Implement a Quality Training Programme to drive and spread improvement Leaders for Safety Improvement starting training programme 	<ul style="list-style-type: none"> Define and share the programmes available. 	<ul style="list-style-type: none"> Leadership and skills at all levels and part of what we do to embed our QMS and culture of continuous improvement 	<ul style="list-style-type: none"> Implement a Quality Training Programme to drive and spread improvement
Medicine Management	<ul style="list-style-type: none"> Validate incidents via Datix Implement medicines safety strategy 	<ul style="list-style-type: none"> Track progress with medicines safety strategy 	<ul style="list-style-type: none"> Track progress with medicines safety strategy 	<ul style="list-style-type: none"> Track progress with medicines safety strategy 	<ul style="list-style-type: none"> Reporting and action plan via Medicines Safety Group 	<ul style="list-style-type: none"> Delivery of objectives set medicines safety strategy

QUALITY PRIORITY 5: Provide care that is **EFFICIENT** by taking a value-based approach to improve outcomes that matter most to people in a way that is as sustainable as possible and avoids waste

Objective	Actions for each Quarter for 2023				Delivering (so what)	Measure
	Q1	Q2	Q3	Q4		
Datix infrastructure	<ul style="list-style-type: none"> Review resources and infrastructure for Datix management and reporting 	<ul style="list-style-type: none"> Establish reporting processes Datix awareness and use training 	<ul style="list-style-type: none"> Datix awareness and use training 	<ul style="list-style-type: none"> Datix awareness and use training 	<ul style="list-style-type: none"> Patient experiences are visible and acted on 	<ul style="list-style-type: none"> Qualitative feedback use of the learning section in Datix Increase in the number of actions plans completed
Falls (also an Objective under Safe)	<ul style="list-style-type: none"> Embed the multifactorial risk assessment Falls prevention training Falls review panel in place 	<ul style="list-style-type: none"> From the Fall Review Pannel, Themes identified to inform an improvement action plan Review the Community Falls action plan and revise and update improvement action plan 	<ul style="list-style-type: none"> Hold a learning and design event for Community and Inpatient falls 		<ul style="list-style-type: none"> Reduced risk and prevalence of falls Prevention of risk for those vulnerable to fall 	<ul style="list-style-type: none"> Decrease in the number of falls treated in ED which have had a previous admission – reattendance Improvement in the severity of harm following a fall in hospital Decrease in the number of Falls by 10,000 occupied IP Bed days
Maximising capacity and resources in outpatients	<ul style="list-style-type: none"> As part of the Outpatient Transformation programme, improvement programme targeting DNA's commences 23/24 actions 	<ul style="list-style-type: none"> Continue Implementation of Did not attend (DNA) action Plan. 5% target. Plan also linked in with Cancer Services DNA improvement plans 	<ul style="list-style-type: none"> Continue Implementation of Did not attend (DNA) action Plan. 5% target. Plan also linked in with Cancer Services DNA improvement plans 	<ul style="list-style-type: none"> Review sustained DNA improvements and success of the interventions 	<ul style="list-style-type: none"> Improved utilisation of capacity reducing waste and access to care 	<ul style="list-style-type: none"> Decrease in the DNA's and CNA'S

QUALITY PRIORITY 6: Provide EQUITABLE care, ensuring equal opportunities for individuals to attain their full potential for a healthy life which does not vary in quality and is non-discriminatory.

Objective	Actions for each Quarter for 2023				Delivering (so what)	Measure
	Q1	Q2	Q3	Q4		
Improve care at the end of life	<ul style="list-style-type: none"> Completion of the mortality review 	<ul style="list-style-type: none"> Learning and theme action plan agreed Meet compliance of issuing of Medical Certificates within 5 days 	<ul style="list-style-type: none"> Meet compliance of issuing of Medical Certificates within 5 days 	<ul style="list-style-type: none"> Meet compliance of issuing of Medical Certificates within 5 days 	<ul style="list-style-type: none"> Improving quality at the end of life for people and families 	<ul style="list-style-type: none"> Decrease in the % of hospital as a place of death Increase in compliance of issuing of Medical Certificates within 5 days
Safeguarding resources and processes	<ul style="list-style-type: none"> Review of resources and processes for reporting, staff and patients Review of training available to different staff groups within the Health Board 	<ul style="list-style-type: none"> Actions from reviews communicated and action plan development with Operations, Workforce and OD and leadership teams Develop and mandate safeguarding training in line with All Wales Guidance. Develop a model of safeguarding supervision for Adult Safeguarding 	<ul style="list-style-type: none"> Delivery of Safeguarding Training Role out of Safeguarding Supervision in targeted teams 	<ul style="list-style-type: none"> Formal evaluation of Safeguarding Training continued delivery Evaluation of safeguarding supervision Roll out of additional safeguarding supervision Continued delivery of Safeguarding Training 	<ul style="list-style-type: none"> Improving quality of life and equitable access Timely response to concerns People and staff able to raise concerns to prevent as well as address Staff will better understand their role and duty in the safeguarding of children and adults. Staff will feel supported to support and manage the care of patients who require safeguarding 	<ul style="list-style-type: none"> Increase in the access to Safeguarding Training Timely closure of Safeguarding incidents Appropriate responses irrespective of where the patient presents
Violence and aggression incidents	<ul style="list-style-type: none"> Review and analyse V&A incidents Return to face-to-face Management of Violence & Aggression training 	<ul style="list-style-type: none"> Review and update the ABUHB Violence & Aggression Policy and develop supporting procedures & protocols, including the internal sanctions procedure 	<ul style="list-style-type: none"> Launch Violence & Aggression campaign across the Health Board 	<ul style="list-style-type: none"> Conduct staff survey relating to violence and aggression incidents Continued delivery of Management of Violence & Aggression Training 	<ul style="list-style-type: none"> Improving staff experience 	<ul style="list-style-type: none"> Decrease in the incidents of violence and aggression towards staff

Next Steps

- Establish limitations with reporting of the data and quality limitations.
- Increase validity of the data.
- Develop PQSOC work planner for when reports will be presented to PQSOC.
- Devise timeline will be produced for when reports will need to be submitted to the Committee and details of what reports are expected from each of the Groups.
- Reports that are not part of the quality operating framework will be on a rolling agenda from the Groups to provide narrative of outputs and delivery.

Progress on our 2023/24 priorities

As part of the implementation plan for the Quality Strategy the Health Board set a number of objectives aligned to the Health and Care Quality Standards. These were aligned to each of the domains of quality. There were a number of actions set throughout the first year as SMART objectives achieved by each quarter.

The implementation plan can be found here, and shows our commitments to the Health and Care Quality Standards. This report presents some of the highlights of the operational work programmes that have been delivered throughout 2023.24.

Our PERSON-CENTRED Commitments

To ensure that our patients, their families, and carers receive an experience that not only meets but exceeds their expectations. To improve patient experience in our hospitals and wherever they access healthcare. To increase patient, public and staff involvement.

Launch a system to capture Patient Experience across the Health Board

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- The Health Board has written and implemented a Patient Experience and Involvement Strategy.
- Aneurin Bevan University Health Board launched the CIVICA Citizen Experience platform in February 2023 to capture patient feedback via QR codes.
- Feedback is anonymous, allowing analysis down to the ward/team/department level.
- A Person-Centered Care Survey was introduced to support quality strategies, providing benchmarks for patient care.
- Feedback is reported to the Quality and Patient Safety Operational Group quarterly.
- A Patient Advice and Liaison Service (PALS) was introduced in November 2023, with data reported to the same group.

To respond and learn from complaints

In 2023/24, the Health Board made significant strides in managing patient concerns, receiving 1,596 formal complaints and resolving an additional 1,555 through early resolution. Efforts are ongoing to meet the Welsh

Government's target of 75% compliance with 30-day response timeframes, while ensuring the quality of investigations and responses.

Key initiatives included:

- **Review and Engagement:** Active participation in the review of the Putting Things Right (PTR) Regulations, currently under public consultation, to ensure preparedness for any new guidelines.
- **Patient-Centered Approach:** Full implementation of the Patient Advice & Liaison Service (PALS) in November 2023, which focuses on early resolution of concerns through a single point of contact.
- **Planned Enhancements:** Introduction of an "Acknowledgement Team" to ensure timely, meaningful engagement with those raising concerns, and the development of Communication Standards to maintain consistency across concerns teams.
- **Process Improvement:** Weekly assurance meetings to address investigation bottlenecks and improve compliance with PTR regulations.

The Health Board continues to work closely with external partners and remains committed to learning and improvement. Common complaint themes in 2023/24 included clinical treatment, assessment issues, appointment delays, and communication problems, particularly in relation to waiting times—a lingering effect of the COVID-19 pandemic.

Our SAFE Commitments

Provide Safe care - Reduce harm, prevent errors, and deliver consistently safe care through increased visibility and insight from multiple sources of patient safety information.

To implement Datix as the main method of reporting

The Incident Reporting module of Datix Cymru was implemented within the Health Board in December 2021. Using Datix as the main method of reporting has highlighted the need for better incident management, the need for increased resources, and improved processes. This will ensure comprehensive closure and follow-up on reported incidents, ultimately aiming to enhance patient and staff safety.

From December 2021 to 31 March 2024, 70,645 incidents were reported, with 95.75% of them closed.

- **Incidents:**
 - 76.6% of these incidents were reported as No or Low Harm.
 - 2,905 incidents remain open as of March 2024.
 - 72% of these open incidents are coded as No or Low Harm.

- 71.3% are classified as patient safety incidents, with the top three types being pressure damage, slip/trip/fall, and medication-related incidents.
- 383 incidents affecting staff remain open.
- **Datix Team Resources:**
 - Aneurin Bevan UHB's Datix Team is significantly under-resourced compared to other NHS Wales organizations.
 - The Health Board's current team consists of 0.8 WTE compared to the NHS Wales average resource is 3.9 WTE.
 - A business case is being developed to increase resources for the Datix Team.
- **Recommendations ending 2023/24**
 - Review of 4,144 closed incidents with no conclusion data.
 - Rapid review of 1,157 open incidents without a 'Managers Interim Harm Assessment'.
 - Develop plans to close the 2,905 open incidents.
 - Implement sustainable incident management processes.
 - Progress a business case to enhance Datix Team resources through the Pre-Investment Panel (PIP).

Reporting – redesign the reports and implement an outcome framework

The Health and Care Quality Standards guide healthcare planning, delivery, and monitoring. Over the past year, Aneurin Bevan University Health Board developed a Quality Outcomes Framework (QOF), aligned with the quality domains and enablers. This framework establishes indicators for care, outcomes, safety, patient experience, and efficiency, aiming for continuous improvement. Key objectives include identifying improvement areas, standardising practices, enhancing patient satisfaction, and ensuring regulatory compliance.

The QOF has been key to the development of our approach to a 'Quality Management System'. It fosters a culture of learning, accountability, and transparency, setting and monitoring performance targets to maintain high care standards. The framework integrates patient experiences and data to provide comprehensive quality insights, promoting a person-centered approach and collaborative service development. This has been continually refined throughout our first year. The end of year report can be found [here](#).

Review the QPS infrastructure to drive and spread improvement and learning

In 2024, the Health Board achieved significant milestones in enhancing quality, patient safety, and shared learning:

- **Centralisation of Teams:** The Quality Patient Safety (QPS), Putting Things Right (PTR), and Quality Improvement (QI) teams were centralised, leading to improved knowledge retention, consistency, and effective triangulation of complaints and incident processes. This centralisation supports a culture of shared learning and person-centred care.
- **Team Building and Workplan Alignment:** The QPS leads embarked on a Team Building Programme to enhance team performance. A QPS workplan was also developed, aligned with the Health Board's Quality Strategy and Priorities, ensuring focused delivery on key objectives.
- **Training and Education Initiatives:** A comprehensive suite of training specific to complaints and incident investigation is being developed. Collaborations with Welsh Risk Pool colleagues and the Public Services Ombudsman for Wales (PSOW) are underway to create accessible video training and bespoke patient safety incident training.
- **Patient Engagement and Involvement:** Progress continues on the Patient Engagement and Involvement Strategy, with ongoing efforts in patient participation panels and evaluations of the Patient Advice & Liaison Service (PALS) and bereavement services.
- **Process Improvement:** The Patient Safety Incident team is refining incident management processes to ensure timely, high-quality, and person-centred responses. The Health Board is also developing a Quality Management System and refining its Quality Outcomes Framework in collaboration with data and digital teams to support continuous, automated reporting.
- **Quality and Accountability Frameworks:** Collaborative efforts with divisional and central teams are focused on developing a QPS Accountability Framework and a Commissioning Assurance Framework (CAF).

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These initiatives reflect the Health Board's commitment to enhancing quality, safety, and patient experience across all services.

Pressure Ulcers Improvement Programme

The Health Board reported increased numbers of unstageable and grade 3&4 Health Acquired Pressure Ulcers (HAPU's). Divisions report data via the HAPU Steering Group and the Quality and Patient Safety Operational Group.

Pressure Ulcer Faculty 2023 launched, led by Nursing Directorate and Senior Nurses with ABCi support, with a focus on reducing HAPUs to meet Welsh Government's 0% avoidable HAPU standard.

Faculty Aim:

- Reduce HAPU incidences by 25% within 4 months.
- Eradicate grade 3 & 4 avoidable HAPUs within 4 months.

Progress and Actions 2023/24:

- Noted downward trend from January to April 2024.
- Develop pre-recorded PowerPoint for teaching.
- Use PANDO app for timely wound review and treatment.
- Implement PDSA cycles for testing changes across all sites.
- Share resources via SharePoint and developed posters across divisions.
- Updated driver diagram.
- Commenced Pressure Ulcer Pilot in February 2024.
- Evaluate collected data at April meeting for signs of improvement.

Falls Improvement Programme

Key Achievements:

- **Data Improvement:** Enhanced availability and analysis of falls data across the Health Board have informed key quality improvement initiatives, leading to better monitoring and reduction of falls.
- **SWARM Methodology Implementation:** Rolled out in April 2023 within the Medicine Division, this multi-disciplinary team (MDT) approach is being expanded across the wards.
- **Digital Integration:** Successful rollout of the Welsh Nursing Care Record Multi-Factorial Risk Assessment (MFRA) to wards, with completion anticipated in October 2024. Additionally, a modified MFRA has been developed for use in Emergency Departments.
- **National Contributions:** Contributed to the development of the Falls National Head Injuries pathway and the National Inpatient Falls Network's work on sensor use, setting a national standard.
- **Ward Accreditation:** Falls prevention and management have been incorporated into the ward accreditation initiative, further embedding these practices into daily routines.

- **Falls Awareness:** A highly successful Falls Awareness Week in 2023 saw significant patient and staff engagement across the Health Board.
- **RIDDOR Compliance:** Established a Standard Operating Procedure (SOP) and developed a compliance dashboard within the Datix system to improve reporting and monitoring.
- **Training:** Continued delivery of falls prevention and management training, adapted for the digital format of the Welsh Nursing Care Record.

Key Challenges:

- **Consistency in Practice:** Ensuring consistent application of the SWARM methodology and MFRA across all wards and specialties remains a challenge.
- **Data Utilization:** While data availability has improved, fully leveraging this data to drive sustained reductions in fall rates and severity of harm requires ongoing effort.
- **Staff Engagement:** Maintaining high levels of staff engagement in falls prevention initiatives, especially in the face of evolving clinical environments and pressures, is a continuing challenge.
- **Technological Integration:** The successful digital integration of falls management tools like MFRA needs continuous support to ensure all staff are proficient and the tools are used effectively.
- **Resource Allocation:** Ensuring that adequate resources, including appropriate flat lifting equipment and trained personnel, are available across all units to effectively manage falls.
- **RIDDOR Reporting:** Despite progress, achieving full compliance with RIDDOR reporting protocols across the Health Board requires ongoing monitoring and training efforts.

These achievements and challenges reflect the Health Board's commitment to reducing falls and improving patient safety across its facilities. The next steps focus on building upon these successes through enhanced training, data utilization, and multi-disciplinary collaboration.

Our TIMELY Commitments

People have timely access to care when they need it. Reducing waits and sometimes harmful delays for both those who receive and those who give care.

Discharge Programme Board Programme

The Discharge Programme Board has taken significant strides to improve patient discharge processes, focusing on enabling individuals to stay at home or close to home. Key achievements include:

- **Training and Protocols:** Refreshed Optimising Hospital Flow Framework training and a ratified Nurse-Led Discharge protocol are being implemented.
- **Initiatives:** The "Move it May" campaign was successfully delivered, with ongoing work to support hospital flow.
- **Team Development:** The Hospital to Home (H2H) team is fully operational in Monmouthshire and Newport, with the programme now under evaluation.
- **Facility Upgrades:** The RGH Discharge Lounge is complete and operational, and NHH Discharge Lounge is running under a new pull model. Planning for a new GUH Discharge Lounge is underway.
- **Digital Solutions:** The CWS2 (D2RA) digital solution was piloted across three wards, with wider rollout expected post-resolution of technical issues.
- **Strategic Workshops:** Future Flow Design workshops identified key areas for improvement in bed allocation and workforce models.

The upcoming plan for 2024/25 emphasizes:

- **H2H Program Expansion:** Building on the 2023 pilot, this initiative aims to reduce acute care stays by transitioning patients to home care more efficiently, with an average pathway duration of 26 days.
- **System Reconfiguration:** Focus on optimizing care delivery at St. Woolos Hospital and improving timely discharge through Patient Safety Team events and bed plan implementation.
- **Performance Goals:** Reducing Delayed Transfers of Care (DTOCs), improving ambulance handover times, and speeding up ED clinician assessments.

These initiatives are aligned with the goal of enhancing patient flow, reducing hospital stays, and improving overall care quality.

Support individuals to stay at home or close to home

Further work throughout 2023/24 has ensured the Health Board aimed to provide proactive support, enhance community-based care, and ensure individuals can stay well at home or close to home. These include:

- **Community Resource Teams (CRTs):** CRTs work across health and social care to support individuals in their homes. The development and expansion of CRTs will be a key focus, aiming to provide greater service consistency and equity across boroughs. This includes additional support for Acute Front Door services to identify and treat those at risk of avoidable admission, thus ensuring seamless care and avoiding duplication.
- **Dementia Support:** this includes Memory Assessment Services: Strengthening these services with additional consultant capacity, advanced nurse practitioners, audiology, and memory rehabilitation to ensure early recognition and holistic support for individuals with dementia.
- **Frailty Programme:** The report highlights the transformation of services for older adults through the Frailty Programme. This includes proactive recognition of individuals at or near crisis and the development of Acute Frailty Response services to increase Healthy Days at Home
- **Neighbourhood Care Networks (NCNs):** These networks support the coordination of health and care services within specific geographic areas. They focus on delivering a wider range of services closer to home, improving equity of service provision, and supporting sustainable services and workforce.

Improve Ambulance handovers

Progress has been made in reducing ambulance handover delays at the Emergency Department (ED). Previously, around 860 patients per month faced delays over 60 minutes. However, through focused efforts, these delays have significantly decreased from 1,497 cases reported in March 2023.

Key Initiatives:

- **APP Role Review:** The Q4 APP pilot at GUH did not significantly reduce patient conveyance to the ED. The clinician grade in the Flow Centre will continue to be monitored as options are considered for various access points into Health Board services (e.g., Flow Centre, GP OOH, Frailty, SPA).

- **Frailty Pathway:** A trial with a Frailty Consultant in the Flow Centre has been undertaken, and will end in 13 June 2024, and its impact on the frailty pathway is under ongoing evaluation within the Six Goals E&U Programme.
- **Falls Pathway:** A revised falls pathway, implemented on 23 December 2023, has better distributed activity across eLGH sites for patients not meeting GUH falls criteria.
- **PRU Activity Review:** A cost-benefit analysis (CBA) of PRU activities has been conducted and is awaiting review at a future Executive meeting. WAST will continue PRU support as agreed until 30 September 2024.

These improvements highlight the ongoing efforts to optimise patient care and service efficiency within the Health Board.

Improved Cancer outcomes

From 2019/20 to 2023/24, there was a 34% increase in suspected cancer referrals, impacting diagnostic capacity. Despite increased referrals, the cancer conversion rate has not significantly increased, indicating a consistent identification rate despite higher scrutiny. The backlog of patients waiting over 62 days has been consistently high, although there was a slight reduction in percentage terms from 2019/20 to 2023/24. The overall goal is to enhance patient outcomes through more efficient pathways, better patient preparation and support, and targeted training and community engagement initiatives.

Quality Initiatives for 2023/24 included:

- **Getting Ready for Treatment Initiative:** Focuses on preparing patients for treatment through early engagement and resources, improving patient understanding and emotional readiness.
- **Cancer Cafes:** Provide emotional support through peer interaction, showing positive feedback and participation from patients and carers.
- **Community Cancer Champions:** Training for skin cancer awareness targeted at hairdressers, beauticians, and nursery schools, with high engagement from the sector.
- **Improvement Initiatives:** Various initiatives are being undertaken to improve planned care pathways, which likely include cancer treatment pathways. These efforts include deep dives into key specialties and an all-Wales workshop to share best practices
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- **Workshops and Planning:** Teams have attended workshops to identify high-impact opportunities for improving planned care, which includes cancer care. This involves assessing current demand, capacity plans, and addressing gaps in both backlog and underlying capacity.

There is a structured timeline to finalise plans and trajectories, including feedback and testing with board members, aimed at enhancing the efficiency and effectiveness of care delivery, potentially improving cancer outcomes.

Timely completion of Duty to Report

An upcoming audit aims to assess the timeliness of duty to report entries within the Wales Safeguarding procedures. Although most reports are submitted within the expected timeframe, concerns have been raised by partners about delays in some cases. The audit will focus on determining how widespread these delays are and understanding the reasons behind them.

The introduction of the national Safeguarding Datix Module will be a key tool in this effort, as it will enable the tracking of the time elapsed between incidents and the submission of reports. This data should help identify specific areas where delays are occurring, allowing for a more focused improvement plan to address the issues and enhance the overall safeguarding process.

Our EFFECTIVE Commitments

To deliver care that is effective, reliable, and based upon the best evidence available. To increase the proportion of patients who receive evidence-based care. To reduce variations in the quality of care. To identify and implement evidence-based best practice guidance. Deliver consistently effective and reliable care.

The following objectives have been added to the main body of the quality report:

- **Implement robust Audit processes and plans**
- **Safe Care Collaborative**
- **Implement Duty of Candour reporting**

The Duty of Candour was implemented on 1 April 2023 under the Health and Social Care (Quality and Engagement) (Wales) Act 2020. This mandate requires all NHS bodies to report, manage, and investigate notifiable adverse patient safety events openly and promptly. It applies when a

patient experiences, or could experience, more than minimal harm during NHS-funded care, with healthcare provision potentially being a factor.

Key Actions and Progress:

- **Training:** All staff have access to Duty of Candour training via the Health Board's electronic platform, with active encouragement to complete it.
- **Team Centralisation:** The Quality, Patient Safety (QPS) teams were centralised in February 2024, with identified Duty of Candour leads working to embed the Act's requirements and ensure consistent training.
- **Reporting Tool:** A Duty of Candour reporting tool is now integrated within the incident and complaint system for continuous monitoring and validation.

Ongoing Challenges and Next Steps:

- **Harm Categorisation:** Initial challenges were faced in distinguishing between actual and healthcare-related harm in lower harm incidents. Ongoing education and support are improving understanding across the Health Board.
- **Future Focus:** In 2024/25, efforts will focus on encouraging staff to complete training, running further sessions, using incident reports to identify improvement areas, and fostering a culture of continuous learning. Quarterly data will be reviewed in QPS meetings, and learning will be discussed at the Patient Quality and Safety Learning and Improvement Forum.

- **Ward accreditation**

The Health Board has launched an accreditation pathway for all wards and teams, utilising the digital system (AMaT) to capture audit data and provide ward-to-board assurance. This system promotes continuous improvement in safety and patient experience through monthly audits. A dashboard allows for easy viewing and sharing of results with the public, staff, and patients.

Key Achievements:

- **Phased Rollout:** Successfully piloted at Ysbyty Aneurin Bevan, with Phase 1 implemented across various wards and Phase 2 and 3 planned.

- **Structured Improvement:** System supports continuous improvement, using audits based on six quality domains and five quality enablers.
- **Real-Time Data:** Utilised AMaT platform for real-time audit results, with accreditation levels (Bronze, Silver, Gold, Platinum) based on 85% compliance.
- **Independent Validation:** Accreditation compliance independently reviewed and validated.

Performance and Metrics:

- **Evidence-Based:** Teams present evidence covering performance indicators, workforce metrics, clinical incidents, complaints, and feedback.
- **Visibility:** Accreditation journey and audit results are displayed on Patient Safety Boards.

Challenges:

- **Audit Proforma Development:** Time-consuming process with monthly updates causing delays.
- **Staff Support:** Need for more support in completing action plans in AMaT.
- **Scheduling Conflicts:** Work pressures impacting meeting schedules.

Goals for 2024/25:

- **Metrics and Standards:** Establish meaningful, evidence-based metrics, balancing quantitative data with patient experiences.
- **Staff Engagement:** Empower staff to lead improvements, overcoming resistance, and managing work constraints.
- **Sustaining Improvements:** Maintain momentum with ongoing support, training, and real-time data monitoring.
- **Operational Needs:** Recruitment of a Business/Data Analyst to enhance digital platform support and data analysis

Implement a Quality Training Programme to drive and spread improvement

ABCi Quality Improvement Skills Development Programme

Objective: Empower staff with the skills, time, and resources necessary for quality improvement.

Key Activities:

- **PocEd Measurement Course:** Trains staff to use data for tracking improvement progress.
- **Basic QI Training:** Over 230 staff trained in quality improvement principles.

- **Quality Coach Development:** 17 QI coaches trained to support local continuous improvement.
- **Spread and Scale Initiative:** Plans to train additional QI coaches over the next four years.
- **Online Resources:** Development of tools like ABCi Charts and Problems to Solutions to support quality improvement efforts.

Challenges and Areas for Improvement:

- **Team Participation:** Three teams withdrew from the Safe Care Collaborative due to service pressures.
- **LifeQI Implementation:** The adoption of the LifeQI system for recording quality improvement has been slower than anticipated.

2024/25 Challenges:

- **Staff Time:** Ongoing challenges with staff availability for quality improvement work.
- **Embedding Practices:** Difficulty in integrating quality improvement into daily clinical and management routines.
- **Quality Management System:** Need to build a system that balances quality improvement with quality control and planning.
- **Financial Constraints:** Budget limitations affecting the scope of quality improvement efforts.

Medicine Management

Key Achievements 2023/24

Exception Reports: This was part of the Medication Safety Group (MSG) Initiatives: Implemented Exception Reports for Divisions to review medication safety incidents, identify trends, and share lessons learned. A collaborative culture was promoted and recognised successful initiatives, with MSG determining further actions like policy changes or education.

Time Critical Medication: A benchmarking exercise was progressed on all ten patient safety recommendations for Parkinson's disease time-critical medication. There was a campaign commitment with continued focus on improving timely administration and education. Training and Awareness was undertaken, included released "Time matters: It's critical" training video and service user posters to emphasize timely medication.

Thematic Reviews: Insulin Safety was a priority and included collaboration with the Diabetic Inpatient Care and Education (DICE) team for a thematic review, issued an Insulin Safety Bulletin, and promoted Insulin Safety Week. As part of anticoagulation safety, the Health Board conducted a thematic review for oral anticoagulant safety. This included updating policies, provided training, and enhanced patient counselling by upskilling pharmacy technicians.

Gabapentinoid Safety: An audit provided insights when conducted an audit on high prescribing practices, leading to ongoing targeted support. Resource development focused on creating a Gabapentinoid Prescribing Resource Pack and offered training sessions in collaboration with the Chronic Pain Group.

Yellow Card (YC) Scheme: There was improved reporting, by forming a cross-sector group, increasing Yellow Card reporting from Secondary Care. Improved reporting accessibility via QR codes and provided targeted training. Collaboration included working with YCC Wales to align national campaigns and celebrate milestones.

Medication Safety Week: A full programme for the week allowed awareness of this week and achieved high engagement during #MedSafetyWeek, focusing on opioid use, yellow card reporting, emergency medication, safe storage, and oxygen safety. An increased visibility of best practices was established as new Medication Safety Boards across wards were used to highlight best practices.

Key achievements for 2023/24:

Our EFFICIENT Commitments

Obtaining the greatest health benefit for our population from the right interventions using the available resources.

Highlights from the following objectives have already been discussed in the report:

- **Datix infrastructure**
- **Falls (also an Objective under Safe)**

Our EQUITABLE Commitments

Providing care that does not vary in quality because of personal characteristics, such as gender, ethnicity, geographic location and socio-economic status.

What we did...

- **Safeguarding resources and processes**

The Health Board is actively working on improving safeguarding training compliance and is effectively identifying and responding to safeguarding issues within the community. However, there are challenges related to staff availability for training and recording compliance in certain areas. Key points for 2023/24:

1. Training Requirements and Compliance Levels:

- There is a national requirement for health board staff to undergo safeguarding training suitable for their roles.
- Current compliance levels for five out of seven training areas are documented. ESR does not yet record compliance for Level 3 Child or Adult Safeguarding, and efforts are underway to address this.
- There is a slow uptake in Level 3 face-to-face training due to staff availability, and some improvement is needed for Level 1 Safeguarding Adults and Ask and Act training to reach the 85% target.
- This compliance issue has been escalated to Divisional Leadership Teams via the Safeguarding Committee.

2. Safeguarding Activity Data:

- The data on safeguarding activities should be interpreted with caution when used as a quality improvement marker.
- For 2023/24, a substantial number of safeguarding referrals were made or addressed by the ABUHB Safeguarding Team.
- The volume of referrals is influenced by external factors beyond control, indicating potential increased harm, but also reflects the workforce's effectiveness in recognizing neglect and abuse.

• Violence and aggression incidents

This summary highlights the Health Board's commitment to addressing violence and aggression through multi-agency collaboration, data-driven strategies, and proactive policy development and implementation.

Multi-Agency Risk Assessment Conference (MARAC)

- **Purpose:** MARACs are meetings where information is shared on high-risk domestic abuse cases among various local agencies.
- **Participation:** In Q4 2023/24, the Corporate Safeguarding Team attended 33 MARACs.
- **Impact:** Contributed to safety plans for 432 domestic abuse survivors.
- **Trend:** 87% increase in individuals discussed in MARAC.
- **Future Focus:** Sustainability of MARAC, led by Gwent MARAC Steering Group and Gwent VAWDASV work.

Sexual Safety

- **Context:** National report by Women's Rights Network on sexual assaults in hospital settings.
- **Incidents:** 48 incidents reported from 1 August 2023 to 31 January 2024.
 - **Nature:** Mostly inappropriate behaviour by patients towards staff, followed by patient-on-patient incidents, and two allegations against staff.
 - **Severity:** No incidents resulted in physical harm or met the national definition of serious sexual assault.
- **Current Efforts:**
 - Developing a Chaperone Policy.
 - Refreshing referral pathway to the Sexual Abuse Referral Centre (SARC).
 - Creating an overarching sexual safety policy covering risk assessment, incident recording, and escalation.

Serious Violence

- **Legislation:** The Serious Violence Duty 2022 mandates Health Boards to engage in regional strategy development for tackling serious violence.
- **Data Contribution:** ABUHB provides a dataset to the Office of the Police and Crime Commissioner (OPCC) for strategic needs assessment and strategy development.
- **Funding and Initiatives:**
 - Funding for 2023/24 allocated to violence reduction in urgent care areas.
 - Hiring a Violence Reduction Worker to engage in emergency areas and minor injury units.
 - Focus on staff training, data collection improvement, and early intervention for individuals at risk of serious violence or organized crime/exploitation.

QUALITY ENABLERS

As part of the Health and Care Quality Standards here are some highlights of the work undertaken on the Quality Enablers in 2023/24.

Throughout 2023/24, the Health Board has made collective efforts to enhance leadership capabilities, optimise workforce management, and foster a positive organisational culture that supports staff wellbeing and engagement through the People's Plan.

Leadership

The Health Board has made a commitment to Person-Centred Care: Emphasising that patients and families are equal partners in healthcare planning, development, and monitoring. There has been a Quality and Safety Pledge: Promoting a culture of openness, transparency, and continuous improvement, with staff encouraged to raise concerns and engage in quality improvement initiatives. Other progress in 2023/24 includes:

- **Leadership Development Programs:**
 - The Clinical Directors (CDx) and Directorate Managers (DMx) training programs continue to support leadership development, emphasizing collaborative, inclusive, and compassionate leadership skills. Over 300 colleagues have participated in bespoke leadership development programs tailored to their challenges.
 - The Leading People Programme, now in its eighth cohort, has shown positive impacts on leadership confidence, self-awareness, and the ability to foster psychologically safe and compassionate cultures.
- **Raising Concerns and Speaking Up:**
 - The NHS Wales Speaking Up Safely Framework's self-assessment and action plan have been implemented, with initial engagement and awareness events held. An internal raising concerns email address and an external Employee Assistance Programme are being launched.
- **Occupational Health and Wellbeing:**
 - Initiatives like the Wellbeing Centre of Excellence and integrated psychological wellbeing practitioners aim to support staff health. The avoidable employee harm programme has significantly reduced investigations, sick days, and costs, promoting a culture of minimizing harm in HR processes.

Workforce

The Workforce Demographics of the Health Board are vast, employing 13,117 WTE (15,558 individuals), with an increase in clinical services and nursing staff. Efforts focus on reducing turnover and addressing the aging workforce, where 36% are over 50 years old. The Health Board recognises staff contributions and enhancing their experience through feedback and learning opportunities.

- **Workforce Sustainability and Planning:**
 - Actions include promoting Band 4 opportunities, creating promotional videos, and increasing training for Healthcare Support Workers (HCSWs) to transition into professional roles like registered nurses.
 - The Clinical Futures Workforce Group has been re-established to align people management strategies with Health Board priorities. A workshop with local authorities helped outline key deliverables, which were reviewed by the Gwent Workforce Board.

- **Workforce Analytics and Optimisation:**
 - A workforce establishment controls workstream is linking financial budgets with electronic staff records for better workforce planning and vacancy management. The rollout of systems like SafeCare and new medical e-systems supports this initiative.

- **Recruitment and Retention:**
 - Efforts have led to a reduction in turnover from 11.36% to 9.04%, decreased sickness from 6.9% to 6.2%, and successful international recruitment of 74 nurses. The time to hire has been reduced, meeting the national target of 70 days.
 - Vacancy reductions include 100WTE HCSWs, 60WTE registered nurses, and 47WTE medical vacancies over 12 months. Variable pay has been reduced by approximately £18 million.

Culture

The Health Board is focused on learning from Experience: emphasising the importance of learning from patient and staff feedback to improve care quality and safety. There is a focus on ensuring a culture of Openness and Transparency, encouraging a culture where issues can be raised and addressed proactively, fostering a safe and supportive work environment. Supporting the work on culture:

- **Employee Wellbeing:**
 - The Wellbeing Centre of Excellence provides a supportive environment for staff, increasing capacity for clinical space. Psychological therapy services have seen a 20% increase in demand, with additional support secured to manage this.
 - The avoidable employee harm program has been instrumental in reducing the negative impacts of employee investigations, contributing to a healthier culture.

- **Diversity and Inclusion:**
 - The Strategic Equality Plan was launched, focusing on equality, diversity, and inclusion over the next four years. There has been an increase in the translation of Welsh language materials and self-reported Welsh language competencies.
- **Engagement and Experience:**
 - The Leadership Development Program (LDP) is fully subscribed, indicating strong engagement. The coaching network and various learning masterclasses have been established to enhance leadership skills and team success.

Freedom to speak up

We are committed to fostering an open, learning organization with a 'Just Culture' that promotes safety through support and psychological safety. Our aim is to nurture quality and system safety, valuing people in a collaborative and inclusive workplace where they feel safe to raise concerns and try new approaches.

We encourage staff and patients to 'Speak up for Patient Safety,' raising awareness of escalation processes and early learning mechanisms. Our learning and improvement forum enables sharing of errors, near misses, and incidents.

Over the past year, our human factors development program has supported openness and transparency in patient safety incidents, using simulation sessions and debriefs for all involved staff. We ensure that staff involved in incidents receive support for reflective practice, embedding learning, and preventing recurrence.

Following the NHS Wales Speaking up Safely Framework, the Health Board conducted a self-assessment and developed an action plan for its implementation. An initial engagement event was held in October 2023, and a cross-organizational steering group was established in March 2024. Workforce & OD launched an internal email for raising concerns, transitioning to an external Employee Assistance Program and Speaking Up service by July 2024.

We are rolling out a ward and team accreditation process to ensure teams understand their quality and safety data, fostering ownership of learning and improvements for sustainable change. This cultural shift engages staff in quality improvement and supports them in raising concerns and receiving organizational backing for learning and improvement.

Information

The integration of digital, data, and technology into healthcare is pivotal for enhancing patient safety and quality. By focusing on real-time information, patient access to health data, Artificial Intelligence and health data analytics, the health board aims to improve service delivery and patient outcomes. Addressing challenges like digital inclusion and cybersecurity, and leveraging strategic initiatives, ensures a sustainable digital transformation that benefits both healthcare providers and patients.

Digital technology is integral to daily operations, improving accessibility and connectivity in healthcare. The demand for digital services is increasing, providing numerous opportunities to enhance healthcare processes and patient experiences.

Opportunities for Improvement

- **Real-Time Information:** Electronic ward boards and data dashboards improve patient flow by providing real-time updates on patient and bed status.
- **Patient Access:** Local and national applications empower patients with access to their health data, giving them control over their healthcare decisions.
- **Artificial Intelligence (AI):** AI is being used in radiology, delivering tangible benefits in diagnosis and treatment.
- **Health Data Analytics:** Advanced analytics offer insights into population health, guiding public health initiatives and helping citizens maintain their health at home.

Welsh Nursing Care Record (WNCR) Implementation:

Achievements: Significant progress in rolling out WNCR across most wards. High engagement and substantial digital documentation recorded.

- Rolled out to 86% of wards, with all adult in-patient wards expected to be live by September 2024, including Critical Care Areas.
- Over 34,000 assessments opened, with significant numbers recorded, such as 44,000 Falls assessments and 821,000 skin bundles.
- Monthly user engagement around 3,700, resulting in 1,476,744 risk assessments and 3,724,000 in-patient notes recorded.
- Introduction of additional digital documentation, such as Bowel Chart, Skin Inspection & Repositioning Chart, and Mouthcare risk assessment.
- Upcoming Version 2.5 will include comprehensive IV catheter and urinary cannula bundles.

Areas for Improvement

Multi-Disciplinary Record Limitation: WNCR is not implemented as a multi-disciplinary record in high turnover areas like medical assessment units, leading to continued use of paper nursing notes. National challenges in standardizing and digitizing nursing documents result in dual record-keeping (digital and paper), impacting nursing efficiency.

Digital Access and Capability: Some nursing staff face challenges with digital systems due to lapsed Nadex accounts, unfamiliarity with laptops, and limited typing skills. Implementation required additional support and training, particularly for hard-to-reach staff, such as night shift workers.

Challenges for 2024/25

Expansion to Paediatric Settings: The move to paediatric settings is complex due to the multi-disciplinary nature of admission and assessment records, delaying full digital integration. Digital Health and Care Wales is pausing development for paediatrics while standardization continues.

New Functionality and Support: Regular updates (2-3 versions annually) will introduce new forms, requiring extensive training and support from nurse educators, specialist nurses, and other stakeholders.

Data Utilization: With the system operational, the focus will shift to leveraging available data for quality improvement initiatives. Development of tools to provide meaningful ward-level data to managers, identifying at-risk patients and compliance with patient assessments.

Learning, Improvement and Research

These have been included in the main body of the report.

- **Listening and Learning**
- **Participation in clinical audit**
- **Quality improvement**

Participation in clinical research

Key Achievements for 2023/24

Implementation of the 2022-2027 Research and Development Strategy

- **Research Champions Scheme:** Volunteers from staff and the public enrolled.

- **Leadership Appointment:** Associate Medical Director for Research and Development appointed.
- **Non-Commercial Studies:** 112 studies open and recruiting, with 1587 patients enrolled.
- **Welsh Government Key Indicator:** 97% of studies recruiting to Time and Target compared to All Wales' 76%.
- **Commercial Trials:** Increased from 7 (2022/23) to 16 (2023/24), with 52 patients recruited; additional trials in setup and awaiting approval.
- **Industry Partnerships:** Established relationships with industry partners like Sanofi.
- **Haematology Research:** Funded a full-time Band 6 Research Nurse, facilitating growth in commercial research.
- **Budget Autonomy:** Regained control over the budget from HCRW due to high achievement in metrics.
- **Global Recruitment Achievement:** Reached 10% of the global recruitment target for a commercial Haematology clinical trial involving Chronic Myeloid Leukaemia.
- **Quality Management:** Established a Quality Management group and an Inspection Ready sub-group.

Areas for Improvement

- **Lung Cancer Study Sponsorship:** Faced challenges and had to withdraw from the extension stage due to contractual complexities.
- **Staffing Issues:** Vacancies and inexperienced staff affected timely processing of research projects.
- **Funding Limitations:** Covid funding ended, limiting permanent staffing and research capacity.
- **Communication:** Poor communication of service redesigns affected research continuity.
- **Accommodation Shortages:** Lack of R&D accommodation at YYF and GUH sites hindered research delivery and oversight.

Challenges for 2024/25

- **Research Fellow:** Employ to work with Principal Investigators to expand clinical trials.
- **Capacity Building:** Increase research delivery team capacity to set up and oversee a commercial hub.
- **Promotional Materials:** Develop a brochure to showcase clinical trials facilities for building commercial relationships.
- **Commercial Portfolio:** Establish a phased commercial portfolio focusing on areas with existing expertise.
- **Sponsorship Role:** Update documentation and establish a Sponsorship group for study oversight.
- **Commercial Trial Setup:** Improve setup times for commercial trials.

- **IT Infrastructure:** Review and enhance IT systems to support commercial activity and regulatory compliance.
- **Sustainable Commercial Research:** Collaborate with HCRW/WG to develop a sustainable commercial research presence in Wales with UK Government VPAG funding.
- **Velindre Radiotherapy Unit:** Ensure research opportunities for patients at the new unit.
- **R&D Committee:** Re-establish to meet current departmental needs.

Whole Systems Approach

Integrated Care: Fostering collaboration across different care settings to ensure continuity and coordination of care, with a focus on holistic and person-centered approaches. The Health Board plans to coordinate and develop the Integrated Medium-Term Plan (IMTP) for an integrated planning group. Key Activities include:

- **Integration and Connectivity:** Align short-term plans with long-term strategies. Ensure coordination across Divisions, Corporate Functions, and wider partnerships like Regional Partnership Board and Cluster Plans.
- **Bottom-Up Planning:** Develop plans based on demand and capacity, grounded in Executive Team directives.
- **Alignment with Priorities:** Ensure plans meet Ministerial and National Priorities.
- **Financial Management:** Deliver plans within financial limits, articulating risks and consequences.
- **Community of Practice:** Standardize planning approaches, share best practices, and promote consistent methodology.
- **Championing Planning:** Embed planning principles across teams, acting as planning advocates within respective areas.
- **Issue Resolution:** Provide guidance and mediate conflicts to maintain the plan's progress.

Population Health Management: Addressing broader health determinants through programs focused on prevention, early intervention, and comprehensive care models.



**CYFARFOD BWRDD IECHYD PRIFYSGOLN
ANEURIN BEVAN
ANEURIN BEVAN UNIVERSITY HEALTH BOARD
MEETING**

DYDDIAD Y CYFARFOD: DATE OF MEETING:	02 September 2024
CYFARFOD O: MEETING OF:	Patient Quality, Safety and Outcomes Committee
TEITL YR ADRODDIAD: TITLE OF REPORT:	PTR Annual Report 2023-2024
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Jennifer Winslade - Executive Director of Nursing
SWYDDOG ADRODD: REPORTING OFFICER:	Tracey Partridge-Wilson Deputy Director of Nursing Gemma Couch - Head of QPS, Learning and Improvement

**Pwrpas yr Adroddiad (dewiswch fel yn addas)
Purpose of the Report (select as appropriate)**

Er Sicrwydd/For Assurance

**ADRODDIAD SCAA
SBAR REPORT**

Sefyllfa / Situation

The Putting Things Right (PTR) Annual Report has been prepared in accordance with the PTR Regulations. The annual report demonstrates our ongoing commitment to the population of the Health Board, which covers Blaenau Gwent, Torfaen, Monmouthshire, Caerphilly, and Newport. This equates to around 600,000 children, young people and adults. It will provide an overview of the 2023/2024 position in terms of how Aneurin Bevan University Health Board (ABUHB) has managed concerns, Redress cases, Claims, Patient Safety Incidents, Duty of Candour and Public Services Ombudsman for Wales (PSOW) cases during this reporting period. It will provide information on progress, performance as well as an overview of emerging themes and trends, including lessons learnt and the subsequent vision for 2024/2025.

Cefndir / Background

The Report focuses on, and describes the successes and challenges related to 'Putting Things Right' during the reporting period. It will encompass, Complaints, Compliments, Redress, Patient Safety Incidents, and PSOW cases and duty of Candour all of which are underpinned by the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.

During the reporting period, the Health Board has welcomed and fully embraced the introduction of the Health and Social Care Quality and Engagement) (Wales) Act and NHS Duty of Candour on 1 April 2023.

The provisions of the statutory Duty of Candour, is an organisational duty on all NHS bodies and primary care providers.

Concerns reporting, management and investigation is intertwined with the principles of being open: communicating with patients and their carers must adhere to the Duty of Candour, so in practice these activities should be fully integrated.

This Report was written with input from the Patient Experience and Involvement team, Legal Services, ABCi and QPS teams.

Assessment

The period 2023/24 has brought both opportunities and challenges.

During the reporting period, the Health Board has welcomed and fully embraced the introduction of the Health and Social Care Quality and Engagement) (Wales) Act and NHS Duty of Candour on 1 April 2023. In preparation for this transition the Health Board reviewed its management of incidents, systems and processes to align to the requirements of the Duty of Candour to minimise disruption to service user experience.

At the heart of the "Putting Things Right" (PTR) and Duty of Candour arrangements is the requirement to be open and honest when dealing with concerns. Most importantly to play a significant role in improving patient safety; endorse a person-centred approach to concerns management and reinforce a culture of organisational learning and quality. This is underpinned by the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) 2011.

The Health Board is committed to making it easy for people to raise concerns, feel that they are being listened to, and that their concerns are being taken seriously.

An Organisational Change Process which brought together the Divisional and Nursing Directorate resources for Quality and Patient Safety concluded in February 2024 with the Quality Improvement team from ABCI joining in May 2024. The new model will ensure that Quality Patient Safety (QPS) , PTR and Quality Improvement (QI) services are joined up and are organised to deliver and achieve the vision which is articulated in Health and Social Care (Quality and Engagement) (Wales) Act 2020; 'A Healthier Wales' (Welsh Government, 2018) and more recently the 'NHS Quality & Safety Framework' 'NHS Quality & Safety Framework' Duty of Quality and Duty of Candour.

As a Health Board we aim to echo the NHS core values by putting Quality and Patient Safety first by providing high value evidence-based care for our communities at all times and delivering that in a Person-Centred approach

The Health Board position for the delivery of the PTR regulations in 2023/24 is as follows: -



Patient Experience: Complimentary to the PTR process the Patient Experience and Involvement team have supported clinical teams in meeting with patients or patients’ relatives who would like to share their experiences following either incidents and or complaints.

Dedicated members of the Patient Experience and Involvement team meet with the person who has agreed to talk about their experiences to support listening and learning. The person agrees to the format of their ‘story’ and consents to their story being used either internally, externally or both. The person is not interviewed. Rather, they speak from the heart about an episode of care that has had the most significant impact on them, either positive or negative. The person is shown the film once it has been edited for their approval. The whole process gives them an opportunity to talk about what has happened and put structure to it in the format of a ‘patient story’, which can then be shared for learning and quality improvement.

The main themes from patient stories to date include:

- Poor or inconsistent communication
- Restricted visiting during COVID, particularly relatives not being with loved ones at end of life
- The need to better consider reasonable adjustments (neurodiversity and physical disabilities)
- Concerns around dementia care
- Positive story relating to rapid discharge

Some patients or carers who have shared their experiences are also invited to participate in involvement events such as the Bereavement Collaborative, People Participation Panels and the Dementia In-Patient Working Group. The involvement of patients and carers is increasing through listening and ongoing collaboration.

Formal complaints: During the reporting period, the Health Board has taken receipt of 1596 concerns which have been managed under the Putting Things Right Guidance, meaning that a formal investigation has been undertaken, the findings of which have been collated into a letter of response which is reviewed and signed by the CEO.

Early Resolution: In addition to concerns Managed Under the Putting Things Right guidelines, the Health Board is able to attempt to address concerns within 48 hours and these are considered as Early Resolution. This aims to bring concerns that are appropriate to a swift resolution for people without needing to await a formal investigation and response.

Serious Incidents: During the reporting period 586 incidents were deemed to meet the Serious Incident criteria whereby the incident requires investigation through either the Corporately led Patient Safety Investigation or a Divisionally led Patient Safety Investigation. Both of these processes follow the same structure, but are chaired by an executive chair or by a member of the divisional triumvirate respectively.

Redress Panel: Of the Redress Panels convened by the Health Board, 46 cases were prepared, heard and deliberated upon. Redress panels assess and determine concerns where potential failings and resulting patient harm have occurred. This is a high-level panel with quorate membership.

PSOW Cases: The Public Service's Ombudsman for Wales (PSOW) referred 175 cases to the Health Board for consideration during the reporting period. These encompass matters which are enquiries only, full investigations, anonymous queries and some cases where a full investigation is undertaken by the PSOW service.

Review of Priorities 2022/23

Priority 1: Introduction of the Health and Social Care (Quality & Engagement) (Wales) Act 2020 – (Duty of Candour)

As Duty of candour becomes law on 1 April 2023, the Health Board must:

- Ensure Health Staff have access to and undertake the All-Wales e-learning package.
- Assistant Director of Nursing to chair DoC Divisional leads meeting.
- Identification of key D of C leads within each division.
- Establish D of C dashboard on RLDatix
- Corporate Team oversight to support Divisional colleagues.

All staff now have access to the Duty of Candour training course via the Health Board's electronic training platform (ESR) and are being actively asked to complete this.

Following the centralisation of the QPS teams in February 2024, D of C leads have been identified and are working collaboratively as part of the wider QPS team to embed the core requirements of the Act and deliver consistent and robust training regarding implementation of the Duty of Candour.

A Duty of Candour dashboard has now been developed and is being utilised within the RL Datix system to support continuous monitoring and validation.

PSI team supporting divisional colleagues.

Priority 2: Remodelling of QPS structure across the organisation

Executive Director of Nursing to undertake review of QPS processes in conjunction with Divisional and Corporate colleagues.

The QPS and Complaints Team centralised in February 2024 in order to realise the following benefits; retention of knowledge, skills and experience across the teams, improving consistency, reducing duplication of effort, effective triangulation of complaints and incidents processes across the Health Board and to ensure improved quality, timeliness and person-centred response, and support a culture of shared learning. Since then, we have been working closely with the complaints and operational teams across the Health Board to try and improve our processes.

Priority 3: Learning Framework/Quality Strategy

To embed the new Quality Strategy through the Health Board which focuses on delivering against the Pillars of quality:

- Patient and staff experience and stories
- Incident reporting – falls, pressure ulcers, medicines management and mortality
- Complaints, concerns and compliments
- Health, safety and security
- Infection Control and Prevention
- Safeguarding
- Develop a robust implementation plan for the quality strategy
- Review and alignment the QPS resources to create a resource structure to deliver the strategy and create a learning framework

The Quality Strategy was implemented throughout Aneurin Bevan University Health Board in April 2023 and has recently been updated. A key focus in the development of this Strategy is progressing on what we have already accomplished and building on existing structures throughout the organisation. Quality is embedded in our culture, and we are committed to continually improving. Delivering the highest quality healthcare to our local communities and putting Quality, Safety and Learning at the heart of everything we do.

Our Strategy was developed in collaboration with a diverse group of people, ranging from healthcare partners to patients and colleagues. This collaborative approach is critical to our journey of improvement.

Priority 4: Improve Complaint Handling

- Set up regular SI and Concern 'drop-in clinics' for Divisions to allow opportunity to network and promote collaborative working to improve quality of responses and investigations at source.
- With closer working divisional/corporate relationships, reduce the backlog of outstanding complaints.
- Audit of IO's trained across the organisation to evaluate effectiveness of IO training delivered through investigations undertaken.
- Historic complaint closure.
- Introduction of PALS to maximise opportunities for early resolution

All actions completed.

An audit was undertaken which identified 309 IO's had been trained, however this piece of work also captured that 142 had not undertaken an investigation post-training. This highlighted the requirement for a reset and refresh of IO training and the target audience. Bespoke training will be offered.

Historic complaint closure remains a top priority across all complaints' teams. Weekly assurance and review meetings are taking place with complaint hubs to identify and alleviate bottlenecks and issues preventing finalisation. completion of aged complaints.

PALS commenced in November 2023.

The 2023/24 year has been challenging for the Corporate Putting Things Right Team with a number of challenges within and external to the team.

Despite the challenges, there has been a number of areas of success:

- Redesign and delivery of effective Concern and Investigating Officer training to an evolving and agile workforce.
- Improvements in the complaints management process and improvements in the quality of complaints.
- Completion of the Covid-19 Investigation requirements.
- The roll out and operationalisation of the Patient Advice and Liaison Service Team in November 2023 – this service seeks to intervene early and resolve concerns at the earliest opportunity and supports both in-patients and out-patients.
- The establishment of the Patient, Quality, Learning and Improvement Forum with the initial scoping meeting March 2024.
- Development of an online complaints form. The new form places emphasis on requesting and capturing the main aspects of the concern and the required details at the outset of patient and family engagement with the Health Board in order to ensure that the complaint response focuses on what matters to the complainant.
- The successful centralisation of the QPS resources within the Nursing Directorate

- A commitment to ensuring the timely and appropriate management of concerns is a priority, this will continue to be a focus for 2024/25 improve in 2023/24, tackling both existing and new challenges.
- Work has continued with the staff, communities and partners to put quality and safety at the heart of everything we do.

The Health Board has identified four key priorities that will frame the PTR Annual Work Programme 2024/2025: -

Priority 1: PTR Regulations and Health Board Concerns Management

1.1. The Putting Things Right Regulations are currently under consultation. The Health Board will ensure we are fully prepared and equipped ahead of any revised guidance being issued, in order to support our staff in the implementation and effective delivery for our communities.

1.2. Early Resolution – Person-centred approach: The Health Board is working to ensure that compliance with the Welsh Government 30-working day target is achieved where possible. Collaborative focus days will be planned to review complex concerns and assist with finalisation and conclusion of high-quality investigations.

Internal streamlining of quality assurance processes. This aims to provide a more consistent approach to the investigating and subsequent responses to concerns.

1.3. Meaningful Engagement: An Acknowledgement Team will be introduced, to understand early on what people raising concerns are seeking and what matters most to them and how we can resolve concerns in a timely and meaningful way so that patients and their families know that they are being listened to and that their concern is being taken seriously.

We will develop Communication Standards to ensure consistency across all our teams. We will be clear in setting out resolution proposals, actions and agreements and dates for contact and updates.

Priority 2: Improving Quality Patient Safety experience, Learning and Improving

2.1 Embed the centralised QPS/PTR/QI teams and revised ways of working.

2.2 A suite of training is being developed which is specific to complaints/ incident investigation. The Health Board also intends to work collaboratively with Welsh Risk Pool colleagues to devise more readily available and accessible video training in the future. The Public Service Ombudsman for Wales (PSOW) will also be supporting bespoke training.

2.3 Patient Safety Incidents (PSI):

- Patient safety incident bespoke 1-2-1 Investigating Officer (IO) training to work with new IO's that have been allocated an investigation.
- Complete a toolkit for IO's, Panel Chairs and staff involved in PSI's in no matter the context.
- Roll-out amended PSI template to align to DoC.
- Revised induction and education and training for PSI chairs.

2.4 The ABCi QI Unit have been working to support the development of Quality Improvement Capability across ABUHB.

In particular, the QI Unit are working with divisional staff to develop Quality Improvement Coaches embedded into clinical teams. To this end, a new Quality Improvement Coach programme has been adapted and tested in ABUHB in conjunction with Improvement Cymru.

The programme will run from Autumn 2024, with 3 cohorts planned each year. Potentially 75 QI Coaches will be trained annually, who can support clinical teams in their improvement priorities.

2.5 Development of the Listening and Learning Framework & Learning Repository: The framework will demonstrate how learning will be identified, stored, triangulated, shared, disseminated and implemented in practice to facilitate and embed a culture of appreciative enquiry and continuous improvement in health care services.

Priority 3: Partnership Engagement & Collaborative working

3.1 To work closely with external partners such as the Public Services Ombudsman for Wales, Llais, Audit Wales, Health Inspectorate Wales through which we will demonstrate an open culture and always seek out opportunities to learn and improve for our ongoing commitment to the population of the Health Board.

3.2 Work with the Medical Examiner's Office to implement the Death Certification Reform.

3.3 Work with the National Bereavement Leads to implement the GRACE bereavement model.

3.4 Continue to meet with and support patients and carers who have raised concerns, either directly or through third parties, such as Llais and the Ombudsman, to improve listening and learning.

3.5 Introduce People Participation Panels for sepsis and dementia.

3.6 Scope existing End of Life Care services and develop an inclusive End of Life Care Pathway in collaboration with people, staff and partners.

3.7 Hold a Big Conversation around Future Care Planning to raise public awareness.

3.8 Divisions to promote the use of the CIVICA system for timely patient feedback.

Argymhelliad / Recommendation

The Committee is asked to: -

- **NOTE** the Putting Things Right Annual Report 2023/2024.
- **NOTE** the four key priorities for the PTR Annual Work Programme.

Amcanion: (rhaid cwblhau) Objectives: (must be completed)	
Cyfeirnod Cofrestr Risg Corfforaethol a Sgôr Cyfredol: Corporate Risk Register Reference and Score:	
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	Governance, Leadership and Accountability 3.1 Safe and Clinically Effective Care 6.3 Listening and Learning from Feedback 3.2 Communicating Effectively
Blaenoriaethau CTCI IMTP Priorities Link to IMTP	Choose an item. Not Applicable
Galluogwyr allweddol o fewn y CTCI Key Enablers within the IMTP	Experience Quality and Safety
Amcanion cydraddoldeb strategol Strategic Equality Objectives Strategic Equality Objectives 2020-24	Choose an item. Choose an item. Choose an item. Choose an item.

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	
Rhestr Termau: Glossary of Terms:	NA
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol: Parties / Committees consulted prior to University Health Board:	NA

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Resource Assessment:	A resource assessment is required to support decision making by the Board and/or Executive Committee, including: policy and strategy development and implementation plans; investment and/or disinvestment opportunities; and service change proposals. Please confirm you have completed the following:
• Workforce	Choose an item.

<ul style="list-style-type: none"> • Service Activity & Performance 	Choose an item.
<ul style="list-style-type: none"> • Financial 	Choose an item.
<p>Asesiad Effaith Cydraddoldeb Equality Impact Assessment (EIA) completed</p>	<p>Choose an item.</p> <p>An EQIA is required whenever we are developing a policy, strategy, strategic implementation plan or a proposal for a new service or service change. If you require advice on whether an EQIA is required contact ABB.EDI@wales.nhs.uk</p>
<p>Deddf Llesiant Cenedlaethau'r Dyfodol – 5 ffordd o weithio Well Being of Future Generations Act – 5 ways of working</p> <p>https://futuregenerations.wales/about-us/future-generations-act/</p>	<p>Choose an item.</p> <p>Choose an item.</p>



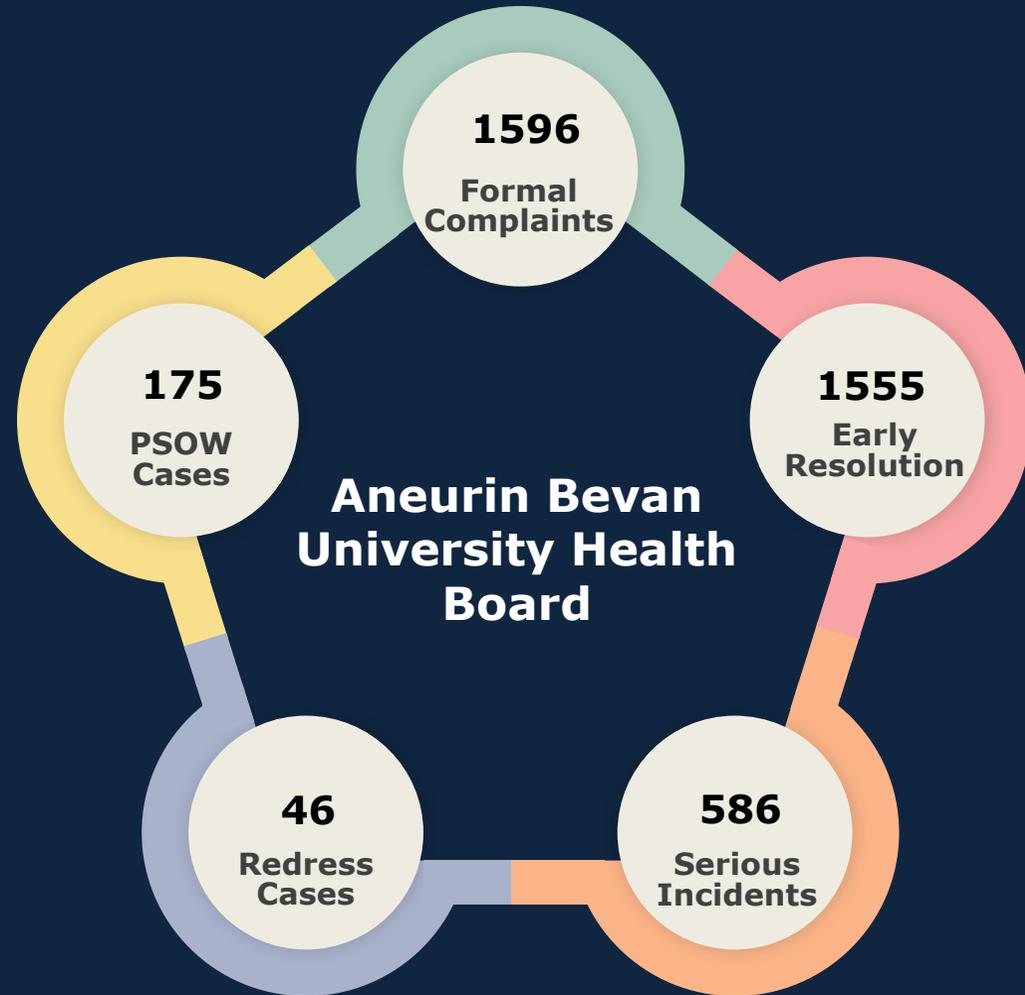
GIG
CYMRU
NHS
WALES

Bwrdd Iechyd Prifysgol
Aneurin Bevan
University Health Board

Putting Things Right

ANNUAL REPORT

2023-2024



Introduction

Welcome to the Aneurin Bevan University Health Board's (ABUHB) Annual Putting Things Right Report. This report will cover the financial year, April 2023 to March 2024. The annual report demonstrates our ongoing commitment to the population of the Health Board, which covers Blaenau Gwent, Torfaen, Monmouthshire, Caerphilly, and Newport. This equates to around 600,000 children, young people and adults.

At the heart of the "Putting Things Right" (PTR) and Duty of Candour arrangements is the requirement to be open and honest when dealing with concerns. Most importantly to play a significant role in improving patient safety; endorse a person-centred approach to concerns management and reinforce a culture of organisational learning and quality. This is underpinned by the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) 2011.

The Health Board is committed to making it easy for people to raise concerns, feel that they are being listened to, and that their concerns are being taken seriously.

During the reporting period, the Health Board has welcomed and fully embraced the introduction of the Health and Social Care Quality and Engagement) (Wales) Act and NHS Duty of Candour on 1 April 2023.

The provisions of the statutory Duty of Candour, is an organisational duty on all NHS bodies and primary care providers.

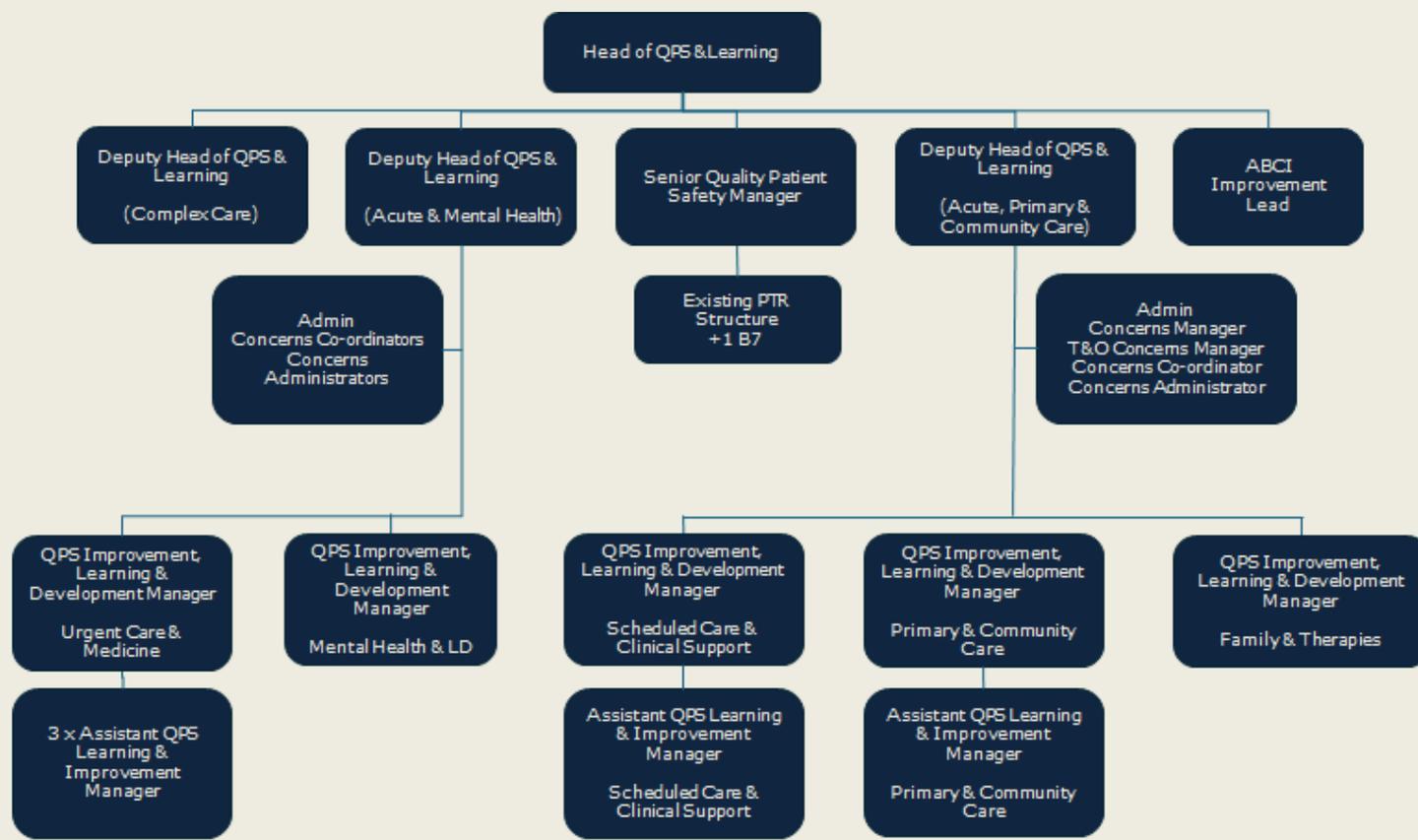
Concerns reporting, management and investigation is intertwined with the principles of being open: communicating with patients and their carers with a requirement that they adhere to the Duty of Candour, so in practice these activities should be fully integrated.

Staffing and Governance

There is a structure underpinning PTR, with executive leadership delegated to the Executive Director of Nursing (EDoN). Since the end of February 2024, the central Divisional Quality Patient Safety (QPS)/PTR teams have been aligned to the Nursing Directorate. Assurance is provided by reporting to the Patient Quality and Safety Learning and Improvement Forum, which in turn reports to the Executive Committee and the Patient Quality and Safety Outcomes Committee.

This committee sets out the Health Board's strategy and objectives to encourage continuous improvement, as well as compliance with national and local policies. It is further tasked with responsibility to develop and implement systems for quality monitoring that are robust, auditable and effective, as well as raising the awareness of the PTR and QPS agenda.

The current Putting Things Right/QPS Team structure is illustrated below:



Review of Priorities 2022/23

Introduction of the Health and Social Care (Quality & Engagement) (Wales) Act 2020 – (Duty of Candour)

As Duty of candour becomes law on 1 April 2023, the Health Board must:

- Ensure Health Staff have access to and undertake the All-Wales e-learning package.
- Assistant Director of Nursing to chair Duty of Candour Divisional leads meeting.
- Identification of key Duty of Candour leads within each division.
- Establish Duty of Candour reporting on RLDatix
- Corporate Team oversight to support Divisional colleagues.

1

All staff now have access to the Duty of Candour training course via the Health Board's electronic training platform (ESR) and are being actively asked to complete this.

Following the centralisation of the Quality, Patient Safety (QPS) teams in February 2024, Duty of Candour leads have been identified and are working collaboratively as part of the wider QPS team to embed the core requirements of the Act and deliver consistent and robust training regarding implementation of the Duty of Candour.

A Duty of Candour reporting tool has now been developed and is being utilised within the Health Boards incident and complaint reporting system to support continuous monitoring and validation of data.

The Patient Safety Incident team are offering support to divisional colleagues in implementation of the Duty.

Remodelling of QPS structure across the organisation

Executive Director of Nursing to undertake review of QPS processes in conjunction with Divisional and Corporate colleagues

2

The QPS and Complaints Team centralised in February 2024 in order to realise the following benefits; retention of knowledge, skills and experience across the teams, improving consistency, reducing duplication of effort, effective triangulation of complaints and incidents processes across the Health Board and to ensure improved quality, timeliness and person-centred response, and support a culture of shared learning. Since then, we have been working closely with the complaints and operational teams across the Health Board to try and improve our processes.

Learning Framework/Quality Strategy

To embed the new Quality Strategy through the Health Board which focuses on delivering against the Pillars of quality:

- Patient and staff experience and stories
- Incident reporting – falls, pressure ulcers, medicines management and mortality
- Complaints, concerns and compliments
- Health, safety and security
- Infection Control and Prevention
- Safeguarding
- Develop a robust implementation plan for the quality strategy
- Review and alignment the QPS resources to create a resource structure to deliver the strategy and create a learning framework

3

The Quality Strategy sets out what the Health Board will do to achieve its vision to continuously improve patient safety by building on two foundations of a patient safety culture and a patient safety system.

The Quality Strategy was implemented throughout Aneurin Bevan University Health Board in April 2023 and has recently been updated. A key focus in the development of this Strategy is progressing on what we have already accomplished and building on existing structures throughout the organisation. Quality is embedded in our culture, and we are committed to continually improving. Delivering the highest quality healthcare to our local communities and putting Quality, Safety and Learning at the heart of everything we do.

Our Strategy was developed in collaboration with a diverse group of people, ranging from healthcare partners to patients and colleagues. This collaborative approach is critical to our journey of improvement.

Improve Complaint Handling

- Set up regular SI and Concern 'drop-in clinics' for Divisions to allow opportunity to network and promote collaborative working to improve quality of responses and investigations at source.
- With closer working divisional/corporate relationships, reduce the backlog of outstanding complaints.
- Audit of IO's trained across the organisation to evaluate effectiveness of IO training delivered through investigations undertaken.
- Historic complaint closure.
- Introduction of PALS to maximise opportunities for early resolution

4

An audit was undertaken which identified 309 members of staff who had undertaken training as Investigating Officer's (IO). However, this piece of work also captured that 142 had not undertaken an investigation post-training. This highlighted the requirement for a reset and refresh of IO training and the target audience of the training package. The Health Board aims to provide accessible video recorded training, supported by bespoke sessions and training materials.

Historic complaint closure remains a top priority across all complaints' teams. Weekly assurance and review meetings are taking place with all concerns teams to identify and alleviate bottlenecks preventing conclusion of investigations.

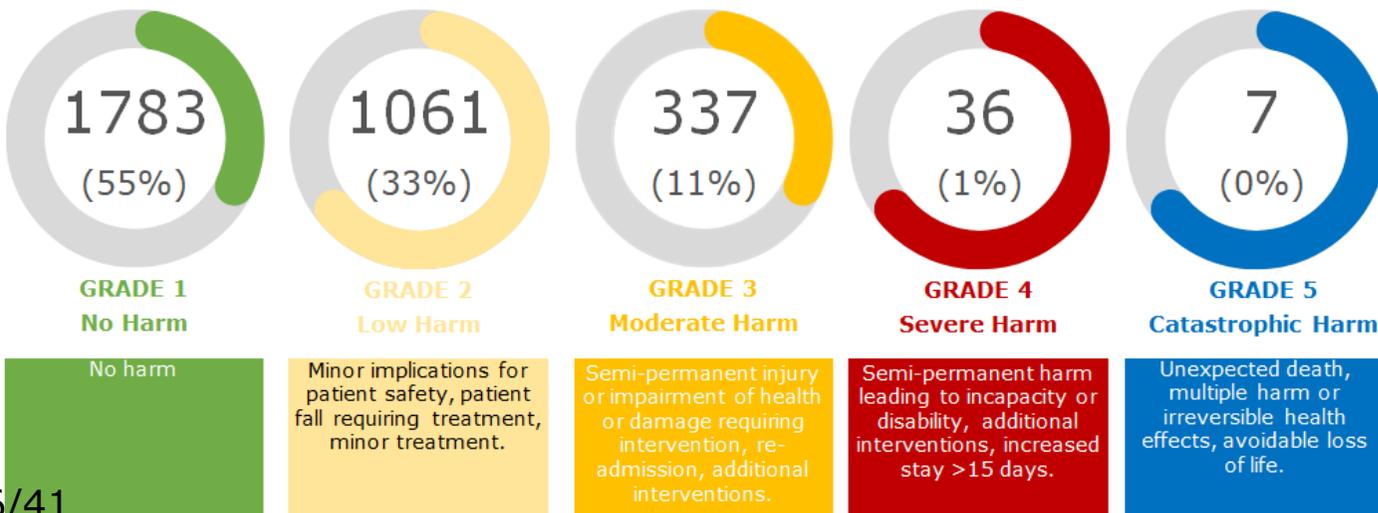
The PALS team fully rolled out in November 2023.

Arrangements for the Management of Concerns

Upon receipt of a concern the central PTR team assume responsibility for review and initial grading supported by the Senior Management Team. Early Resolution is encouraged wherever possible and appropriate to do so. If the matter is more serious or there has been a specific request for a full investigation these matters will be Managed under PTR, with a formal 30-day Investigation. Serious concerns (graded 4 or higher) are shared with the Divisional Triumvirate overseeing the area on first receipt, ensuring they are sighted early. Additionally, the Executive Team are notified of all grade 4/5 complaints via the weekly Safety Briefing.

Concerns are then directed to the relevant division and management team, at which time an Investigating Officer is appointed. It is good practice for the Investigating Officer to contact the Complainant. Under the Putting Things Right Regulations, all formal Concerns have to be acknowledged within 5 working days. We encourage personal contact with each Complainant to ensure that we acknowledge their correspondence in an empathetic and personal manner. For those investigations that require further time, the Concerns Team should contact the Complainant, prior to the 30-day target, to explain the reason for the delay and advise that further time is needed. Within the response, Complainants are offered the opportunity to meet with Health Board Staff. As part of the regulations, there is an obligation on a Welsh NHS body to consider when it is notified of a concern that alleges harm or may have been caused, whether or not there is a qualifying liability. This is included in the response, along with the advice on how concerns can be forwarded to the Ombudsman.

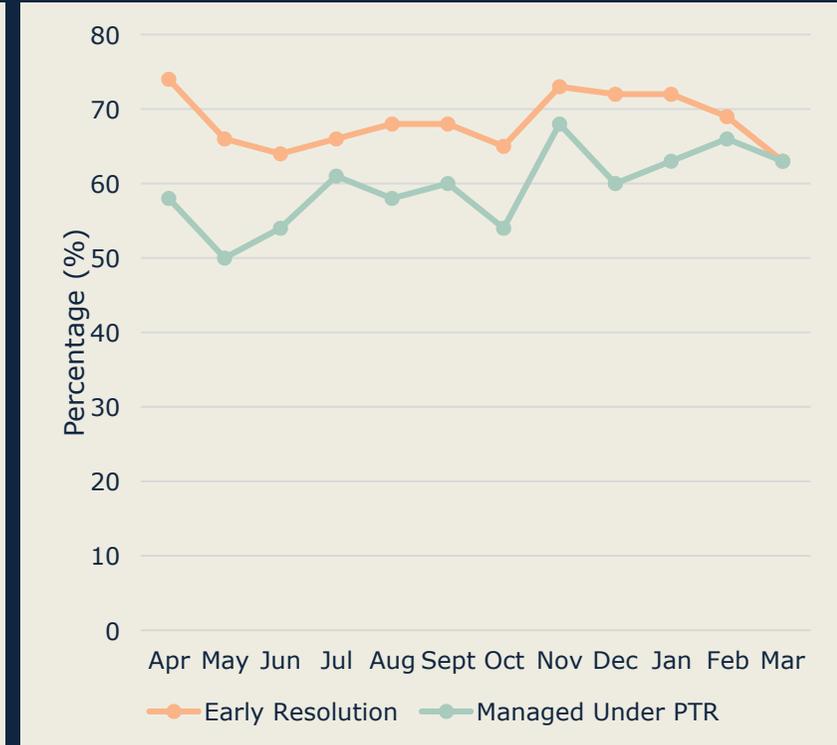
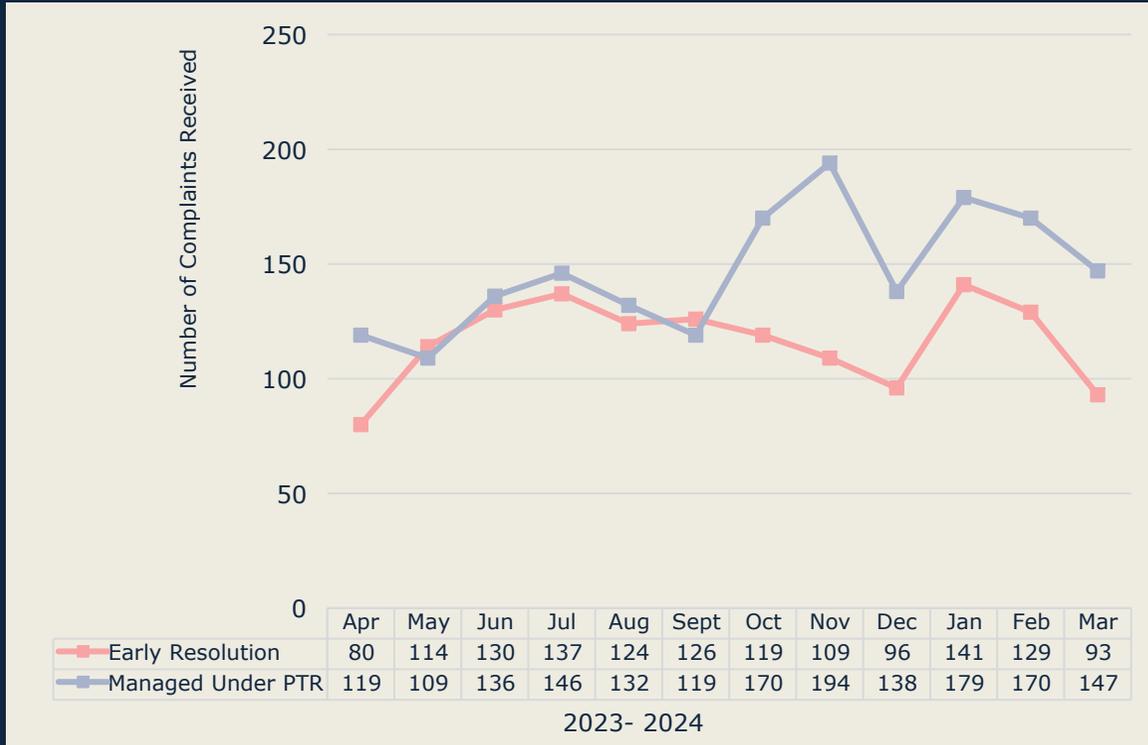
Grading of Complaints Upon Receipt 2023-24



A large proportion of concerns (88%) are graded as low or having caused no harm upon receipt, with moderate representing 11%, and with grades 4 and 5 accounting for 1% of the total received. The grading of complaints is dynamic and should be kept under review throughout the investigation.

Overall Health Board Compliance

Q3 & Q4 saw an overall steady increase in the number of concerns being Managed Under PTR. Positively, the number of concerns being managed through Early Resolution saw the benefits of the inception of the PALS team in Q3.



Compliance with the Welsh Government 30-working day target averaged 60% across the reporting period.

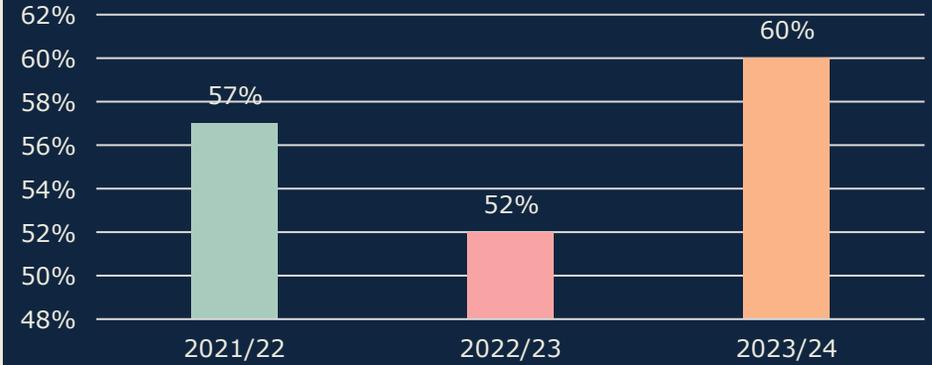
Extensive work by the Assistant Director of Nursing whose portfolio includes PTR, and the Head of Quality Patient Safety & Learning and Senior Quality Patient Safety Manager has taken place in collaboration with the Once for Wales data team and the Divisional leadership teams, to prioritise and finalise concerns investigations. Additionally, work has taken place to ensure concerns are accurately recorded on the RLDatix (Datix Cymru) system.

Trends in Compliance

Trend in Compliance: Early Resolution



Trend in Compliance: Managed under PTR



In 2023/24, the Health Board received 1,596 formal complaints and 1,555 early resolution.

Performance has increased for Managed Under PTR concerns from 52% to 60%. Those concerns tend to be more complex in nature, often spanning more than one division and/or organisation. The Health Board aspires to resolve 75% of concerns as Early Resolution, as well as attaining a 75% compliance with Managed through PTR.

The main themes relate to: Clinical treatment/assessment; Appointments and Communication issues across 2023/24. The effects of the Covid-19 pandemic continue to be evident in relation to concerns raised regarding clinical treatment and assessment; delays in receiving an appointment along with commencement of treatment plans. People continue to express concern about wait times, with waiting list times emerging as a recurring theme across the reporting period.

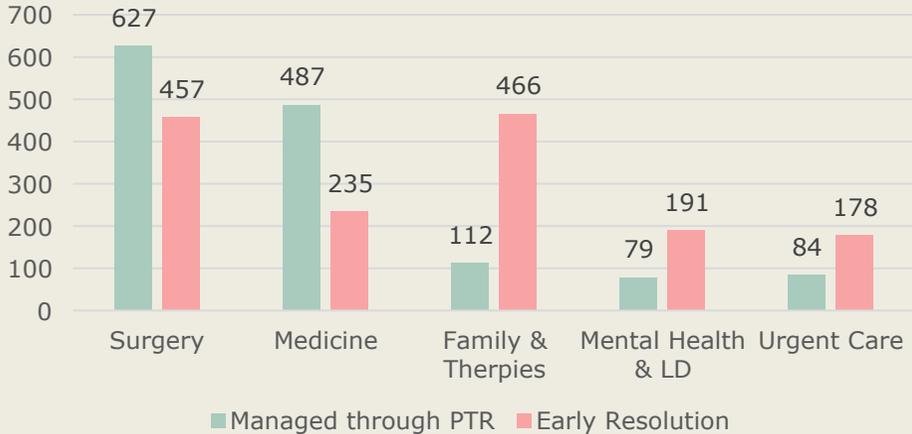
The ongoing work of the Six Goals for Urgent and Emergency Care, Planned Care and Mental Health Improvement Plans seek to improve clinical outcomes and patient experience.

Communication issues continue to be a recurring theme, however positive changes to the management of concerns from the point of receipt and throughout the complaint process are scheduled, beginning with the development of a central acknowledgement team. This will afford people the opportunity to engage with the Health Board early on and ensure a person-centred approach to resolution of their concerns. Meaningful updates throughout the course of investigations to people and families will be the focus of all concerns teams. Both approaches have been recognised by the Public Services Ombudsman for Wales (PSOW), and Llais as positive upcoming changes.

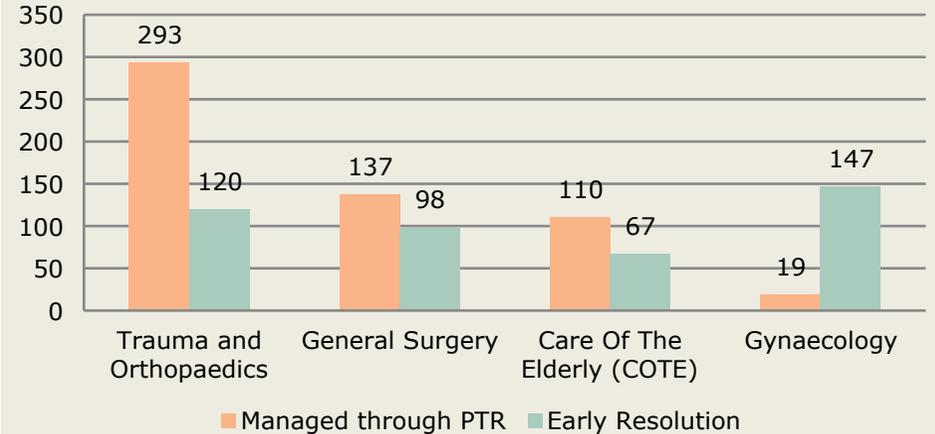
Overall Health Board Compliance

The Health Board reports and monitors concerns received by all services. This allows identification and active engagement with services that are receiving more or less concerns to understand areas of good practice or where targeted improvement and action may be required. This supports the Health Board in its aim to be a proactive learning organisation.

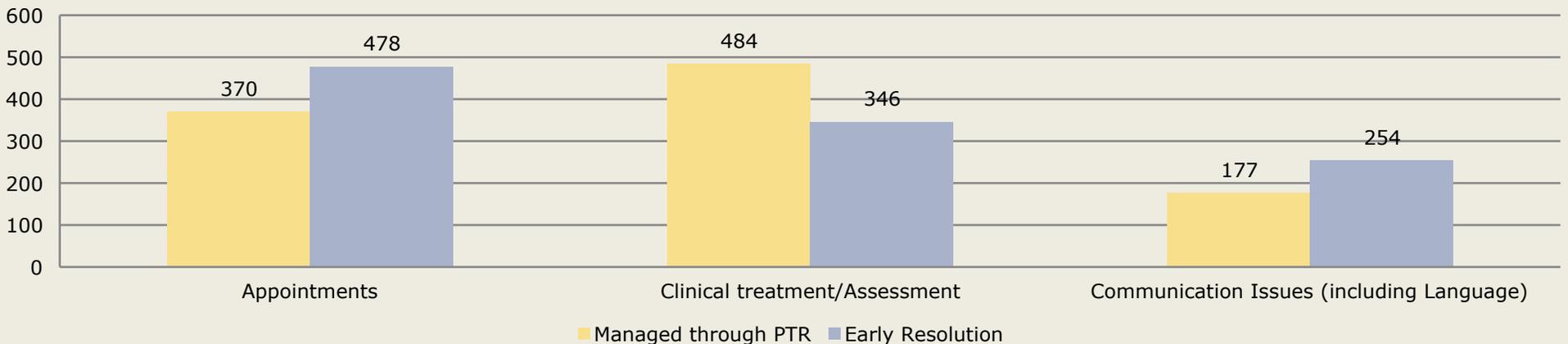
Concerns by Division - Top 5



Concerns by Directorate – Top 4



Top 3 Concerns by Type and Theme



Learning from Concerns

Being open and honest to build trust and ensure transparency with our patients to reinforce our commitment to improving our services and placing quality at the forefront of everything we do.

All complaints and feedback provide us with an opportunity to make changes to improve the services we provide to our population. The following are examples of action that the Health Board has taken following concerns raised by patients and their families in the previous year: the feedback from our Complainants is that they like the use of "You said-We Did" to convey the actions taken.

We have listened to feedback and have implemented the following measures:

The QPS and Complaints Team centralised in February 2024 in order to realise the following benefits; retention of knowledge, skills and experience across the teams, improving consistency, reducing duplication of effort, effective triangulation of complaints and incidents processes across the Health Board and to ensure **improved quality, timeliness, a person-centred approach and support a culture of shared learning**. Since then, we have been working closely with the complaints and operational teams across the Health Board to try and improve our processes.

Over the last year we have listened to patient feedback and plan on introducing an acknowledgement team to ensure early and meaningful contact with patients and their families to understand early on what matters to them and how we can resolve their concerns as timely and appropriately as possible.

A weekly meeting has been set up with all of the complaints teams to **improve communication and to provide direction and support** and to understand the challenges in the system which are escalated following the meeting.

We recognise that there should be a clear and consistent approach to ensure effective and meaningful communication throughout the complaints process. Therefore, we have drafted **Communication Standards** to ensure that **communication with patients and relatives is consistent, timely, meaningful and effective**. We are continuing to focus on complaints over the 30-day target to address unresolved concerns effectively and improve service quality.

Learning from Concerns

The new Head of Quality Patient Safety and Senior Quality Patient Safety Manager have convened regular meetings with PSOW and Llais to ensure our focus on transparency, collaboration and a commitment to improvement in complaint handling. This also allows for detailed conversations regarding emerging themes and areas for focus that external bodies are identifying through their engagement with local people. This provides the Health Board with a broader understanding of the issues that really matter to our community in relation to healthcare.

PALS

The positive impacts on patient experience is significant and includes:

- Single point of contact
- Early intervention and resolution to patient and family queries
- Helping patients and families to keep in touch
- Supporting patients and families at clinical meetings
- Supporting face to face listening meetings
- Positive assurance for families who are unable to visit/live away
- Facilitated ward moves closer to home
- Attended Deaf Club to listen to concerns and take forward access improvements
- Recommended reasonable adjustments for people with protected characteristics
- Secured volunteer visits for people who are lonely
- Developed a visiting poster based on relative's feedback
- Signposting to support services for example, bereavement support
- Reduced escalation to PTR

Based on PALS feedback, to improve the experiences of people who are at end of life or bereaved, the Health Board are now employing a Patient and Relative Support Officer, providing a dedicated contact at the most distressing time of people's lives.

Patient Experience and Involvement

Complimentary to the PTR process the Patient Experience and Involvement team have supported clinical teams in meeting with patients or patients' relatives who would like to share their experiences following either incidents and or complaints.

Dedicated members of the Patient Experience and Involvement team meet with the person who has agreed to talk about their experiences to support listening and learning. The person agrees to the format of their 'story' and consents to their story being used either internally, externally or both. The person is not interviewed. Rather, they speak from the heart about an episode of care that has had the most significant impact on them, either positive or negative. The person is shown the film once it has been edited for their approval. The whole process gives them an opportunity to talk about what has happened and put structure to it in the format of a 'patient story', which can then be shared for learning and quality improvement.

The main themes from patient stories to date include:

- Poor or inconsistent communication
- Restricted visiting during COVID, particularly relatives not being with loved ones at end of life
- The need to better consider reasonable adjustments (neurodiversity and physical disabilities)
- Concerns around dementia care
- Positive story relating to rapid discharge

Some patients or carers who have shared their experiences are also invited to participate in involvement events such as the Bereavement Collaborative, People Participation Panels and the Dementia In-Patient Working Group. The involvement of patients and carers is increasing through listening and ongoing collaboration.

Patient Advice and Liaison Service (PALS)

The Patient Advice and Liaison Service (PALS) was introduced by Aneurin Bevan University Health Board in November 2023.

Consisting of 3 PALS Officers and 3 Patient Support Officers (PSO's), the team operate across the Health Board footprint. PALS officers work 8:00am-8:00pm Monday-Friday (8:00am-5:30pm/11:30am-8:00pm) and 9:00am-2:00pm Saturday, Sunday and Public Holidays and the PSO's work 8:00am-8:00pm 7 days a week. Based in the Grange University Hospital (and travelling across sites) the Team offers confidential advice, support, and information on health-related matters.

Through a **single point of contact**, they support patients, families, and carers who have queries or wish to raise concerns, with their focus on addressing concerns through **early resolution**.

Through a bi-lingual public information leaflet, the service was **promoted** on the Health Board's webpage and through social media.

Patients, families, and carers can contact PALS for various reasons, including:

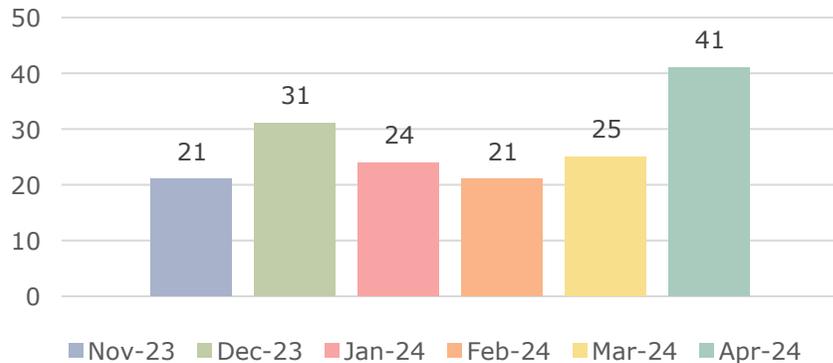
- When they have a problem but don't know who to ask.
- To talk to someone not directly involved in their care.
- To compliment services or individual staff members.
- To provide suggestions for improvements.

The PALS team work closely with clinical staff, supporting communication, concern resolution, and supporting people in face-to-face discussions with clinicians. Clinicians can contact PALS directly to help manage patient concerns and **early resolution**.

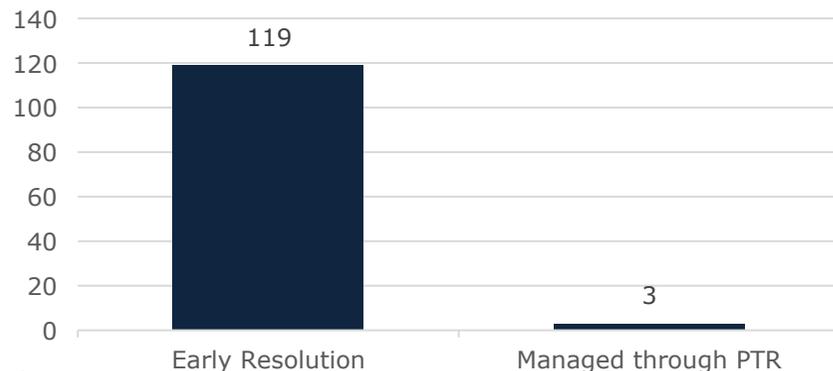
PALS Performance/Impact

- **162 complaints** were made over the 6-month period to the PALS Team.
- Of these **155** were managed by the PALS team.
- The total number of complaints escalated to the Putting Things Right (PTR) Team over the past 6 months = **7 (4.3%)**

Complaints managed through PALS since Launch



Complaints Via PALS November 2023 - March 2024



PALS Successes

A PALS officer received a call from a distressed mother who lived in **Ireland**. Her son, who was in South Wales on a football scholarship, had arrived at the **Emergency Department** (ED) in immense pain. He had contacted his mother and told her it was too busy and was going to return to his student home. She called us as she had no idea what to do and was scared that he'd leave hospital.

The PALS officer spoke to her and did their best to allay her **fears** whilst the PSO on duty went to ED and spoke to the young man (who was outside the department ready to leave) and assured him he would be seen as soon as possible. The mother was relieved that her son was going to stay.

The next morning, the PALS officer called her, as they could see that her son had an **appendectomy** during the night. He was recovering on a ward and his mother said, *"I am so grateful you were on the other end of the phone; it was such a weight lifted off me and I was able to sleep last night when I had originally thought about booking the next flight to Wales."*

The PALS team were contacted by a family who had recently been bereaved by the loss of their wife/mother. Their mother had been in ill health over several years and had been admitted into hospital with a community acquired pneumonia, however, was showing positive signs of recovery following treatment with antibiotics. Sadly, **24 hours following a transfer** from the Grange University Hospital to Ysbyty Ystrad Fawr (YYF), she unexpectedly passed away. The family were contacted by the ward but unfortunately did not arrive to see their wife/mother before she passed.

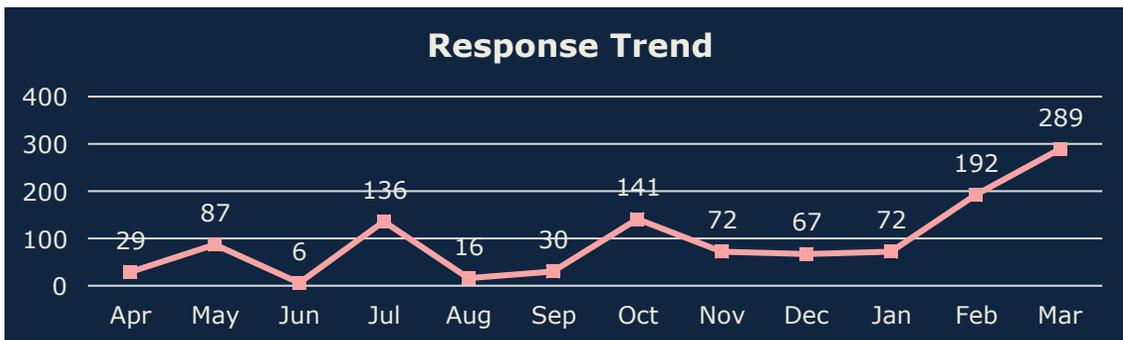
The family did not want to make a complaint but were **seeking closure** following the death of Mrs W. The events of that night were a blur and even though they remember speaking with a nurse and a doctor, they hadn't retained the information due to the shock.

The PALS team were able to **support the family** by listening to their experience. Two of the family members lived locally, but one daughter lived in **New Zealand**. Therefore, the initial contact was made via email so all the family could be part of the communications. The PALS team then facilitated a meeting with the clinical team at YYF, so everyone could sit around the table to have their questions answered. Two of the family members attended in person and the daughter who lived in New Zealand was able to join via Microsoft Teams.

The family found this meeting invaluable as they had a better understanding of the events that happened that night. The PALS team supported the family at the meeting and after, with a **follow up call** to ensure there were no outstanding queries or questions.

Person Centred Care Survey: 01/04/23 - 31/03/24

This is a survey we have produced to gain a person centred care baseline (based on the Picker Institute Research of what 'good' person centred care looks like).



- Of the **190** wards, departments and services that have been set up to use the CIVICA system, **84** have received feedback.
- 1343** responses in total across all surveys.
- Imminently going live on Intranet pages.
- New CIVICA Patient Feedback Branding.
- Working with Divisions to ensure appropriate individuals are identified to receive feedback for their specific area of responsibility, via the CIVICA system.
- Working with Divisions to encourage participation onto the CIVICA system to ensure feedback is captured from all areas.
- Working with Divisional Leads and QPS Teams for Divisional ownership of the feedback and learning.

Survey Live Across Health Board	Total Responses
Health Visiting (survey under review)	1
PEOLC	10
Nosocomial COVID Investigation	0
Emergency Department Survey	123
Person-Centred Care	1137
Care Closer to Home (Parent/Carer Questionnaire)	4
Care Closer to Home (4 - 11 years)	1
Care Closer to Home (11 years and upwards)	3
Your Time in hospital (4 - 11 years)	12
Your Time in Hospital (11 years and upwards)	10
Parent/Carers questionnaire	42

Top 3 Themes	
What did we do well? Q9	What could we have done better? Q10
<ul style="list-style-type: none"> 189 comments around Compassion - 89 patients used the word 'Caring' and 60 patients used the word 'Kind' 150 comments around Friendliness - 107 patients used the word 'Friendly' 141 comments around Emotional and Physical support - 69 patients used the word 'helpful' 	<ul style="list-style-type: none"> 66 comments around Waiting - 29 patients use word 'waiting' 37 comments around Comfort - 13 patients use word 'uncomfortable' 32 comments around Food and Beverage - 4 patients mentioned 'better food'

Person Centred Care Survey: 01/04/23 - 31/03/24

Division	Responses	Person Centred Care								Overall
		I felt listened to	I was able to make my own decisions about my care	I had care and support from staff who understood my needs and respected by choices	I had care and support from staff who understood my needs and respected by choices	I had the support of my family (or friends) when I needed them	I felt safe	I felt physically comfortable	I was given information and advice that I could understand to help me keep well	
Family & Therapies	19	97	96	94	94	100	95	94	100	96
Primary Care & Community	234	80	75	87	88	95	85	76	61	81
Scheduled Care	243	96	93	96	97	97	92	95	89	94
Workforce & OD	0	-	-	-	-	-	-	-	-	-
Complex & Long Term Care	12	71	80	77	79	83	77	86	91	81
Corporate	0	-	-	-	-	-	-	-	-	-
Medicine	476	89	79	91	94	94	84	85	75	87
Mental Health & Learning Disabilities	128	81	66	85	79	84	78	71	73	77
Multi-Discipline	0	-	-	-	-	-	-	-	-	-
Urgent Care	36	61	72	67	90	75	49	56	53	65
	Overall	87	80	90	91	93	84	83	75	86
	Benchmark	85	85	85	85	85	85	85	85	85



What did we do well? (Q9) Top 3 Themes

189 comments around **Compassion** – **89** patients used the word 'Caring' and **60** patients used the word 'Kind'.

150 comments around **Friendliness** – **107** patients used the word 'Friendly'.

141 comments around **Emotional and Physical support**– **69** patients used the word 'helpful'.

What could we have done better? (Q10) Top 3 Themes

66 comments around **Waiting** – **29** patients use word 'waiting'.

37 comments around **Comfort** – **13** patients use word 'uncomfortable'.

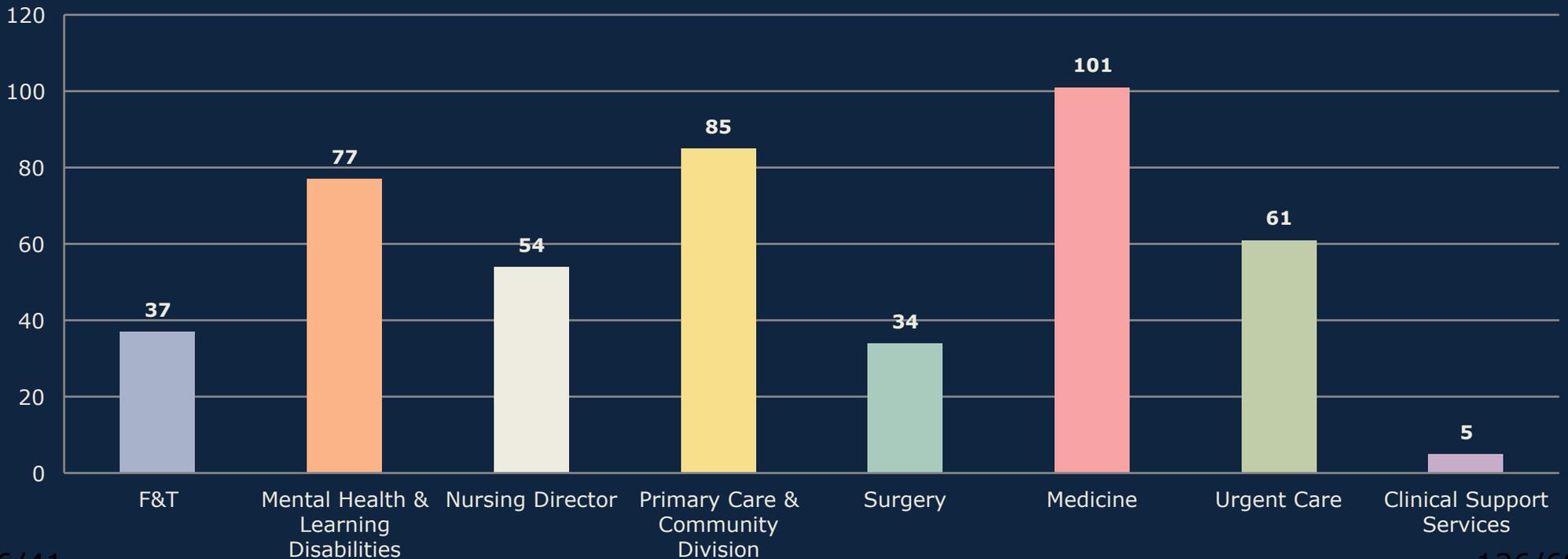
32 comments around Food and Beverage – **4** patients mentioned 'better food'.

Compliments

The Health Board receives compliments in a variety of ways, including letters, emails, telephone calls, thank you cards, conversations and social media. Compliments are useful for measuring and tracking feedback. They can demonstrate improvements in performance and provide a baseline for measuring patient satisfaction, generating meaningful data can help drive continuous improvement. Compliments acknowledge, reward and promote positive behaviours and practices, also providing staff with social recognition. Positive feedback is pivotal for morale and wellbeing; reinforcing what the Health Board is striving to provide. Complainers often include a compliment within a complaint, areas are encouraged to share these with staff.

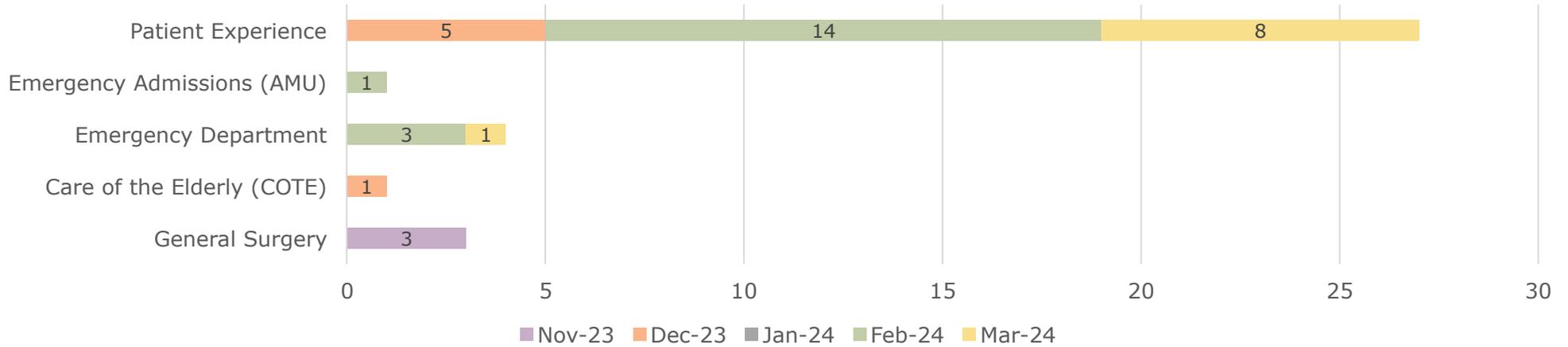
454 compliments were captured on the RL Datix system during 2023/24, which was a 150.83% increase on the compliments recorded in the reporting period 2022/23. Since November 2023 the PALS service have received an additional 36 compliments.

Compliments by Division



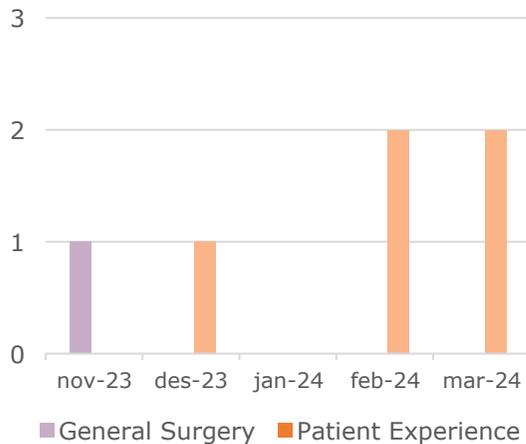
PALS Compliments: November 2023 – March 2024

Compliments received by Department

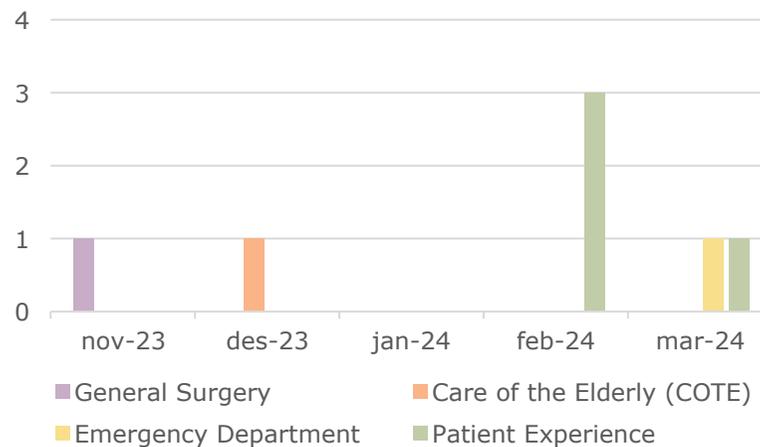


Themes

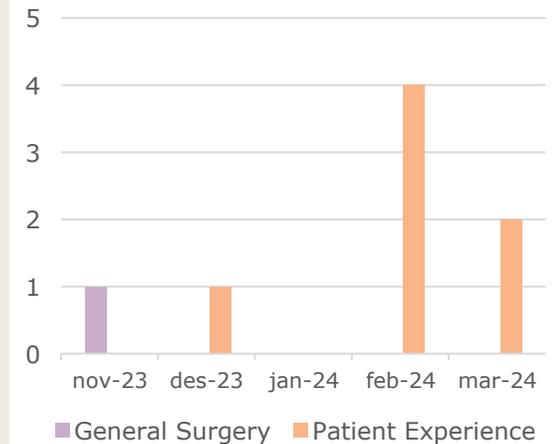
Compliment Theme: Listening



Compliment Theme: Beyond Duty of Care



Compliment Theme: Understanding



Public Services Ombudsman for Wales (PSOW)

During 2023/24, quarterly meetings continued to be held between the PSOW Improvement Officer and Head of Complaints Standards and the Health Board's Concerns Manager, Complaints and PSOW along with the Senior Quality Patient Safety Manager.

Where a concern cannot be resolved to the satisfaction of the complainant, they can refer the matter to the Public Ombudsman for Wales (PSOW), an independent government body offering free, impartial support to those wishing to raise concerns in relation to public bodies and NHS organisations throughout Wales.

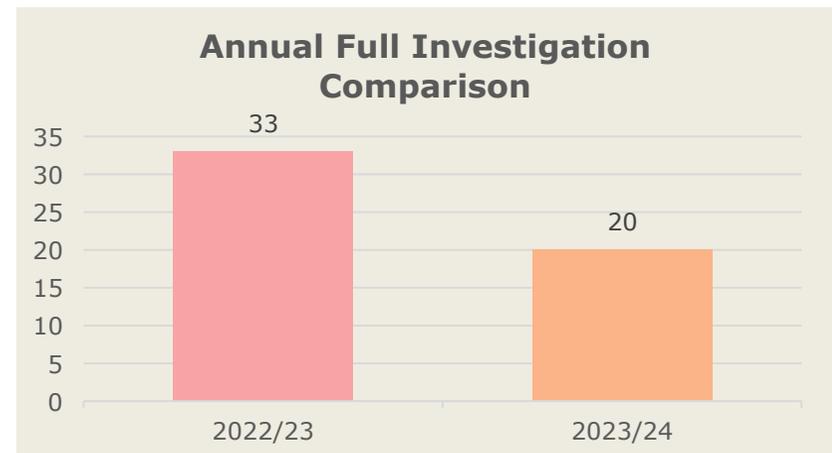
The Ombudsman aims to ensure that public services are delivered properly and fairly and has legal powers to uphold concerns and make recommendations for learning and improvement to prevent similar incidents from happening again. Despite every effort to provide a comprehensive response to complaints there will be occasions when complainants are dissatisfied with the conclusions of the Health Board and they may refer their concerns to the PSOW.

The Health Board recognises that in order to achieve the best outcomes for complainants and their families, open and supportive collaboration with the PSOW is imperative. During 2023/24, quarterly meetings continue to be held with the PSOW Improvement Officer and Head of Complaints Standards. Mutually agreed processes are in place to ensure, wherever possible, deadlines are met.

The Health Board received a [Public Interest Report](#) during this reporting period. The Health Board have apologised for any distress caused and we are currently working through a plan to explore how we can meet the Ombudsman's recommendations in relation to the introduction of fampridine in our Health Board area. We are currently working through a plan to see how we can meet the ombudsman's recommendations in relation to the introduction of fampridine (A drug approved for use in NHS Wales and Scotland to treat adults with Multiple Sclerosis (MS) who have a walking disability) in our Health Board area.

The Health Board received 20 complaints requiring full investigation in 2023/24 in comparison to 33 in 2022/23. This represents a reduction of 39%. Often these are accompanied with an early settlement recommendation to apologise for the delay, with assurances the response will be sent as soon as possible. The Health Board is working hard to embed processes to resolve this.

During 2022/2023, 62% of all referrals led to a full investigation compared to 38% in 2023/24. This represents a positive improvement for the Health Board as a full investigation means that the PSOW do not feel we have adequately addressed the complainants' concerns.



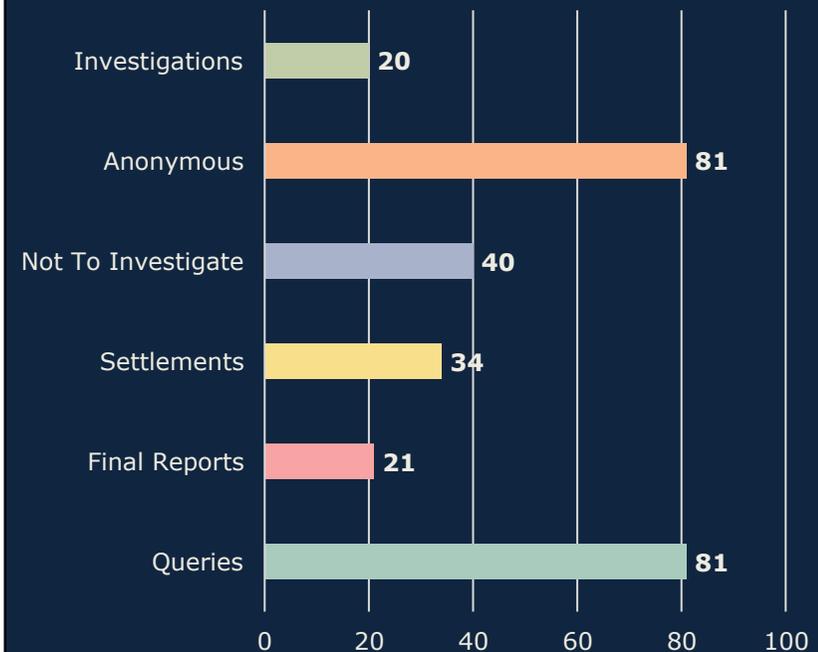
Public Services Ombudsman for Wales (PSOW)

During 2023/24, the PSOW received 175 referrals and 81 queries. Of the 175 referrals, 20 were taken on as full investigations for the Health Board, 34 were settlements and 40 cases were not considered for further investigation. Final reports are included in the overall incoming referrals. The remaining 81 referrals were anonymous, requiring no further action from the Health Board.

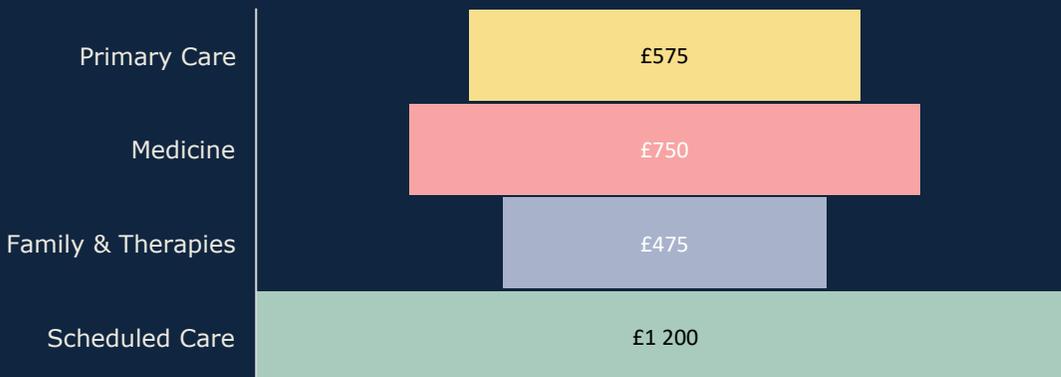
When the PSOW Office decides not to investigate a case, it could be for a variety of reasons. A proportion of these cases are deemed 'premature,' which means the Health Board has yet to complete its investigation, while others are deemed out of time or outside the Ombudsman's jurisdiction. Many of these cases can be considered 'premature' because the PSOW believes that no further information can be gleaned and that the Health Board was thorough in their response.

Settlements are also known as 'early resolutions,' in which the Health Board agrees to respond to the complainant or complete a specific action in order to "settle" the case and avoid a full PSOW investigation.

Closed Referrals



Financial Settlements by Division



Where the PSOW believes there has been an injustice, they can recommend a financial payment. This can happen at any point, such as part of a settlement or as part of the recommendations following a thorough investigation.

There has been a reduction in financial compensation awarded for the year 2023/24, representing a positive reflection of settlements ordered. In 2022/23 it equated to £4550.00, which was approximately 34% more than 2023/24 which was £3000.00.

Public Services Ombudsman for Wales (PSOW)

Feedback from the Ombudsman including Learning and Actions Implemented

The Health Board now has an electronic referral process in place. This is an electronic form which is submitted via Clinical Workstation database by the Surgeon, stating the date of the operation, details of the procedure and any other relevant information. This is then processed by the scheduling team, following which, patients are added to an electronic scheduling diary which the relevant clinical teams have access to. Any digital communication is saved on the electronic diary.

The Operational Manager for the General Surgery Directorate has commenced a 4-month audit of the new and current process for the scheduling of colorectal cancer patients and this will include the introduction of an excel spreadsheet which collates all referrals for the upcoming 3 months, and which must correlate with the information held on CWS. This is another way to ensure any missing referrals are picked up quickly.

The Stroke Consultant and ward team have recently undergone Carotid Endarterectomy training, as referenced in the NICE guidelines 128; section 1.2.4. It is planned that this will be repeated on an annual basis. Direct contact for advice with the local Vascular surgical team on both the Royal Gwent and Nevill Hall Hospital sites has also been put in place.

The Medicine Senior Nursing Team will be monitoring concerns to review any themes relating to documentation and communication. In relation to audits of use of the "This is Me" documentation, staff will regularly check that the use of the booklets align to patients identified on the patient board as having a cognitive impairment.

Care After Death Team (CAD) webpages have recently been updated to include links and information to the CAD Team, Medical Examiner Service, Coroner, Registrar etc. In addition, a simplified leaflet has been drafted which reflects the updated CAD pages and will be available on wards, reception areas, and general offices. The distribution of the new, simplified leaflet will be Health Board wide by the end of December 2023. These actions will hopefully improve ease of access to important information for those who have been recently bereaved.

The Endoscopy Department no longer use paper referrals. All requests are now actioned via an electronic referral process preventing delays and the risk of paper referrals being mislaid.

Redress

Redress is a range of actions that can be taken to resolve a concern.

- An apology and explanation of what happened;
- and/or an offer of treatment/rehabilitation to help relieve the problem;
- and/or financial compensation. In these cases there has to be consideration of Breach of duty and Causation.

Any health professional has a duty to treat patients properly and this is known as 'the duty of care'. A clinician is expected to offer a diagnosis and treatment which a reasonably competent professional acting in this area would have provided. It therefore has to be proved that the majority of reasonably competent professionals would not have acted in this way. Even if a breach of duty of care is established, causation and damage also need to be established.

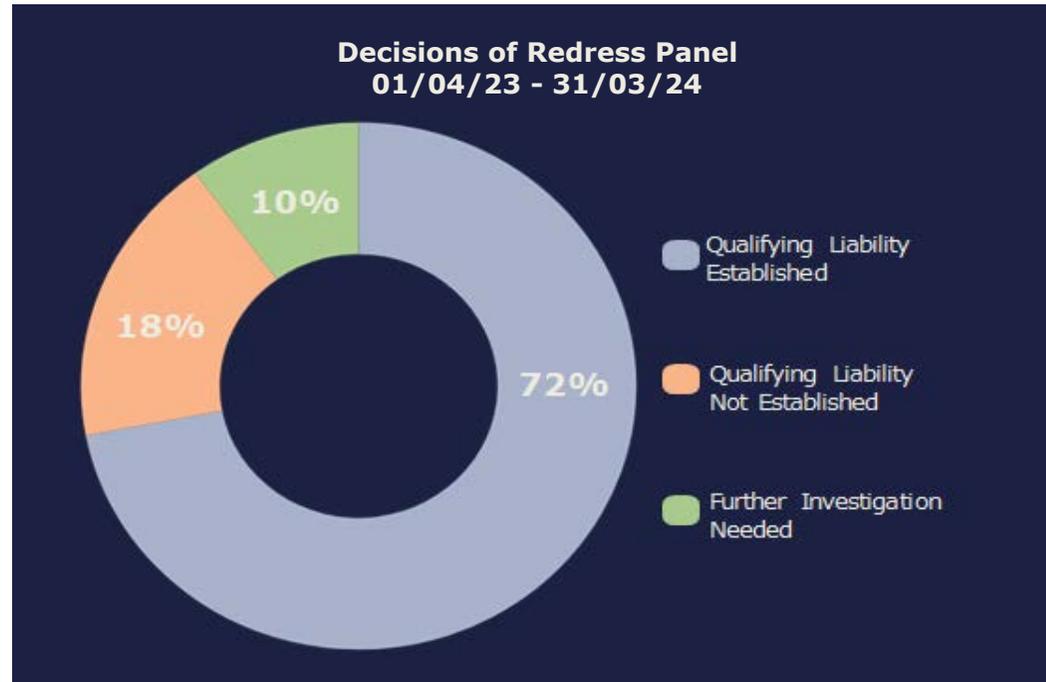
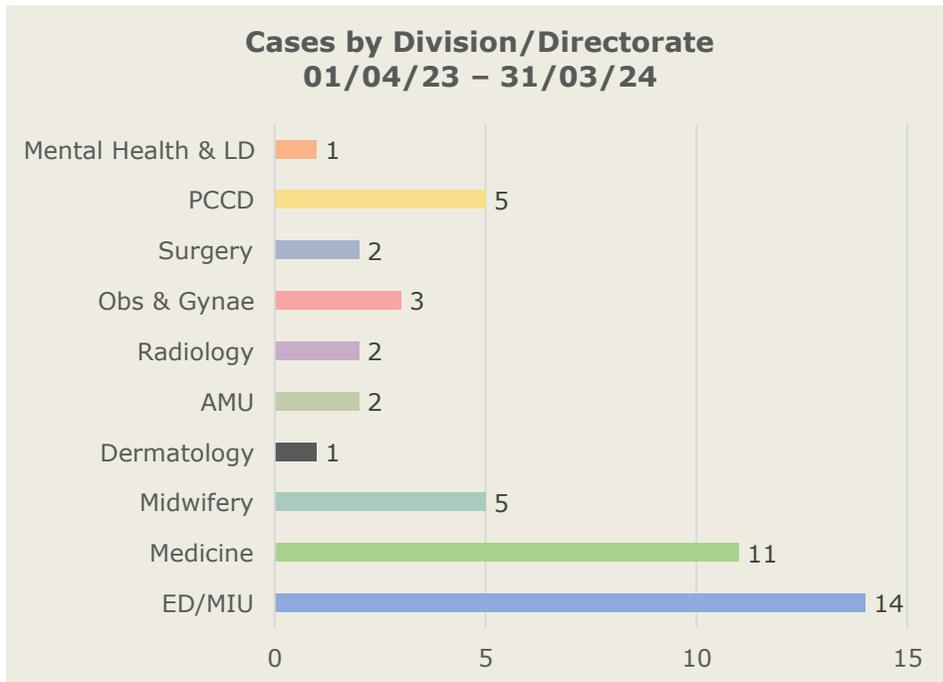
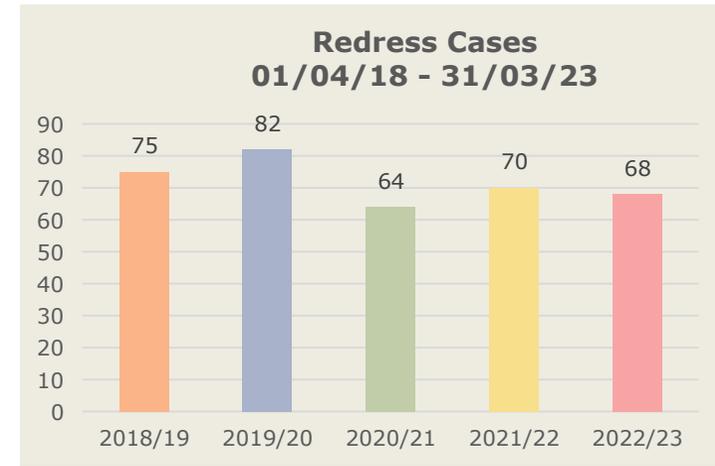
If the patient did not sustain injury as a result of the breach of duty, there is no qualifying liability. There must be a causal link between the breach of duty and the damage complained of by the patient.

Qualifying liability refers to determining whether a particular act or omission by the Health Board has caused harm or damage to a patient.

The Health Board's Redress Panel continues to assess and determine concerns where potential failings and resulting patient harm have occurred. This is a high-level panel with quorate membership for Medical, Nursing and Therapies Executives or nominees, together with Chair. In addition to determinations of qualifying liability, there is a strong emphasis on ensuring that learning and actions have taken place to try to prevent future patient harm. Areas of good practice are also highlighted and shared.

10 Panels have been convened over the course of the year on a monthly basis. This year has also seen the introduction of extra-ordinary panels as a mechanism to bring and determine cases where there has been an urgent need for consideration.

Redress



Themes of Cases Taken to Redress Panel

The majority of cases concerned issues of clinical treatment and diagnosis (including delays), although 25% down on the same category of cases in the preceding year. Whilst again the largest class of cases, there continues to be a very mixed picture in the detail of the cases, spread over multiple Divisions/Directorates, sites and timescales, with no evident area of concern or outlier identified.

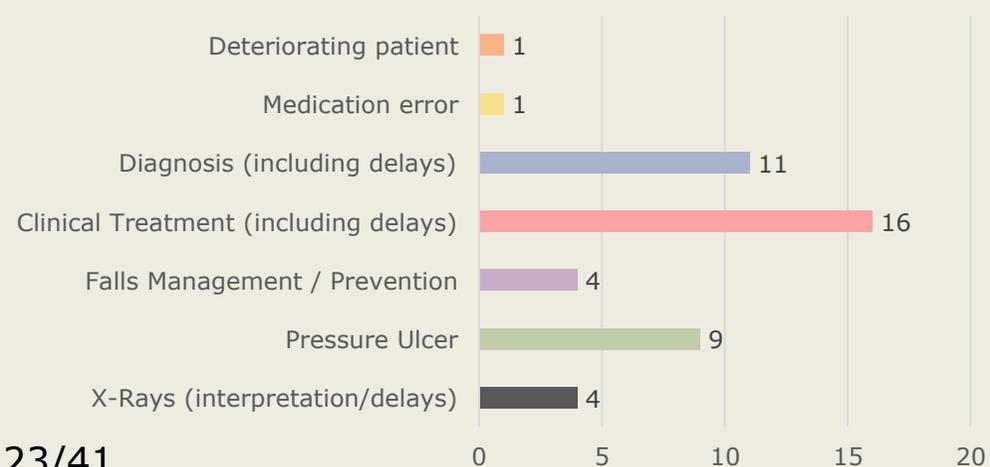
Only 4 cases involving falls prevention and management feature, these are down in number for the fourth year in a row, and over 50% down on the preceding year.

Pressure ulcer cases were down slightly on the year before, with figures overall below 10 in number

Issues with x-ray interpretation/delays have dropped nearly 75% on the preceding year, a significant drop in this category of case.

In summary, whilst overall case numbers are down, all categories of cases are lower in number than seen the preceding year.

Cases by Category



Learning from Redress

DIATHERMY SAFETY IN THEATRE

Diathermy Safety training delivered to theatre practitioners across sites following a patient safety incident. Incident shared with local and wider Theatre Staff and Theatre Users. Standardised method of control adopted to store instrument safely. Theatre Bulletins were developed and shared.

DETERIORATING PATIENT IMPROVEMENT CYMRU INITIATIVE

The Health Board continues to participate in a substantial piece of work around deteriorating patient with Improvement Cymru and the Institute for Healthcare Improvement (IHI).

Each Health Board in Wales is part of the Safer Care Collaborative which aims to demonstrate significant improvement and performance across four workstreams, one of which is safe and effective acute care and ensuring structures and processes are robust in response to acute deterioration or concern.

GROWTH SCANS IN PREGNANCY

GAP & GROW training is now incorporated into mandatory study sessions for all midwives. Compliance is monitored via the senior midwives meeting.

GAP & GROW 2.0 package was implemented in 2023 and this aligns to the new digital maternity records system 'Badgernet'. The 2.0 package enables online plotting for greater accuracy and provide prompts for referral if baby's growth is slow or static.

DISSEMINATION OF LEARNING

A number of tools have been deployed to help share and maximise the dissemination of learning from Redress cases across the Health Board, including Education and Recommendations after Significant Events (ERASE) bulletins; case presentations to local Clinical Governance days; issuing of ABU Internal Alerts, and Health & Safety Information Sheets.

Claims

ABUHB Legal Services oversee the management of clinical negligence claims, personal injury claims, concerns progressed under the PTR Redress Scheme, and Coroner inquests.

Clinical Negligence and Personal Injury are indemnified activities under the Welsh Risk Pool all-Wales indemnity scheme.

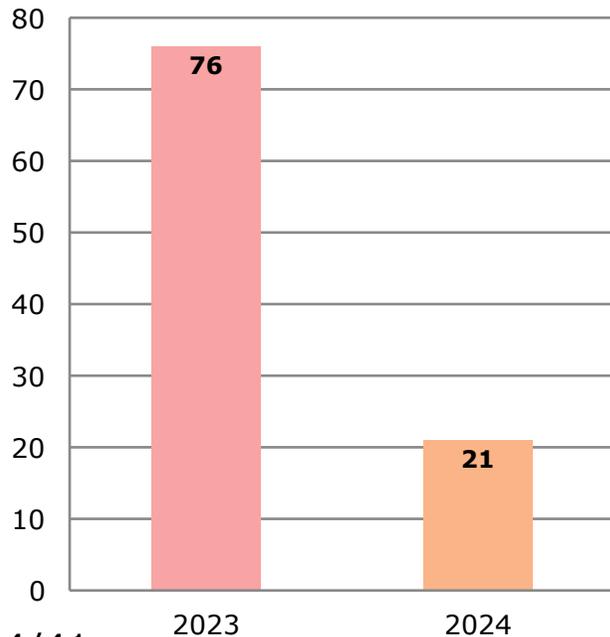
As at 31 March 2024 the Health Board had a combined **436** live claims under management.

Clinical negligence claims remain very steady at **368** with preceding year at 369.

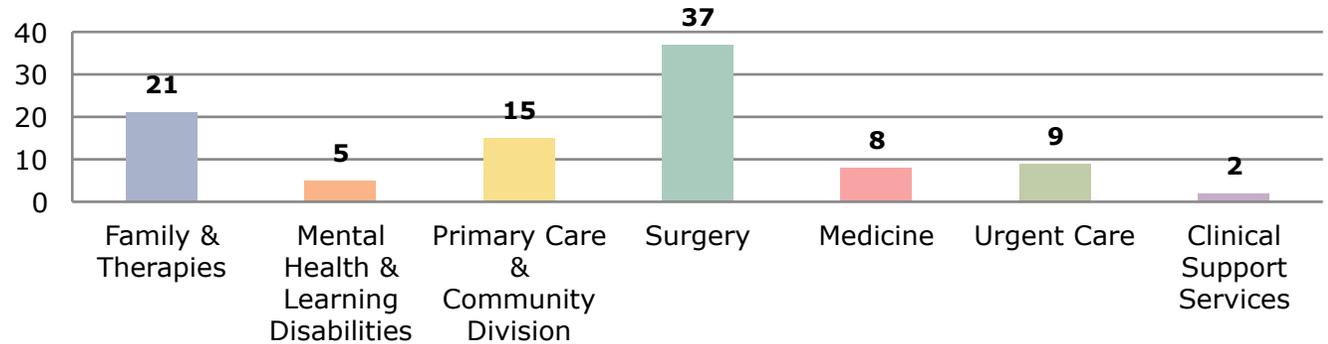
Personal injury claims continue a year-on-year 15-year downward trend. Total live claims were well under 100 at **68** claims, of which 38 were received in the last 12 months.

Clinical Negligence

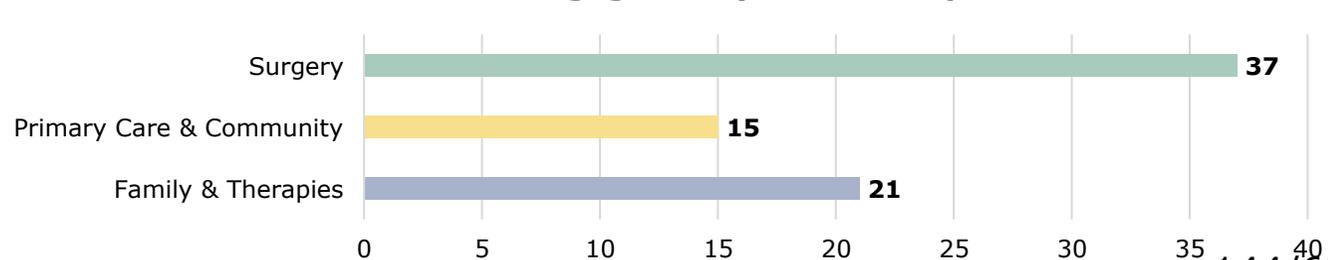
Clinical Negligence Claims Received



Clinical Negligence by Division



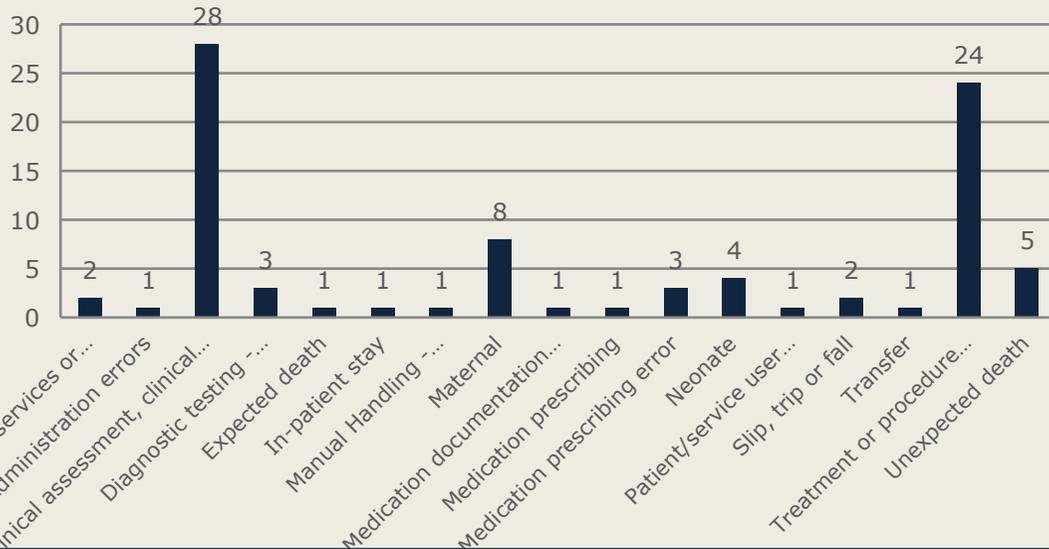
Clinical Negligence by Division Top 3



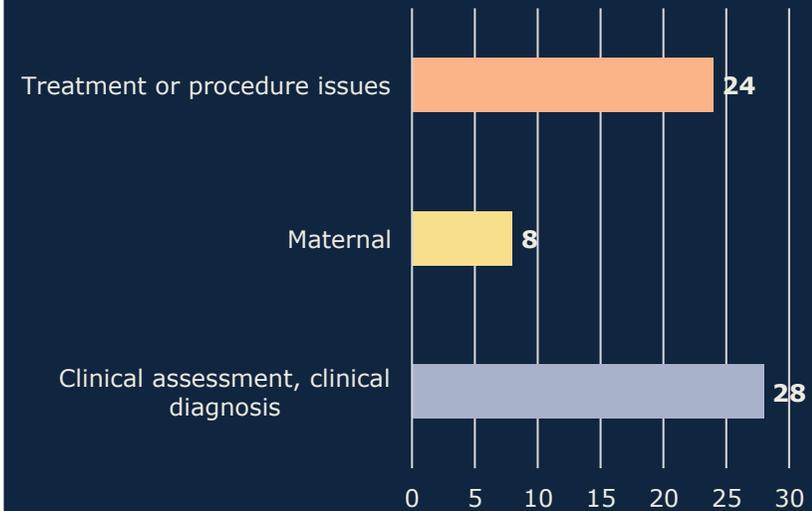
Clinical Negligence

Claims encompass Clinical Negligence and Personal Injury matters. The Health Board aims to provide people with the best level of healthcare and treatment possible and most people do not experience any difficulties. But occasionally things can go wrong and this may result in adverse outcomes for patients. This may then lead to people seeking out independent legal advice in relation to the care they received from the organisation.

Clinical Negligence by Category



Clinical Negligence by Category -Top 3



Themes Raised in Claims

Claims are spread across Divisions and Directorates. Numbers are higher as expected in higher risk areas, including surgery, trauma & orthopaedics, urgent care, midwifery and obstetrics.

Whilst clinical treatment remains the largest class of cases, there continues to be a very mixed picture in the detail of the cases, spread over multiple Divisions/Directorates, sites and timescales, with key themes:

Delays: Diagnosis / Treatment

Misdiagnosis

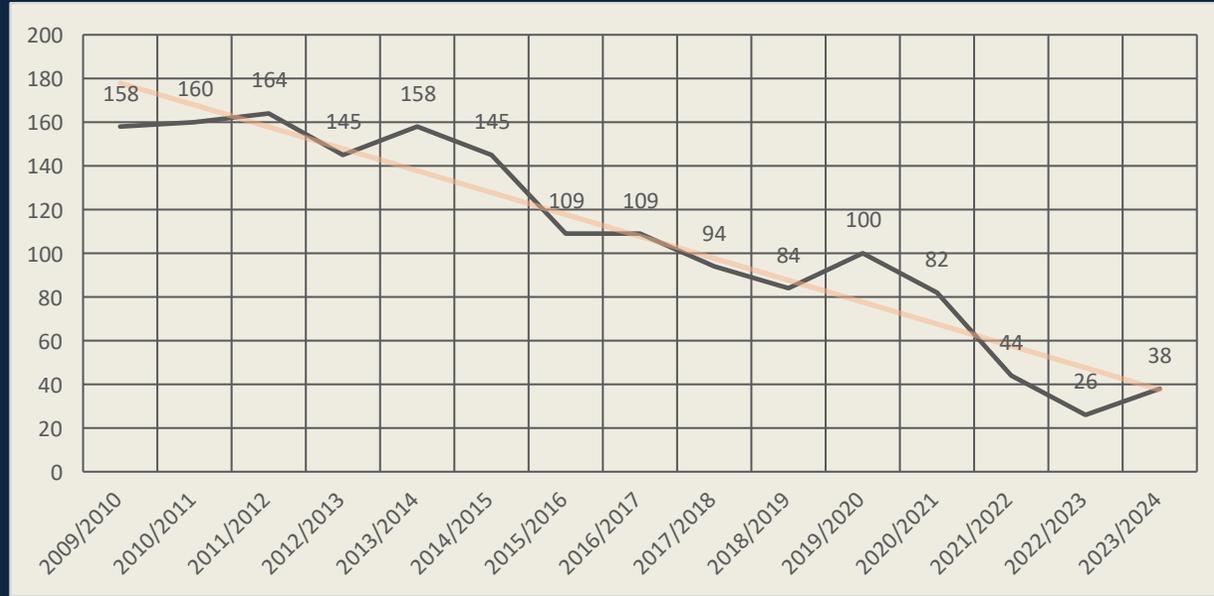
Deteriorating Patients / Observations

X-ray: Reporting & Interpretation

Procedure / Technique / Human Error

Personal Injury

Personal injury claims continue a year-on-year 15-year downward trend. Total live claims were well under 100 at **68** claims, of which 38 were received in the last 12 months. By comparison, 15 years ago the Health Board was running in excess of 160 live claims. Whilst some year-on-year variation, the linear line is a very clear downward trend. This is testament to the commitment and work of multiple teams across the Health Board to mitigate and prevent personal injury incidents on our Health Board sites. The introduction of Safer Sharps has been a significant factor.



Learning from Claims

Clinical negligence and Personal Injury claims require submission of 'Learning from Events Reports' (LFER) to the Welsh Risk Pool. A Divisional Learning from Events Report (LFER) is produced for each case where failings in care identified, setting out the key 'issues' identified from the investigation and the resulting 'actions' by way of learning, improvement and assurance of all actions taken and to be taken to prevent future harm.

Learning is at the heart of all claims investigated by the Health Board, with local Divisional teams responsible for the development of Learning from Events Reports, the assurance of actions taken, and onward future monitoring, with support from the Divisional senior leadership team and Divisional Director final approval and sign off of LFER's.

LFER's undergo several stages of vigorous scrutiny and assessment by the Welsh Risk Pool, including clinical and peer review via a 'Learning Advisory Panel' (LAP) to provide robust assurance and approval of the Health Board's actions taken, improvements and learning.

Learning from Claims

CLINICAL SUPPORT SERVICES: RADIOLOGY

Case involved a never event where a spinal nerve root block injection was administered on the patient's wrong side, patient injected on the right side instead of the correct left side. Root cause identified as human error but steps put in place to reduce risk of re-occurrence include amendment to the Surgical Safety List for Radiological MSK so it now includes a "stop before you block" check and also a "simulation before block" check. In addition "stop before you block" posters displayed in all areas where blocks are administered.

MINOR INJURIES UNIT TRAINING ON FRACTURES

To aid correct diagnosis of fractures MIU guidance for assessment of neck injuries produced and published with focus on improving the selection of patients who require imaging, noting the challenges in clinical assessments of older patients. ENP's received updated neck injury training at ENP teaching session, and communication issued.

HEALTH & SAFETY ALERT TRIPPING HAZARDS

A Health & Safety Department Alert has been issued with regard to identified tripping hazard to remind staff of the safe management of bed and air pump power cord cables to keep staff safe from tripping and electrocution risks.

IMPROVED COMMUNICATION IN THEATRE

A swab was accidentally left behind during insertion of grommets under general anaesthetic. One identified issue was poor communication by staff in theatre with swab counting. Since index event Theatre teams throughout ABUHB have implemented the new revised National Safety Standards for Invasive Procedures (NatSSIPs 2), which were published by the Centre for Perioperative Care in January 2023 and designed to reduce misunderstandings or errors and to improve team cohesion.

IMPROVED ECHOCARDIOGRAM REFERRALS

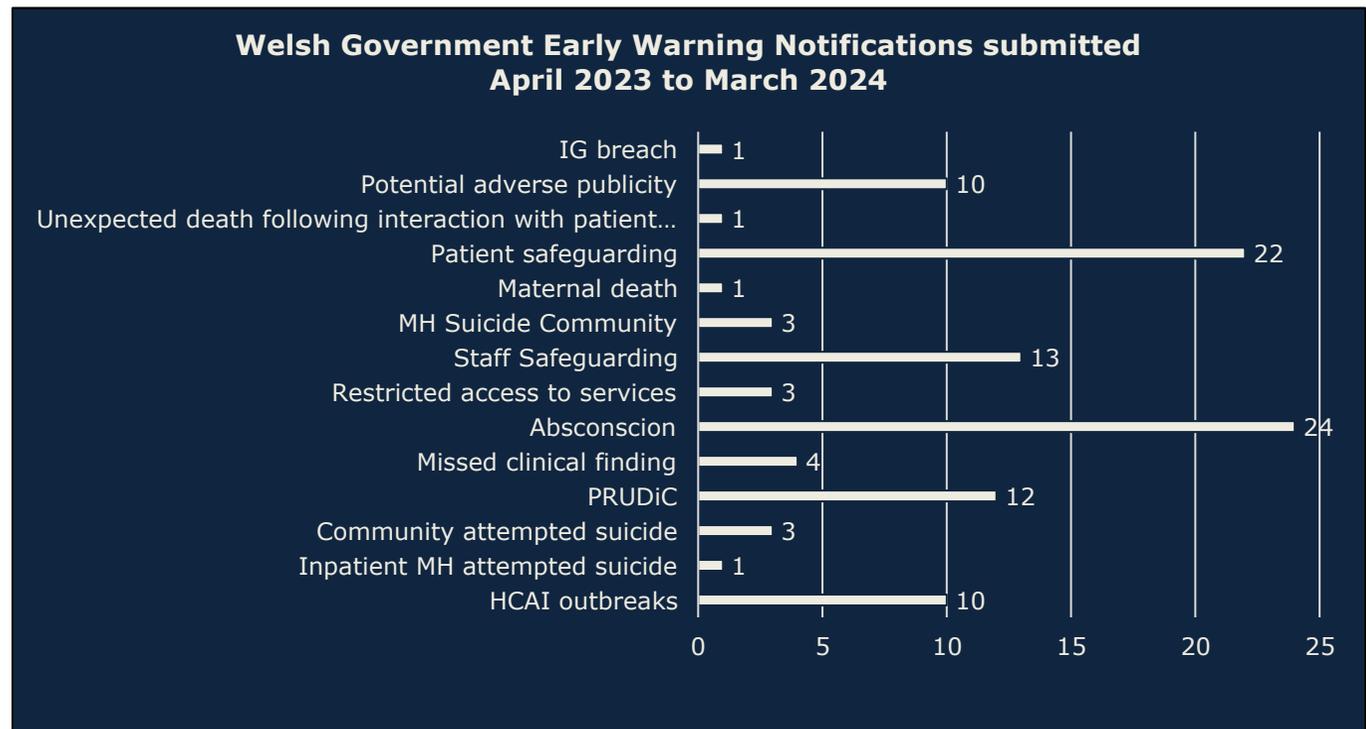
Significant service improvements following a claim concerning an echocardiogram referral. e-referrals are now live for echocardiogram referrals at the Health Board. All echo physiologists now undergo a formal induction process on joining the Health Board and a 'Red flag' echocardiogram reporting system is in place.

Early Warning Notifications (EWNs)

Welsh Government Early Warning Notifications (EWN) (previously No Surprise Reporting) is a communication function established by Welsh Government. Its purpose is to provide rapid information to Welsh Government on a range of issues, which may or may not relate to patient safety incidents. The EWN process is independent of the incident reporting systems, which are overseen and managed by the NHS Wales Executive. For clarity, where a patient safety incident meets both the requirements of a EWN and a NRI, then both processes will be followed. All Health Boards within Wales are required to alert Welsh Government of any incidents using an Early Warning Notification (EWN) which may trigger media attention, unexpected child deaths (PRUDiC) and incidents of infection outbreaks within a health care setting (i.e. Covid-19, C Difficile).

During this reporting period a total of 108 Early Warning Notifications (EWN's) were submitted to Welsh Government. EWNs are submitted to Welsh Government when it is recognised they need to be alerted to an issue or concern or they require prior warning that an issue might relate to the following:

- Has the potential to affect a number of patients/ staff/ communities etc.
- Has a significant impact on service provision
- May have an adverse impact in the media
- Might cause national or political embarrassment
- Following an Inquest which has resulted in a Regulation 28 or public interest in a Public Services Ombudsman for Wales (PSOW) report
- A positive good news story



Patient Safety Incidents

From 1 April 2023 to 31 March 2024 a total of **24958** (a 9% increase from 2022-23) patient safety incidents were reported via RL DATIX across all ABUHB sites.

Top Three Patient Safety Incident Themes

1

UNEXPECTED ADMISSION TO NEONATAL INTENSIVE CARE UNIT (NICU)

121 cases. This was up from 62 in 2022/23. However, of the 121 PSIs reported via RL DATIX, none of these were categorised as moderate or above harm post-investigation.

2

INPATIENT FALL WITH FRACTURE

Continued focused work continues through education of the Falls Policy for Hospital Adult Inpatients and through learning identified by the Falls and Bone Health Steering Group.

3

MENTAL HEALTH SERVICE USER UNEXPECTED DEATH IN THE COMMUNITY

These cases pertain to service users open to Mental Health Services in the last 12 months are reviewed at the Mental Health and Learning Disabilities Safeguarding panel weekly.

Patient Safety Incidents (PSI) resulting in Moderate harm and above in the reporting period now undergo scrutiny by the Clinical Executives on a weekly basis to determine level of investigation required (divisional or corporate investigation).

Nationally Reportable Incidents (NRI's)

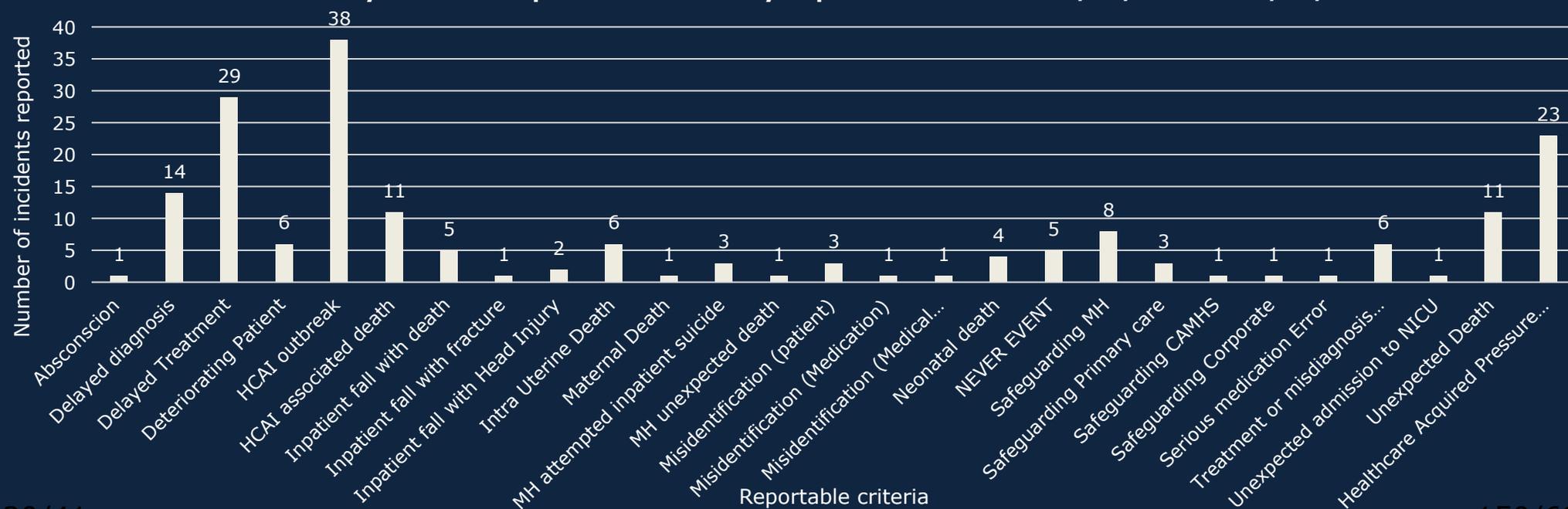
Patient Safety Incidents that meet the reporting criteria of the National Reporting Framework are reported to the NHS Executive as Nationally Reportable Incidents (NRI's)

From 1 April 2023 to 31 March 2024, 187 incidents were identified as meeting the reporting criteria of the National Reporting Framework. This demonstrates a significant rise in reported incidents in comparison, to the reporting period of 1 April 2022 - 31 March 2023 33 PSIs were reported.

Since November 2023, all Intrauterine Deaths (IUDs) of 22+ weeks gestation meeting the Mothers & Babies: Reducing Risk through Audits & Confidential Enquiries UK (MBRRACE-UK) reporting criteria are now reportable, a change in policy from 22-23. These account for 11 submissions.

In addition, all Health Care Associated Infection (HCAI) outbreaks and HCAI associated deaths (49) are now reported as National Reported Incidents to the NHS Executive, rather than being reported previously as Early Warning Notifications (EWNs) to Welsh Government.

Patient Safety Incidents reported as Nationally Reportable Incidents 01/04/2023 to 31/03/2024



Never Events

Never Events are one of the categories of Patient Safety Incidents that are always nationally reportable, even where no harm has occurred. These are defined as `

"Patient safety incidents that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers".

Reduction in Never Events

Five Never Events were captured in the reporting period. These included 2 incidents relating to retained foreign bodies in Theatre (retained swabs), 1 relating to wrong site surgery (wrong site dermatological biopsy), 1 wrong site surgery (wrong site anaesthetic block) and 1 incident relating to the transfusion of ABO incompatible blood products. There has been a continued downward trend in Never Events at the Health Board, down from 10 Never Events in 2021-22 and 7 in 2022-23.

Never Events April 2023 to March 2024



Wrong Site Surgery



Retained Foreign Body



Transfusion of ABO incompatible blood product

Learning & Improvements from Patient Safety Investigations

Ophthalmology

There has been an increase in delayed treatment PSIs in relation to Ophthalmology patients in the reporting period. These PSIs are predominantly glaucoma patients who have been lost to follow-up due to lack of senior reviewers. As such there have been 18 PSIs in this category.

These PSIs are subject to local department harm review by Governance and Clinical Teams

In response to these incidents, a number of improvements have been made to mitigate future harm and improve and optimise capacity:

- A diagnostic hub was funded and opened in late January 2024, increasing capacity, offering 8 sessions per week and will continue to review patients.
- A Second Glaucoma Consultant post
- Exploration of training of community optometrist to support the service.
- Redistribution of directorate budget to allow for a part-time optometrist to be employed to see new (and follow-up) glaucoma patients.
- Stratification tool has been successfully implemented, allowing for those being virtually reviewed to also be risk-stratified.
- Implementation of in- house scanning to ensure high risk patients are booked into consultant led clinics in a timely manner with all patient related information available.

Mental Health & Learning Disabilities

During 2023/24, the Mental Health and Learning Disability Division has developed data in relation to unexpected deaths of patients known to the Division. Data from September 2023 required further exploration, and this has led to the development of a more robust database. The information within the database was analysed and the conclusion has been included in the Health Board Learning from Death report.

Awareness raising sessions have been held in relation to actual risk factors evidenced within the National Confidential Inquiry into Suicide and Self-Harm (NCISH).

The Adult Mental Health Directorate have taken part in a national programme of development of person-centred safety planning. Person centred safety planning in mental health services encourages to work collaboratively with service users, patients and where possible people that matter to them, to develop their knowledge and confidence to try out different strategies to help them feel safer in times of crisis or distress. There is a growing body of evidence supporting the benefit of person-centred safety planning on service user outcomes, in addition to improvements to service user experience. In March 2024, early feedback from patients and staff was positive.

The Mental Health and Learning Disability Division have developed 'Top Tip Tuesday' posters to aid the dissemination of learning from Patient Safety Incidents throughout the Division and to date the topics have been WARRN risk formulation, section 115 meetings, documentation of assessments, physical health monitoring, resuscitation procedures, risk management and rationale for discharge being documented when patients did not attend appointments. The posters are distributed via e-mail but are displayed on staff notice boards, backs of toilet doors etc. The use of these has been evaluated and most of the respondents to the survey found the posters informative.

Learning & Improvements from Patient Safety Investigations

Radiology

There were 6 PSIs reported as National Reportable Incidents in relation to missed radiological findings.

The Executive Director of Therapies and Health Sciences is leading a focused review to identify actions to minimise future harms including the introduction of a red flagging radiology Standard Operating Procedure through which Radiology will add significant incidental findings to reports, and email the referring clinician to alert them, as an additional safety net.

Theatre Safety

Theatre Safety improvement workstreams are ongoing to ensure that Theatre Safety systems are enhanced. These currently include –

Supporting the ABUHB roll out of National Safety Standards for Invasive procedures (NatSSIPS)

- Updated World Health Organisation (WHO) Surgical Safety Checklist to incorporate NatSSIPS (8 Sequential Steps).
- NatSSIPS is covered during staff induction sessions and rolling audit day training.
- Ongoing audit of compliance with WHO Surgical Safety Checklist.
- Current workstream for standardisation for surgical item count boards across all ABUHB Theatre sites.
- Current workstream for standardised Local Safety Standards for Invasive Procedures (LocSSIPS) for regional anaesthetic blocks to be used for these procedures across ABUHB.
- Current workstream to improve and streamline the emergency theatre booking system.
- Team briefings are now captured on the IT system.
- Ongoing 'back to basics' training provided monthly around key theatre safety topics.
- 'Pause for the Gauze' / 'Quiet for Count' project across all theatre sites highlighting the importance of quiet focus time for surgical counts.

Human Factors and Quality Improvement (QI) workstreams

- Regular human factors scenarios including team debriefs and identifying areas for improvement/change.
- Capturing learning from human factors scenarios and sharing summaries and action plans – ensuring learning is shared with the wider teams.
- Audit day training has been re-aligned to allow spread of human factors training to other theatres sites
- Ongoing collection of Safety Culture & Psychological Safety surveys of staff.
- Regular staff surveys asking for ideas for quality improvement and exploring projects.
- Building QI coaching capacity within Theatres.

Patient Safety Team - Successes

The corporate Patient Safety Incident (PSI) Team oversee the investigation and management of Patient Safety Incidents where patient harm is moderate, severe or catastrophic.

The Team have enjoyed a number of successes over the 2023-2024 period: -

- ABUHB Patient Safety Incident Reporting & Management Policy updated and refreshed to map to current best practice, patient and family feedback and the National Reporting policy
- Revised PSI Reporting template incorporating current best practice in Human Factors methodologies
- Revised PSI meeting Agenda, with Actions and Outcomes focus, moving away from meeting minutes
- Patient safety incidents information leaflet updated to align to Duty of Candour.
- 'Time Out' improvement focussed sessions with the team
- Successful reduction of NHS Executive historical closures
- Welcomed new colleagues into the team
- Continued to train new organisational investigating officers.
- Providing 1-2-1 support for Investigating Officers
- Contributing bi-monthly National Patient Safety Forum to share learning and network, including presenting in this forum.
- Presenting at Deteriorating Patient Forum.
- Positive feedback from HM Coroner with regards to report quality.

Duty of Candour

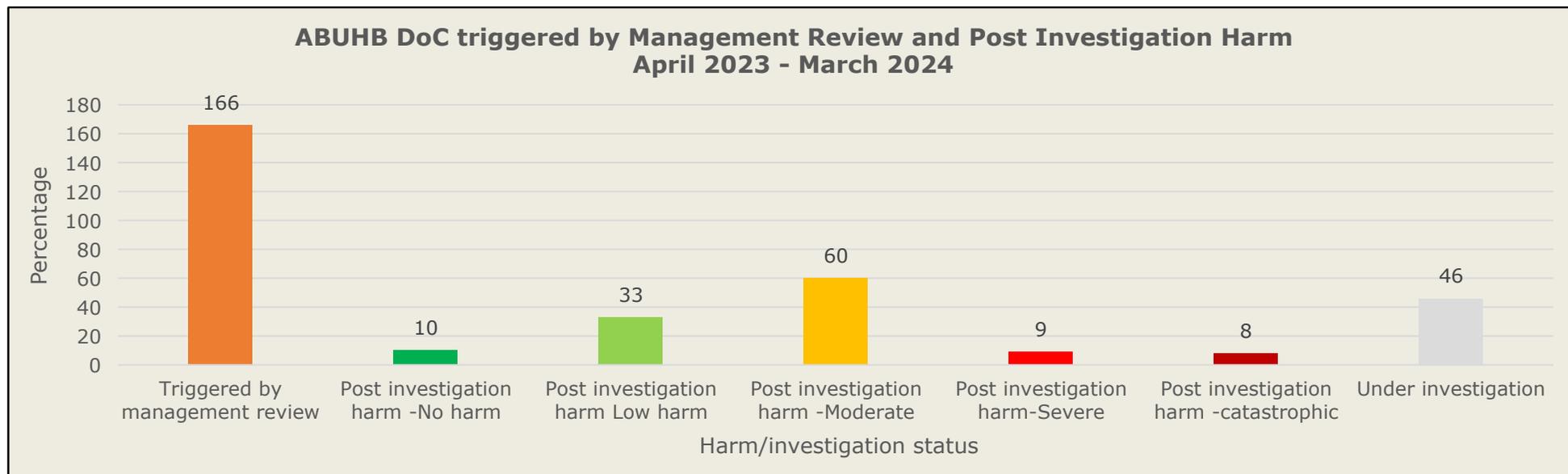
The Duty of Candour came into effect on 1 April 2023 with statutory provisions set through the Health and Social Care (Quality and Engagement) (Wales) Act 2020.

The organisational duty on all NHS bodies requires incident reporting, management and investigation into the circumstances of a notifiable adverse patient safety event to be undertaken in an open and timely manner, including any actions to be taken under the Concerns, Complaints and Redress Arrangements (Wales) Regulations 2011.

The Duty of Candour is triggered when a review of an adverse patient safety event identifies that the service user experienced, or could experience, unexpected or unintended harm that is more than minimal (moderate, severe, death), whilst in receipt of NHS funded care and where the provision of health care was, or could have been a factor in that harm occurring.

In preparation for this transition the Health Board reviewed its management of incidents, systems and processes to align to the requirements of the Duty of Candour to minimise disruption to service user experience.

Following the DoC triggered by management review of incidents, there were 166 incidents in the period, The chart below breaks these incidents down by level of Harm:



Out of these 166 triggering incidents, 44 were then categorised as no/low harm, 60 moderate and 17 severe/catastrophic . Whilst 46 are still under investigation.

Duty of Candour

The harm categorised in the first quarter demonstrated that we required additional education on the harm categories, particularly in distinguishing between actual and healthcare-related harm in lower harm incidents. This is reflected in the feedback from the Divisional Duty of Candour leads who have advised that, when the DoC was first introduced, those submitting and reviewing Datix incidents often found it difficult to distinguish between actual harm and healthcare related harm. The tide is turning and understanding is increasing as this agenda is discussed in multiple forums across the Health Board, thanks to education and support, as well as collaboration with the Divisions and the administrative head within the PSI Corporate team.

Next Steps for 2024/25

Encourage all staff to complete the Duty of Candour (DoC) training on ESR.

Quality, Patient and Safety leads to run further sessions on DoC.

Use incident reports and investigations to identify trends and areas for improvement.

Implement changes and improvements based on lessons learned.

Foster a culture of continuous learning and improvement.

To produce quarterly data for divisional review at the QPS, Learning and Improving meetings.

Learning and Improvement to be discussed at Patient Quality and Safety Learning and Improvement Forum.

Medical Examiner Service within the Health Board and Mortality Review (MR) Screening Panel

Overview:

The Medical Examiner (ME) Service is hosted by NHS Wales Shared Services Partnership and provides an independent scrutiny of deaths in Wales (a similar system is in place in NHS England). This scrutiny is undertaken by a Medical Examiner (ME), who is an experienced doctor with additional training for this role. They are assisted by a Medical Examiner Officer (MEO).

The main role of their service is to; improve the quality of death certification, reduce and avoid unnecessary stress for the bereaved and to strengthen safeguards for the public.

The ME service ensures that an accurate cause of death is recorded. They identify any concerns surrounding the death itself which can then be further investigated by the care provider or coroner if required. They also take the views of the bereaved into consideration. Following this independent review of the death by the ME, the Health Board receives a referral if further action is needed. This provides details of the concern raised and/or highlights any learning for the Health Board with regards to the death.

The scrutiny of deaths by the ME Service began in January 2021 at Aneurin Bevan University Health Board. This process started slowly at each hospital and has gradually spread over two years. All deaths are now reviewed at all sites (excluding maternity, paediatric and neonatal). Approximately 25% of total deaths are referred back to the Health Board for further action by the ME. The Medical Director's team sift and sort the ME referrals and prioritises what needs to be taken to a Mortality Review (MR) Screening Panel.

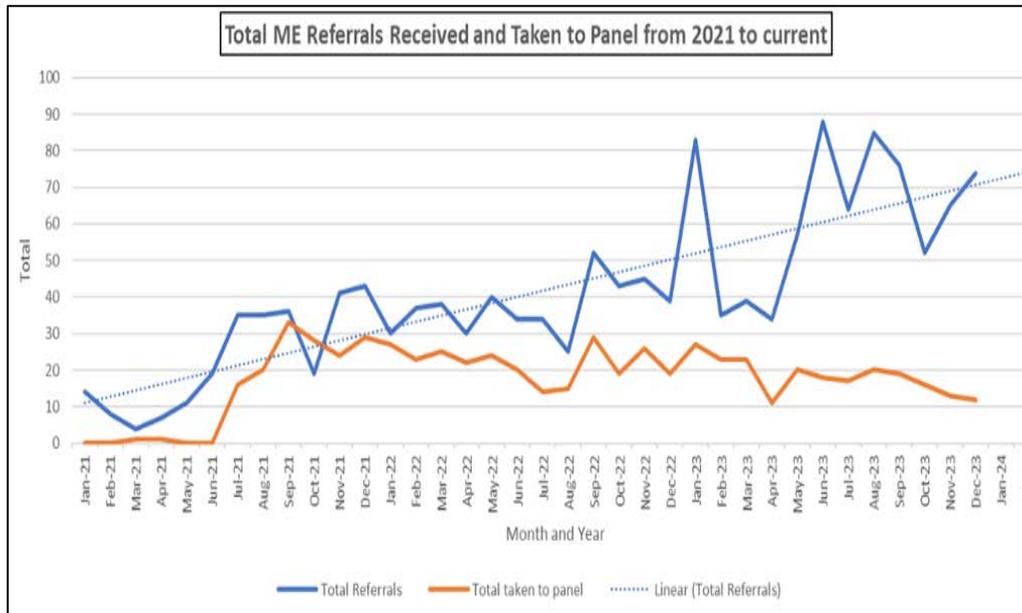
In April 2023, Welsh Government passed legislation for the scrutiny of all deaths (excluding direct coronial cases) by the ME Service. In June 2024 the ME Service expanded their reach to include scrutiny of community deaths throughout Wales. This process is being reviewed ready for implementation by the Health Board. There is no clear timeline at present for provision of ME scrutiny for deaths in the maternity, paediatric and neonatal areas.

Medical Examiner Service within the Health Board and Mortality Review (MR) Screening Panel

Current Work:

Referrals received from the ME that require a review are assigned to a member of the Health Board's Mortality Review (MR) Screening Panel. This is a multidisciplinary group with cross divisional representation that meets weekly. An assigned panel member reviews and presents the case to the group. The panel establishes whether further investigation is required. These actions are then clarified and sent out to the relevant team or clinician for completion.

Throughout 2023/2024 the Health Board's MR Screening Panel has continued to grow and adapt to reflect the expanding nature of the service. The chart below illustrates the increase in the number of referrals received by the Health Board per month since the commencement of the ME Service in 2021. The MR Screening Panel has adapted to reflect the rise in referrals over the past three years.



In April 2023 the Health Board released its first MR Screening Panel Newsletter which focused on themes from the ME referrals and learning. An additional newsletter followed in Spring 2024. Both provided an opportunity for the MR Screening Panel to share information about the ongoing work.

During 2024, the panel membership for level 2 and 3 reviews has increased. Expanding the multi-disciplinary membership of the group allows for more detailed and well-rounded scrutiny of the referred cases.

Medical Examiner Service within the Health Board and Mortality Review (MR) Screening Panel

Future Goals:

Aims for the remainder of 2024 include: -

1. Further expansion of the MR Screening Panel service to adapt and include the deaths in the community, resulting in a further increase in referrals received.
2. Continuing with the biannual newsletter, providing a valuable opportunity for shared learning and themes from ME referrals received.
3. Sharing good news. The ME referral letters often provide positive feedback about the care received for their loved ones, from the bereaved. Going forward we will continue to share these compliments with the clinical areas.

Learning:

Themes are extracted from the ME referral letters that the Health Board receives to inform learning and improvement. Currently one of the most common reasons for ME referrals relate to completion of DNACPR forms. It has been found that forms are not being countersigned in part 6 of the DNACPR form. This theme has been linked into the recent Healthcare Inspectorate Wales report on DNACPR. A memo has been produced to remind staff on the actions needed to be taken to complete DNACPR forms accurately. There is also signposting to the All-Wales DNACPR Policy and information on a training video and highlighting the importance of mental capacity assessment when considering resuscitation status.

There have been a number of concerns related to communication (most frequently relating to the bereaved). We are reviewing how feedback (both good and bad) can be received and captured into the Health Board to share themes and cascade learning. The newsletter that has been produced helps to capture and disseminate the learning and will be produced quarterly.

Conclusion

The 2023/24 year has been challenging for the Corporate Putting Things Right Team with a number of challenges within and external to the team.

Despite the challenges, there has been a number of areas of success:

- Redesign and delivery of effective Concern and Investigating Officer training to an evolving and agile workforce.
- Improvements in the complaints management process and improvements in the quality of complaints.
- Completion of the Covid-19 Investigation requirements.
- The roll out and operationalisation of the Patient Advice and Liaison Service Team in November 2023 – this service seeks to intervene early and resolve concerns at the earliest opportunity and supports both in-patients and out-patients.
- The establishment of the Patient, Quality, Learning and Improvement Forum with the initial scoping meeting March 2024.
- Development of an online complaints form. The new form places emphasis on requesting and capturing the main aspects of the concern and the required details at the outset of patient and family engagement with the Health Board in order to ensure that the complaint response focuses on what matters to the complainant.
- The successful centralisation of the QPS resources within the Nursing Directorate
- A commitment to ensuring the timely and appropriate management of concerns is a priority, this will continue to be a focus for 2024/25 improve in 2023/24, tackling both existing and new challenges.
- Work has continued with the staff, communities and partners to put quality and safety at the heart of everything we do.

Priorities for 2024/25

Priority 1: PTR Regulations and Health Board Concerns Management

1.1 The Putting Things Right Regulations are currently under consultation. The Health Board will ensure we are fully prepared and equipped ahead of any revised guidance being issued, in order to support our staff in the implementation and effective delivery for our communities.

1.2 Early Resolution – Person-centred approach: The Health Board is working to ensure that compliance with the Welsh Government 30-working day target is achieved where possible. Collaborative focus days will be planned to review complex concerns and assist with finalisation and conclusion of investigations.

Internal streamlining of quality assurance processes. This aims to provide a more consistent approach to the investigating and subsequent responses to concerns.

1.3 Meaningful Engagement: An Acknowledgement Team will be introduced, to understand early on what people raising concerns are seeking and what matters most to them and how we can resolve concerns in a timely and meaningful way so that they know that they are being listened to and that their concern is being taken seriously.

We will develop Communication Standards to ensure consistency across all our teams. We will be clear in setting out resolution proposals, actions and agreements and dates for contact and updates.

Priority 2: Improving Quality Patient Safety Experience, Learning and Improving

2.1 Embed the centralised QPS/PTR/QI teams.

2.2 A suite of training is being developed which is specific to complaints/incident investigation. The Health Board also intends to work collaboratively with Welsh Risk Pool colleagues and Networks to devise more readily available and accessible video training in the future. The PSOW will also be supporting bespoke training.

2.3 Patient Safety Incidents (PSI):

- Patient safety incident bespoke 1-2-1 IO training to work with new IO's that have been allocated an investigation.
- Complete toolkit for IO's, Panel Chairs, staff involved in PSI's in whatever context.
- Roll-out amended PSI template to align to DoC.
- Induction and education and reset for PSI chairs.

2.4 The ABCi QI Unit have been working to support the development of Quality Improvement Capability across ABUHB.

In particular, the QI Unit are working with divisional staff to develop Quality Improvement Coaches embedded into clinical teams. To this end, a new Quality Improvement Coach programme has been adapted and tested in ABUHB in conjunction with Improvement Cymru.

The programme will run from Autumn 2024, with 3 cohorts planned each year. Potentially 75 QI Coaches will be trained annually, who can support clinical teams in their improvement priorities.

2.5 Development of the Listening and Learning Framework & Learning Repository: The framework will demonstrate how learning will be identified, stored, triangulated, shred disseminated and implemented in practice to facilitate and embed a culture of appreciative enquiry and continually improving health care services.

Priority 3: Partnership Engagement & Collaborative working

3.1 To work closely with external partners such as the Public Services Ombudsman for Wales, Llais, Audit Wales, Health Inspectorate Wales. We will demonstrate an open culture and always seek out opportunities to learn and improve for our ongoing commitment to the population of the Health Board.

3.2 Work with the Medical Examiner's Office to implement the Death Certification Reform.

3.3 Work with the National Bereavement Leads to implement the GRACE bereavement model.

3.4 Continue to meet with and support patients and carers who have raised concerns, either directly or through third parties, such as Llais and the Ombudsman, to improve listening and learning.

3.5 Introduce People Participation Panels for sepsis and dementia.

3.6 Scope existing End of Life Care services and develop an inclusive End of Life Care Pathway in collaboration with people, staff and partners.

3.7 Hold a Big Conversation around Future Care Planning to raise public awareness.

3.8 Divisions to promote the use of the CIVICA system for timely patient feedback



**CYFARFOD BWRDD IECHYD PRIFYSGOLN
ANEURIN BEVAN
ANEURIN BEVAN UNIVERSITY HEALTH BOARD
MEETING**

DYDDIAD Y CYFARFOD: DATE OF MEETING:	02 September 2024
CYFARFOD O: MEETING OF:	Patient Quality, Safety and Outcomes Committee
TEITL YR ADRODDIAD: TITLE OF REPORT:	HTA Governance Group – Annual Report 23/24
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Peter Carr Executive Director of Therapies & Health Science
SWYDDOG ADRODD: REPORTING OFFICER:	Craig Roberts Assistant Director of Therapies & Health Science

Pwrpas yr Adroddiad (dewiswch fel yn addas)

Purpose of the Report (select as appropriate)

Er Sicrwydd/For Assurance

The HTA Governance Group Annual Report 23/24 is intended to appraise the organisation of the effectiveness of the quality management systems in place across the HTA licenced sectors.

The intention of the report is to provide assurance to the Patient Safety Quality Outcomes Committee that the standards required to maintain the licences are met.

ADRODDIAD SCAA

SBAR REPORT

Sefyllfa / Situation

The organisation holds Human Tissue Authority (HTA) licences for the following 3 sectors: -

- Post-mortem provision – GUH (hub), RGH & NHH (satellite)
- Human application – bone bank - RGH
- Research - RGH

Each licence requires differing numbers of standards to be met, for example, the post-mortem licence requires satisfaction of 72 separate standards

Inspections are undertaken on a random basis but can be triggered following excessive reporting of incidents.

The organisation has a newly formed HTA governance group which met for the first time in February 2023. The group was chaired until recently by the IM for Community, however the term of office has concluded and a replacement chair is in the process of being identified.

The context for the Human Tissue Authority (HTA) Governance Group is the necessity to provide a mechanism for the monitoring, review, and reporting of HTA licenced activity within Aneurin Bevan University Health Board (ABUHB)

Membership of the group includes stakeholders from across the organisation who are involved with licenced activity such as T&O, Pathology, Maternity and the Wales Cancer biobank

Outcomes include

- Ensure that appropriate and timely actions are taken in response to HTA related matters
- Provide a mechanism for the internal review of compliance with HTA requirements and subsequent reporting
- Minutes from the HTA meeting assist in the provision of assurance for the Health Board and Licence Holder (CEO)

This is the first annual report produced by the group

Cefndir / Background

The Human Tissue Authority (HTA) is a regulatory body in the United Kingdom that oversees the removal, storage, use, and disposal of human tissues and organs for a range of purposes. It was established by the Human Tissue Act 2004, which came into force in 2006, in response to scandals involving the unauthorised retention of human organs and tissues.

Overall, the HTA plays a critical role in maintaining public confidence in the ethical use of human tissues and organs in the UK, ensuring that these activities are carried out with respect and dignity.

The HTA regulates six key areas:

1. **Anatomy:** Use of bodies for anatomical examination, teaching, and training.
2. **Post Mortem:** Post-mortem examinations, tissue retention, and disposal.
3. **Public Display:** Display of human bodies and tissue.

4. **Organ Donation and Transplantation:** Organ and tissue donation, retrieval, and transplantation.
5. **Research:** Use of human tissue in research.
6. **Human Application:** Use of human tissues and cells for medical treatment.

All organisations that carry out procedures covered by any of the above areas will be regulated by the Human Tissue Authority

It is recommended that organisation have a governance structure in place to support maintenance of the quality systems which wrap around the regulatory standards

Asesiad / Assessment

A comprehensive overview of regulatory activity is embedded in the main body of the report. The key assurance is the status of the licences within the organisation

Post-mortem sector

GHU (Hub) - Licensed
RGH (Satellite) - Licensed
NHH (Satellite) - Licensed

Human Application sector

RGH (Hub) - Licensed

Research sector

RGH (Hub) - Licensed

Argymhelliad / Recommendation

The Committee is requested to note the contents of this annual report and HTA licence status for assurance.

Amcanion: (rhaid cwblhau)

Objectives: (must be completed)	
Cyfeirnod Cofrestr Risg Corfforaethol a Sgôr Cyfredol: Corporate Risk Register Reference and Score:	Not Applicable
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	4. Dignified Care 6.3 Listening and Learning from Feedback 3.5 Record Keeping 7.1 Workforce
Blaenoriaethau CTCI IMTP Priorities Link to IMTP	Not Applicable Not Applicable
Galluogwyr allweddol o fewn y CTCI Key Enablers within the IMTP	Not Applicable
Amcanion cydraddoldeb strategol Strategic Equality Objectives Strategic Equality Objectives 2020-24	Not Applicable

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	Not applicable
Rhestr Termau: Glossary of Terms:	ABUHB – Aneurin Bevan University Health Board APT - Anatomical Pathology Technician BCP – Business Continuity Plan

	<p>CAD – Care After Death</p> <p>CAPA – Corrective/Preventative Action Plan</p> <p>CAVUHB – Cardiff and Vale University Health Board</p> <p>DI – Designated Individual</p> <p>HTA – Human Tissue Authority</p> <p>HTARI - Human Tissue Authority reportable incidents</p> <p>PD – Persons Designate</p> <p>RAAC – Reinforced Autoclaved Aerated Concrete</p> <p>SAEAR - Serious Adverse Event and Reaction</p> <p>WCB – Wales Cancer Biobank</p> <p>WHSCC – Welsh Health Specialised Services Committee</p>
<p>Partion / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol:</p> <p>Parties / Committees consulted prior to University Health Board:</p>	<p>Human Tissue Authority</p>

Effaith: (rhaid cwblhau)	
Impact: (must be completed)	
Resource Assessment:	A resource assessment is required to support decision making by the Board and/or Executive Committee, including: policy and strategy development and implementation plans; investment and/or disinvestment opportunities; and service change proposals. Please confirm you have completed the following:
• Workforce	Not Applicable
• Service Activity & Performance	Not Applicable
• Financial	Not Applicable

<p>Asesiad Effaith Cydraddoldeb</p> <p>Equality Impact Assessment (EIA) completed</p>	<p>No does not meet requirements</p> <p>An EQIA is required whenever we are developing a policy, strategy, strategic implementation plan or a proposal for a new service or service change.</p> <p>If you require advice on whether an EQIA is required contact ABB.EDI@wales.nhs.uk</p>
<p>Deddf Llesiant Cenedlaethau'r Dyfodol – 5 ffordd o weithio</p> <p>Well Being of Future Generations Act – 5 ways of working</p> <p>https://futuregenerations.wales/about-us/future-generations-act/</p>	<p>Not Applicable</p> <p>Choose an item.</p>



GIG
CYMRU
NHS
WALES

Bwrdd Iechyd Prifysgol
Aneurin Bevan
University Health Board



**Human Tissue
Authority
(HTA)
Committee**

Annual Report 2023/2024

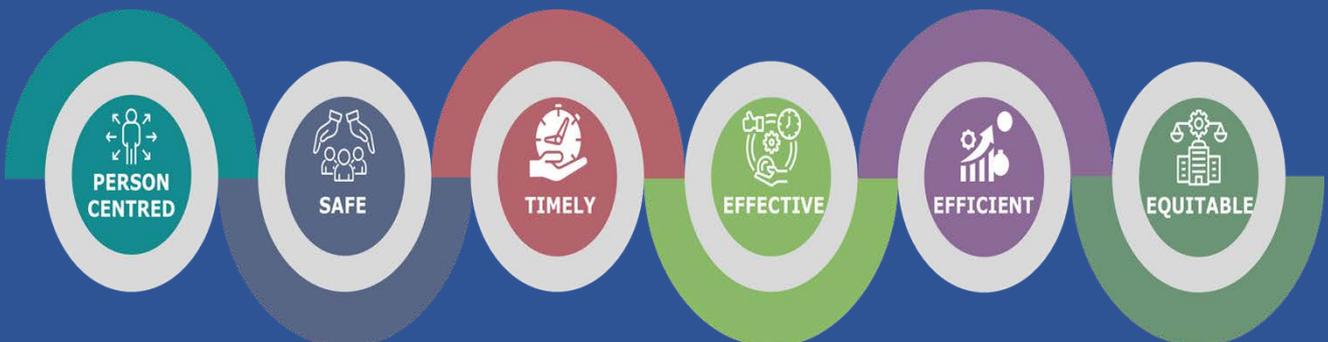


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2023/2024 HTA Committee Annual Report

Introduction

Welcome to the 23/24 Aneurin Bevan University Health Board's Annual HTA committee activity Report.

The HTA committee forms part of the wider Quality Management System for the organisation and is in place to ensure and assure the organisation is meeting and maintaining the standards required to undertake activities involving human tissue removal and retention across several services.

The committee is chaired by an Independent Member of the board with vice-chair responsibility designated to the Executive Director of Therapies and Health Science. Membership is made up of senior stakeholder representation from across the health board including but not limited to: Pathology, Maternity, Trauma & Orthopaedics as well as corporate representation.

The committee sat 5 times during the reporting period

This is the inaugural report from the committee as it was formed in late 2022.

This report is intended to provide an update with respect to the HTA licensable activities undertaken in the organisation, and to provide assurance that our regulatory responsibilities are being met in terms of the HTA standards of practice.

This report covers the financial year from April 2023 to March 2024, however, some of the data used spans parts of the calendar years.

This reporting period has seen significant change in the way care after death (CAD) services are delivered within the healthboard as well as changes in key personnel. It has been a difficult period in terms of mortuary service delivery following high profile HTA reportable incidents, however, thorough investigation of the incidents has led to an improvement plan being effectively rolled out across the organisation.

It should also be noted that the Chair, Independent Member Shelley Bosson, will be stepping down from her term of service at the end of March 2023. The committee would like to thank Shelley for her efforts to ensure that the committee was set-up and effective from inception. The HTA committee will identify a replacement chair and the structure and terms of reference will be reviewed during the next report period.

The organisation remains fully licenced for all HTA licenced activities for the reporting period

Who are the HTA?

The Human Tissue Authority (HTA) is a regulatory body in the United Kingdom that oversees the removal, storage, use, and disposal of human tissues and organs for a range of purposes. It was established by the Human Tissue Act 2004, which came into force in 2006, in response to scandals involving the unauthorised retention of human organs and tissues.

Key Functions of the HTA:

- **Regulation of Activities Involving Human Tissue:** The HTA regulates the removal, storage, and use of human tissue and organs for various purposes, including research, transplantation, education, training, and public display
- **Licensing and Inspection:** The HTA issues licenses to organizations that handle human tissue and regularly inspects these establishments to ensure compliance with legal and ethical standards
- **Ensuring Consent:** The HTA ensures that proper consent is obtained for the removal, storage, and use of human tissue. The principle of informed consent is central to the HTA's operations
- **Regulating Organ Donation and Transplantation:** The HTA oversees the donation and transplantation of organs in the UK, ensuring that the process is ethical, safe, and transparent
- **Public Display of Human Remains:** The HTA regulates the display of human remains in public exhibitions, ensuring that such displays are done respectfully and with proper consent
- **Regulation of Post-Mortem Examinations:** The HTA oversees the conduct of post-mortem examinations, ensuring they are carried out with proper consent and respect for the deceased
- **Guidance and Support:** The HTA provides guidance to professionals and the public on issues related to the handling of human tissues and organs, including best practices and compliance with legal requirements

Overall, the HTA plays a critical role in maintaining public confidence in the ethical use of human tissues and organs in the UK, ensuring that these activities are carried out with respect and dignity.

HTA regulated activities in ABUHB

The HTA regulates six key areas. ABUHB carries out licenced activity under three of these: -

- **Post Mortem:** Post-mortem examinations, tissue retention and disposal
- **Research:** Use of human tissue in research
- **Human Application:** Use of human tissues and cells for medical treatment

Each licence has a designated individual (DI). The DI is the person under whose supervision the licenced activity is authorised to be carried out. They have the primary legal responsibility under section 18 of the Human Tissue Act to secure:

- **That suitable practices are used in undertaking licenced activity**
- **That other persons working under the licence are suitable**
- **That the conditions of the licence are complied with**

Whilst each activity has a designated hub (where majority of work carried out) some smaller premises maintain a satellite licence. These are under the same governance process as the hub and supervised by the same DI. The DI at the hub must have systems in place to ensure that the governance framework is properly implemented and maintained.

The post-mortem sector encompasses the majority of this report given the scale of the activity undertaken across the terms of the licence.

Human application activity is significantly less and covers a much smaller range of activity. This is represented as a smaller component of this report.

The research licence is held due to potential requirements for research activities under this licence.

Licenced Activity Reports – Post Mortem Sector

LAST UPDATED ON 27 FEB 2024

Grange University Hospital

LICENCE NUMBER 12036	LICENSED PREMISES Grange University Hospital
DESIGNATED INDIVIDUAL Majid Hamid Rashid	LICENCE STATUS Licence Granted
SECTOR Post Mortem	

Licensed activities

- Making of a Post Mortem Examination
- Removal of Relevant Material
- Storage of a Body or Relevant Material

The hub licence, 12036, is assigned to the Grange University Hospital (GUH). This is where the majority of the Post-mortem examinations, removal and storage of tissues occurs. Dr Majid Rashid is identified as the DI, however during this reporting period Dr Ian Thompson was DI.

LAST UPDATED ON 27 FEB 2024	LAST UPDATED ON 27 FEB 2024		
<h2>Royal Gwent Hospital</h2>	<h2>Nevill Hall Hospital</h2>		
LICENCE NUMBER 12036	LICENSED PREMISES Royal Gwent Hospital	LICENCE NUMBER 12036	LICENSED PREMISES Nevill Hall Hospital
DESIGNATED INDIVIDUAL Majid Hamid Rashid	LICENCE STATUS Licence Granted	DESIGNATED INDIVIDUAL Majid Hamid Rashid	LICENCE STATUS Licence Granted
SECTOR Post Mortem		SECTOR Post Mortem	

Licensed activities

- Making of a Post Mortem Examination
- Removal of Relevant Material
- Storage of a Body or Relevant Material

Licensed activities

- Removal of Relevant Material
- Storage of a Body or Relevant Material

ABUHB also maintains two satellite licences for the post-mortem sector. Human tissue is stored in the form of archive paraffin embedded tissue blocks and microscopic slides. The medium-term intention is to centralise all archive on one site and discontinue the satellite licences.

HTA Inspections

The HTA last visited the three sites in November 2022 (Appendix 1.)

[HTA-TEM-017 Post Mortem inspection report template](#)

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Grange University Hospital (the establishment) had met the majority of the HTA's standards, eight major and five minor shortfalls were found against standards for Consent, Governance and Quality Systems and Premises, Facilities and Equipment.

These related to the consent seeking policy, standard operating procedures (SOPs), audits and risk assessments, consent seeking training and competency assessment, the governance framework across the hub and satellite sites, mortuary security arrangements, freezer storage, and bariatric transfer arrangements to the mortuary. One of the shortfalls, PFE1(e), relates to findings from the last inspection.

The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment. Concerns were discussed with the establishment as part of this inspection and the current DI has provided assurance that the establishment is committed to meeting the regulatory requirements.

Based on this assurance, the HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

A corrective action/preventative action (CAPA) plan was produced to plan and implement the required actions to satisfy the HTA's findings (Appendix 2.). This was submitted to the HTA in April 2023.

The HTA accepted the corrective and preventative actions put in place and granted the licence, but wanted closure of three longer term recommendations that remained open, but had plans, relating to: -

- **Temperature monitoring across all site body stores including alarm testing**
- **Lone working for staff supporting family viewings**
- **Fridge and Freezer capacity**

The HTA held a virtual follow up meeting in October 2023 and consequently fully signed off the licence as all recommendations had been addressed

Quality Metrics

Human Tissue Authority reportable incidents (HTARI)

HTARIs are serious incidents that may affect the dignity of the deceased and damage public confidence.

Any incident that meets one of several classes of incident should be report as per the

[HTARI Guidance for establishments](#) – Guidance on HTA reportable Incidents (HTARI's) in the post mortem sector

Incidents must be reported within 5 calendar days of being notified and should also included near misses (as described in guidelines)

DIs are responsible for ensuring the HTA is notified of incidents in areas covered by the HTA licence.

ABUHB HTARI's reported 2023/2024

The DI for the post-mortem sector reported 5 HTARIs to the HTA within the calendar year.

Classification	Number of Incidents	Outcome
Accidental damage to a body	1	Identified that significant work required around porter training
Accidental damage to a body – NEAR MISS	1	Identified that significant work required around porter training
Loss, disposal or retention of a whole foetus or foetal tissue (gestational age less than 24 week) against the express wishes of the family – NEAR MISS	1	Advice from HTA considered due to gestational age, that the tissue was maternal and not foetal. No further action required
Release of the wrong body	2	Serious Incident investigation carried out. Action plan developed and progress reported to executive team and Patient Quality, Safety & Outcomes committee (PQSOC) (Appendix 3)

ABUHB Datix submissions 2023/2024

9 datix submissions relating to mortuary, body store or Care After Death team were received during 23/24. All incidents have been actioned and closed

Initial Harm Assessment	Number of Incidents	Classification
Low	3	<ul style="list-style-type: none"> - Communication Issues - Breach of patient/service user confidentiality - Patient ID
Moderate	4	<ul style="list-style-type: none"> - Struck against or by an object - Patient ID - Concerns handling - Contact with object
Catastrophic/Death	2	<ul style="list-style-type: none"> - Release of wrong body for both incidents

Audit

The HTA standards highlight the need to have a process of audit in place. The audit calendar is designed to audit the standards across a three-year period.

Tissue traceability and body release audits are carried out on a more regular basis

The audit calendar is managed through the directorates electronic quality management system

Example audit calendar for March 2024 below

Audit Calendar					
Printed on: 19 August 2024					
Calendar within MORTUARY AND Scheduled Start Date between 01/04/2023 & 31/03/2024					
Grouped By:		Scheduled Month			
Scheduled Month 13/03/2024 00:00					
Number	Title	Scheduled Start Date	Scheduled End Date	Actual Start Date	Actual End Date
AUD3274	MORTUARY/CAD Body Traceability Audit - RGH	12/03/2024	13/03/2024	13/03/2024	14/03/2024
Scheduled Month 26/03/2024 00:00					
Number	Title	Scheduled Start Date	Scheduled End Date	Actual Start Date	Actual End Date
AUD3347	MORTUARY/CAD Examination audit - Release Process GUH	26/03/2024	26/03/2024	26/03/2024	26/03/2024
Scheduled Month 28/03/2024 00:00					
Number	Title	Scheduled Start Date	Scheduled End Date	Actual Start Date	Actual End Date
AUD3348	MORTUARY/CAD Examination audit - Procedure for flagging same or similar names GUH	24/03/2024	28/03/2024	26/03/2024	26/03/2024
AUD3346	MORTUARY/CAD Examination audit - Release Process GUH	26/03/2024	28/03/2024	26/03/2024	26/03/2024

Information for noting – 23/24

Event	Comment	Further action
CAD team review – May 2023 (Appendix 3.)	The care after death (CAD) team was hosted within the estates and facilities division however the disconnect with Pathology and the mortuary teams created several challenges. The Deputy Director of Operations undertook a review of the service, the outcome of which was that the CAD team moved permanently into Pathology. During this period a replacement CAD team manager was recruited.	Integration of the CAD team into Pathology requires close managerial oversight to ensure connected working between CAD and mortuary teams
Freezer and Fridge Capacity – December 2023	Space within the decommissioned RGH post-mortem suite has been converted to extra fridge and freezer storage capacity. The installation has satisfied one of the major findings from the HTA visit	Ensure that regular audit is maintained with respect to temperature monitoring and maintenance
Medical Examiners (ME) role implemented – April 2023	<p>The new role of ME within Wales & England was introduced into the process for investigating the death of patients.</p> <p>This is a non-statutory role, however there is a clear expectation that ABUHB has process in place</p> <p>Further information on ME role - Medical examiners: a new role for England and Wales (medicalprotection.org)</p> <p>The ME service links in with the organisations mortality review process chaired by the Deputy Medical Director</p>	Continue to monitor process through HTA committee agenda
Fuller report – Welsh Government - Ongoing	<p>David Fuller inquiry: phase 1 report was published on 28/12/23 David Fuller inquiry: phase 1 report - GOV.UK (www.gov.uk)</p> <p>The report made 17 recommendations that will become a blueprint for health boards in Wales.</p>	<p>An initial gap analysis is to take place as requested by the DoTHS in an email to division on 22/04/24.</p> <p>Progress against actions to be monitored through HTA committee</p>
Maternity paediatric post-mortem reporting times - across 23/24	ABUHB has a WHSCC agreement in place with CAVUHB to provide paediatric post-mortem support. Feedback from the Maternity service through HTA committee highlighted poor performance for providing reports. This could take up to 12-months, causing significant concern to relatives. The contracting finance business partner made contact with WHSCC who confirmed that an issue with capacity was experienced,	Continue to monitor through HTA committee in 24/25

	however CAVUHB had recently recruited two paediatric pathologists and expectation was for improvements. Improvement experienced as of March 24 with delay down to 6-months though this is expected to improve further still	
RAAC hazard at NHH mortuary – September 2023	A RAAC hazard has been identified within the main body store at NHH. Business-continuity plans produced in case deemed unsafe to work in the vicinity. Scaffolding props are currently employed to ensure structural integrity.	Continue to monitor safety through HTA committee and divisional management. Ensure regular reviews of BCP takes place
Change of DI – February 2024	Dr Ian Thompson has retired and DI responsibilities now assigned to Dr Majid Rashid. The HTA have been updated and the licences changed accordingly	No further action
HTA legal directions 004-2033 notice	A statutory HTA legal directions notice was received relating to winter body store capacity and the requirement undertake 8 actions by 23/11/2023 Legal Directions 004-2023_0.pdf (hta.gov.uk) Actions completed by Pathology governance manager and returned by due date. Winter planning BCP reviewed and updated	

Successes and Challenges 23/24

Successes

- Transition of CAD team from E&F into Pathology
- Satisfying HTA requirements to ensure continued licencing in place across hub and satellite sites
- Recruitment of new CAD team manager
- Capital purchase and installation of new fridge/freezer capacity at RGH
- HTA committee has brought several services together who would historically work in a silo fashion. This has led to sharing of learning as well as helping each other to find solutions
- Improvement in reporting time for paediatric post-mortem reports

Challenges

- Transition of CAD team
- Porter training. HTARI demonstrated need for stronger emphasis around training porters to handle the deceased
- Release of wrong body HTARI's has put a significant amount of focus and pressure on the mortuary team. This has resulted in several members of the team reporting absence due to stress related illness. The wellbeing team were invited into the department to help support
- Standardising body-store/mortuary services across several sites

LAST UPDATED ON 06 JUN 2024

Royal Gwent Hospital

LICENCE NUMBER	LICENSED PREMISES
11130	Royal Gwent Hospital
DESIGNATED INDIVIDUAL	LICENCE STATUS
John Martin Lloyd	Licence Granted
SECTOR	
Human Application	

Licensed activities

Distribution Procurement Storage Testing

The Royal Gwent Hospital hosts the human application licence, 11130. RGH is where the bone bank is located and therefore regulatory standards apply on this site. There are no satellite licences.

The licence covers distribution, procurement, storage and testing of tissues such as femoral heads and other orthopaedic applications

The licence DI is Mr John Lloyd, Consultant Orthopaedic Surgeon

HTA Inspections

The HTA last visited the Royal Gwent Hospital site in May 2022 (Appendix 4.)

[HTA-TEM-016 Human Application inspection report template](#)

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Royal Gwent Hospital (the establishment) had met the majority of the HTA's standards that were assessed during the inspection, two major and nine minor shortfalls were found against standards for Consent, Governance and Quality, and Premises, Facilities and Equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

A corrective action/preventative action (CAPA) plan was produced to plan and implement the required actions to satisfy the HTA's findings (Appendix 5.) This was submitted to the HTA in late 2022

The HTA requested further evidence against 2 minor findings. Evidence provided and CAPA plan closed off on 21/11/23

The HTA will schedule another visit for 2024

Quality Metrics

Human Application Serious Adverse Event and Reaction (SAEARs)

Two types of reporting process are in place for Human Application:

1) Serious Adverse Events (SAE)

A serious adverse event is defined as 'any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of tissue or cells intended for human application and which, in relation to a donor of tissue or cells intended for human application or a recipient of tissue or cells: (a) might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions, or (b) might result in, or prolong, hospitalisation or morbidity

2) Serious Adverse Reaction (SAE)

A serious adverse reaction is defined as 'an unintended response, including a communicable disease, in a donor of tissue or cells intended for human application or a recipient of tissue or cells, which may be associated with the procurement or human application of tissue or cells and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity

Any SAEARs are required to notify the HTA within 24 hours of discovery

[Human application serious adverse event and reaction \(SAEARs\) reporting | Human Tissue Authority \(hta.gov.uk\)](#)

There were **zero adverse incidents** relating to material for human application recorded in the reporting period

Annual activity data collection

All establishments licensed to carry out activities under the [Human Tissue \(Quality and Safety for Human Application\) Regulations 2007](#) must submit data relating to the activities undertaken and the tissue types worked with between 1 January and 31 December on an annual basis

Submission of the data is a condition of maintaining the HTA licence



ANNUAL ACTIVITY
DATA January 1ST 2023

The attached file shows activity data for 2023 only as the reporting profile does not allow splitting into 23/24 and 24/25. This was submitted in March 2024

Audit

The HTA standards highlight the need to have a process of audit in place.

17 audits, testing a wide range of the service scope were undertaken in 23/24

NON CONFORMANCE REVIEW	04/04/2023	NON - CONFORMANCE COMPLIANCE DOCUMENTATION REVIEWED. - REF RJ005 RE TELEPHONED POSITIVE RESULT FOR SYPHILIS
NON CONFORMANCE REVIEW	04/04/2023	NON - CONFORMANCE COMPLIANCE DOCUMENTATION REVIEWED - FAILURE OF MICROBIOLOGY TO REPORT AS PER SOP - REF RJ005
EXTERNAL AUDIT COMPLETED AGAINST STANDARDS	11/05/2023	INDEPENDANT AUDIT UNDERTAKEN WITH MR A GRANT - THE AUDIT WAS UNDERTAKEN TO REVIEW COMPLIANCE TO CAPA FROM PREVIOUS HTA INSPECTION AND IN ADDITION A REVIEW THE PROCESS AGAINST THE STANDARDS. - 1 MINOR SHORTFALL NOTED AND 2 RECOMMENDATIONS MADE.
NON CONFORMANCE REVIEW	13/06/2023	NON - CONFORMANCE COMPLIANCE DOCUMENTATION REVIEWED. - NEW DOCUMENT TO RECORD TELEPHONED RESULTS RE REF RJ005
RE AUDIT TEMPERATURE & HUMIDITY	21/08/2023	34 ENTERIES REVIEWED FROM 13/06/- 07/08/23 - 3 ENTERIES EXCEEDED ACCEPTABLE LIMIT FOR HUMMIDITY WITH A RECORDING OF 81% - DISCREPENCY NOTED BY STAFF AND COMPARED WITH THEATRE HUMMIDITY READING WHICH WAS REPORTED AS ELEVATED AT 65% BUT WITHIN ACCEPTABLE RANGE - FAILURE OF STAFF TO INFORM CO-ORDINATORS
NON CONFORMANCE REVIEW	05/09/2023	NON - CONFORMANCE COMPLIANCE DOCUMENTATION REVIEWED. - ONE ONGOING RE TELEPHONED RESULTS
MEDICAL HISTORY FORM REVIEW	05/09/2023	MEDICAL HISTORY FORM REVIEWED AMENDED AND VERSION CONTROLLED.
SOP REVIEW	05/09/2023	SOP REVIEW FOR CONSENT REVIEWED, AMENDED AND VERSION CONTROLLED
NON CONFORMANCE REVIEW	05/09/2023	NON - CONFORMANCE COMPLIANCE DOCUMENTATION REVIEWED -TEMPERATURE AND HUMMIDITY REF RJ101 RE AUDIT SHOWED NON COMPLIANCE
AUDIT TPA'S / EUA'S / SLA'S	05/09/2023	AUDIT TO REVIEW CONTRACTS. ALL CONTRACTS & ACREDITATION STATUS REVIEWED - FINDINGS - NOTED MOST CONTRACTS WILL BE UP FOR REVIEW 2024. UCLH UPDATED AND SENT FOR SIGNING. - OSU NOTED 4 NEW STAFF DOCUMENTS TPA'S DRAWN UP FOR SIGNING - NOTED RECORD MAINTENANCE SECTION OF SOME TPA'S HAD NOT BEEN UPDATED WITH THE HTA RECOMMENDATION OF'MAINAINING ALL RECORDS FOR 10 YEARS FROM USE, DISPOSAL, EXPIRY'. NEW CONTRACTS DRAWN UP TO INCLUDE RECOMMENDATION AND AGREED FOR KC TO RENEW ON NEXT REVIEW AND SEND FOR UPDATED SIGNATURES.

SOP REVIEW	18/10/2023	SOP 7 REVIEWED AMENDED AND VERSION CONTROLLED.
AUDIT OF CONSENT	19/12/2023	40 DONORS NOTES WERE REVIEWED TO ASSESS TIMESCALES FROM TIME OF CONSENT AND MEDICAL HISTORY TAKING TO SURGICAL DATE, RE HTA CONCERNS. 39 DONORS CONSENT AND MEDICAL HISTORY WERE WITHIN THE ACCEPTED TIME FRAME OF 12 WEEKS. ID 3881 WAS NOTED TO HAVE CONSENT AND MEDICAL HISTORY PERFORMED ON 26/05/22 AND SURGERY PERFORMED ON 15/05/23
SEROLOGY SPIN DOWN TIME FRAMES	19/12/2023	AUDIT TO REVIEW COLLECTION AND RECIEPT TIMES IN REPOSNSE TO HTA GQ5b STANDARD - 40 DONORS NOTES AND SEROLOGY RESULTS WERE REVIEWED - 38 DONORS WERE FOUND TO HAVE AN APPROPRIATE TIME FRAME FROM COLLECTION TO RECIEPT OF < 24 HRS. - ID 4272 PRE OPERATIVE SEROLOGY TAKEN 16/03/2023 AND RECIEPTED 22/03/23 ID 3988 POST DONATION SEROLOGY TAKEN 20/10/23 AND RECIEPTED 02/11/23
RE AUDIT TEMPERATURE & HUMIDITY	21/12/2023	35 ENTERIES REVIEWED FROM 08/08/23 - 20/10/23 - 7 ENTERIES EXCEEDED ACCEPTABLE LIMIT FOR HUMMIDITY WITH A RECORDING OF 81% OR ABOVE. DISCREPENCY WAS NOTED AND COMPARED WITH THEATRE HUMMIDITY READING WHICH WAS REPORTED AS ELEVATED BUT WITHIN ACCEPTABLE RANGE OF 60% - 1. FAILURE OF STAFF TO REPORT DISCREPENCY TO CO-ORDINATORS
AUDIT RECALLS	02/01/2024	59 DONORS RECORDS WERE REVIEWED FOR 180 RECALLS INCLUDING 12 REPEAT RECALLS - 35 SEROLOGY RESULTS RECOVERED ON FIRAT RECALL = 59% - 1 DONOR DECEASED = 1.5 % - 6 DONORS DNA 2ND RECALL AND HEADS TO BE DISCARDED= 10% - REPEAT RECALL RATE = 50%
SOP REVIEW	23/01/2024	BONE BANK MANUAL REVIEWED, AMENDED AND VERSION CONTROLLED TO REFLECT CHANGES TO ST JOSEPH'S PROCUREMENT.
SOP REVIEW	05/03/2024	SOP 21 AMENDED TO REFLECT PACKAGING PROCESS TO JO, MANUAL UPDATED AND VERSION CONTROLLED

Information for noting – 23/24

Event	Comment	Further action
Change to HTA licence holder – August 2023	The T&O directorate manager is the 'licence holder'. The HTA was notified of a change in T&O manager by the DI on 23/08/23	No further action necessary
Agreement to distribute excess femoral heads to independent contractor – September 2023	Experienced full freezer capacity with excess stock of femoral heads. SBAR to work with commercial company to distribute excess stock developed. Division agreed to commercial agreement and SLA signed by both parties	Ensure that any agreement is reviewed with respect to remaining appropriate for stock size
Malaria Testing – February 2024	Malaria Testing, still waiting for SLA agreement to be completed, at this moment in time cannot provide HTA with an SLA with the testing hospital site for malarial testing. No longer accepting patients from high risk, malarial countries	Ensure malaria testing site identified and SLA agreed so that testing can be re-established Identify a person designate (PD) in Microbiology to attend Bone Bank governance meeting

Successes and Challenges 23/24

Successes

- Closing off CAPA plan and maintaining HTA licence
- Finding solution to excess femoral head stock challenge
- No SAEARs for two years

Challenges

- No current site to send specimens for Malaria testing
- WHSCC contracting issues with regard to ABUHB providing articular cartilage defect treatment

Licensed Activity Reports - Research

A satellite licence for the Wales Cancer Biobank is in place, however there was no activity against this licence in 23/24. There is an expectation that this licence will be revoked in 24/25

Historical background to the Wales Cancer Biobank – HTA research licence 12107

The Wales Cancer Biobank (WCB) consents patients in Wales, with a known or suspected cancer diagnosis, to donate bio samples and data to the biobank for future use in cancer related projects. The samples are made available to cancer researchers worldwide and projects in which samples may be used are not necessarily known at the time of donation. Tissue samples that are removed during diagnostic or treatment procedures, and are surplus to diagnostic requirement, are sourced from histology departments for storage in the biobank and patients are asked to give additional blood samples (and occasionally other samples such as saliva or urine) for the biobank.

www.walescancerbank.com

WCB has approval from Wales REC3 as a Research Tissue Bank to consent, collect and issue samples. Storage of samples is regulated under Human Tissue Authority research licence 12107, with the hub licence in UHW and satellite licences to cover any other locations where samples, consented and collected under WCB approvals, are stored. Dr Alison Parry-Jones, Operations Director of WCB, is the Designated Individual on the licence and Cardiff University is the Licence Holder.

WCB funds a part time research nurse (0.4fte) in Aneurin Bevan and a research agreement is in place between Cardiff University (WCB's host institution) and Aneurin Bevan. Patients are consented in multiple settings, and potentially in multiple hospitals. One of WCB's satellite licences is to cover storage in the Royal Gwent hospital.

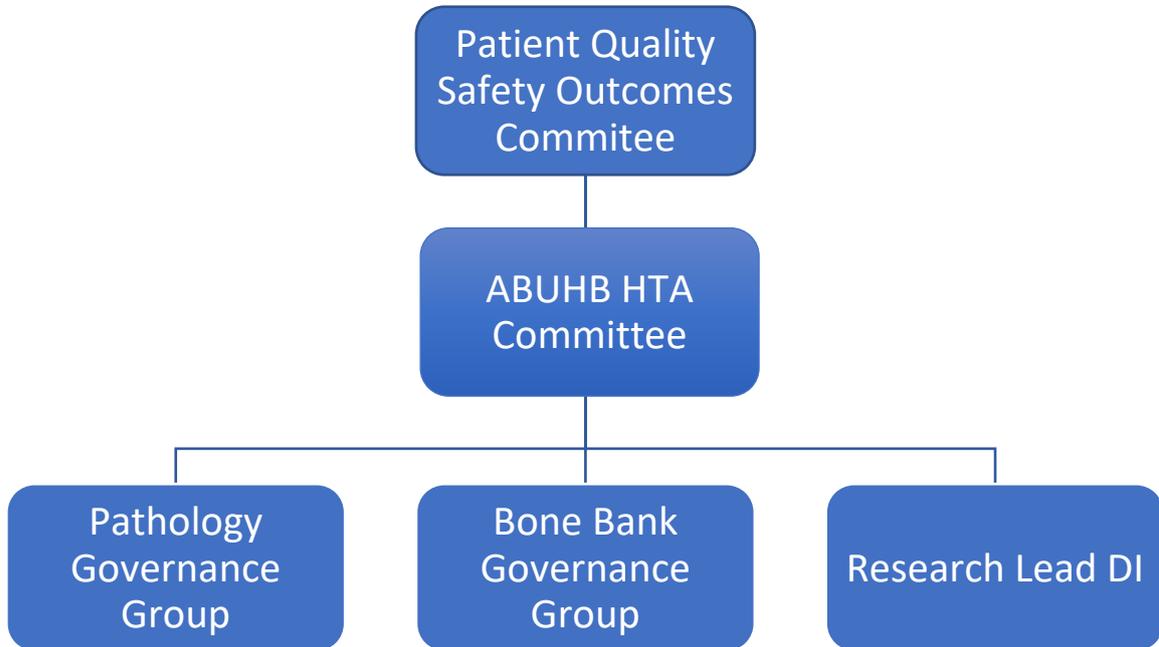
Prior to December 2019, a -80 freezer and paraffin block and slide storage were located in the Haematology lab (4th floor, Block C) and used for storage of WCB samples. WCB held quarterly HTA governance meetings which were attended by representatives from Aneurin Bevan.

All samples were relocated to Cardiff in December 2019 and there has been no onsite storage in Royal Gwent since that date. The HTA is aware there is no current storage under the satellite licence, and they did not visit RG when WCB was last inspected, in January 2020.

The decision was taken to retain the licence in case of future need to store samples, rather than remove the licence and be potentially unable to support storage of a collection at short notice.

The satellite licence is currently inactive but still 'live'. Therefore, there are currently no governance issues to report.

Governance Structure



Terms of reference



HTA Committee ToR
2023.docx

Goals for 2024/25

Over the next 12 months the HTA committee team will work collaboratively with Divisions and the governance groups to achieve the following:

Ensure effective training plan for porters is produced by the CAD team/E&F and implemented

Carry out GAP analysis on recommendations from Fuller report phase 1

Ensure a workplan is produced and implemented to address gaps in the recommendations of the Fuller report

Ensure post-mortem and human application have effective systems of audit in place and are carrying out audit on a regular basis

As part of quality planning, ensure DIs report quality metrics and quality improvement into the committee as well as divisions

Review HTA committee structure and terms of reference for effectiveness. New chair to be identified

Prepare for HTA inspection visit for Human Application licence in Bone Bank – Expected Autumn 2024

Re-establish Malaria testing capability for T&O

Continue to build on effective relationship with the HTA and their licence managers

Appendices

1. GUH Post-Mortem Inspection report on compliance with HTA licensing standards 2022



2022-11-07 09 10
12036 Grange Unive

2. Post-Mortem - Corrective and preventative action (CAPA) plan - Grange University Hospital - 12036 - Routine on 7/11/2022



2022-11-07 09 10
12036 Grange Unive

3. Care After Death (CAD) team review



CAD Review - May
2023.pdf

4. RGH Human Application Inspection report on compliance with HTA licensing standards



2022-05-17-18
11130 Royal Gwent ,

5. Human Application - Corrective and preventative action (CAPA) plan Royal Gwent Hospital - 11130 - Routine on 17/5/2022



Human Application
CAPA Plan.docx

ANNUAL ACTIVITY DATA January 1ST 2023 – DECEMBER 31ST 2023

3534 – 4147 DATABASE CHECKED ON 18/03/2024

TOTAL DONORS CONSENTED 344

TOTAL NUMBER OF HEADS TAKEN 205

TOTAL NUMBER OF HEADS NOT TAKEN = 82

HEADS NOT TAKEN = 67

OPERATIONS CANCELLED = 12

HEADS USED DURING CASE = 2

PATIENT DECEASED = 1

TOTAL NUMBER OF HEADS TESTED = 205

TOTAL NUMBER OF UNITS IMPORTED FROM OUTSIDE EEA = 0

TOTAL NUMBER OF UNITS IMPORTED FROM UK = 0

TOTAL NUMBER OF HEADS IMPORTED FROM ANOTHER COUNTRY = 0

NO PROCESSING

TOTAL DISCARDS FROM THIS YEAR'S DONATIONS = 32

DISCARDED DONOR UNSUITABLE = 14

DISCARDED OUT OF TIME = 2

DISCARDED BACTERIA POSITIVE = 8

DISCARDED VDRL POSITIVE = 1

DISCARDED HEP C POSITIVE = 0

DISCARDED HEP B POSITIVE = 0

DISCARDED SPECIMENS NOT TAKEN = 9

DISCARDED DNA POST OP BLOODS = 1

DISCARDED POT BROKEN = 2

DISCARDED NO PRE OP BLOODS = 2

DISCARDED SEE NOTES = 2

READY FOR RELEASE FROM THIS YEARS DONATIONS = 24

RELEASED FOR USE FROM THIS YEARS DONATIONS = 36

PENDING REPEAT BLOODS = 16

PENDING BACTERIA AND BLOOD RESULTS = 28

TOTAL NUMBER OF HEADS USED = 57

TOTAL NUMBER OF HEADS FOR JO = 79

STOCK TAKE FREEZERS 23/01/2024

F1 = UNIDENTIFIED = 11

F2 = 9

F3 = 186

Human Tissue Authority (HTA) Group Terms of Reference

Background

The context for the Human Tissue Authority (HTA) Group is the necessity to provide a mechanism for the monitoring, review, and reporting of HTA licenced activity within Aneurin Bevan University Health Board (ABUHB)

Purpose

The purpose of the meeting is to provide a forum for the monitoring and review of actions in relation to maintaining the HTA licence requirements for the following:

- | | |
|--|----------------------------|
| - Licence #11130 Human Application – RGH | DI – Mr John Lloyd |
| - Licence #12036 Post Mortem – NHH, RGH, GUH | DI – Dr Ian Thompson |
| - Licence #12107 Research – RGH | DI – Dr Alison Parry-Jones |

Deliverables

The format of the meeting and the expected deliverables from the HTA group are illustrated below:

- Through exception reporting the Designated Individuals (DI) for the HTA licences will report on activity related to their area of the licence
- Review and update the risk register related to HTA activity
- Prepare for local inspections, identifying actions required to achieve compliance. This will include feedback from inspections and monitoring any subsequent actions
- Receive reports on any HTA related reportable Incidents (HTARI) and ensure timely response to identified actions. This will include any identified 'near misses'
- Ensure internal audits are completed against the HTA Codes of Practice and any non-compliance or recommendations are implemented in a timely manner
- Ensure there is timely participation in national audits and review annual audit data submissions
- The HTA group will formally report to the Quality and Patient Safety Operational Group through the Governance Report, or by exception in the event of an incident or if considered necessary by the group with onward assurance to the Board's Patient, Quality, Safety and Outcomes Committee

Structure and Meeting Frequency

The HTA group will meet quarterly and include representation from staff involved in HTA regulated activity.

An emergency meeting can be stood up at short notice in the event of an extraordinary event that relates to any of the licences occurring

Membership

The membership of the group will be at an appropriate level to ensure actions can be agreed and taken. Members will come to the meetings prepared and able to participate. If they are unable to attend, they are required to send a representative with the authority to participate fully.

Membership will include:

Chair – Independent Member
Deputy chair – Executive Director of Therapies and Health Science
Designated Individual (DI) for post mortem
Designated Individual (DI) for human applications (bone bank)
Governance Manager – Bone Bank
Governance Manager – Pathology
Cellular Pathology Manager
Care After Death Team (CAD) Manager
Maternity Manager
Mortuary Manager
Histopathologist

Other members will be co-opted as required

Administration

Pathology Business Support Officer

Outcomes

There are expected outcomes from the HTA meeting:

- Ensure that appropriate and timely actions are taken in response to HTA related matters
- Provide a mechanism for the internal review of compliance with HTA requirements and subsequent reporting
- Minutes from the HTA meeting assist in the provision of assurance for the Health Board and Licence Holder (CEO)

Grange University Hospital
 HTA licensing number 12036

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licenced for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem examination	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site Grange University Hospital	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
Satellite site Royal Gwent Hospital	Not licensed	Licensed	Licensed
Mortuary (satellite site)	-	<i>Carried out</i>	<i>Carried out</i>
Pathology lab	-	-	<i>Carried out</i>

Satellite site	Not licensed	Licensed	Licensed/Not licensed
Nevill Hall Hospital			
Mortuary (satellite site)	-	<i>Carried out</i>	<i>Carried out</i>

Summary of inspection findings

The HTA found the Designated Individual (DI) and the License Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Grange University Hospital (the establishment) had met the majority of the HTA's standards, eight major and five minor shortfalls were found against standards for Consent, Governance and Quality Systems and Premises, Facilities and Equipment. These related to the consent seeking policy, standard operating procedures (SOPs), audits and risk assessments, consent seeking training and competency assessment, the governance framework across the hub and satellite sites, mortuary security arrangements, freezer storage, and bariatric transfer arrangements to the mortuary.

One of the shortfalls, PFE1(e), relates to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment.

Concerns were discussed with the establishment as part of this inspection and the current DI has provided assurance that the establishment is committed to meeting the regulatory requirements. Based on this assurance, the HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
<p>C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice</p>		
<p>a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice</p>	<p>The overarching consent policy is not fully reflective of the requirements of the HT Act or the HTA Codes of practice:</p> <ul style="list-style-type: none"> • Whilst the policy details that consent for post mortem (PM) examination should be obtained from an appropriate person, there is no subsequent detail of who would qualify as the most appropriate person to also include the person in life or a nominated representative of the deceased. • The policy does not detail that those seeking consent should be trained and assessed as competent in the consent seeking procedure. • The policy does not cover the retention of tissue or the scheduled purposes for which consent may be obtained to retain tissue from the deceased. 	<p>Major (cumulative)</p>
<p>b) There is a documented standard operating procedure (SOP) detailing the consent process</p>	<p>The consent SOP in place for the seeking of adult PM examination is not fully reflective of the consent seeking process and does not detail how a change or withdrawal of consent would be communicated to the mortuary.</p> <p>An SOP detailing the process for the seeking of consent for perinatal PM examination was not provided as part of the inspection.</p>	
<p>C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent</p>		

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	The mortuary manager, alongside Consultant Pathologists, provides 'just in time' training to clinicians seeking consent for adult PM examination as requests are infrequent. Whilst the mortuary manager has a good understanding of the consent seeking process, he has not undertaken any formal consent training in the last 10 years.	Major (cumulative)
b) Records demonstrate up-to-date staff training	The establishment were unable to provide assurance that all staff involved in the adult consent seeking process have up-to-date training as there is no consistent record of training.	
d) Competency is assessed and maintained	Competency for those seeking consent for adult PM examination has not been assessed or maintained.	
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	The establishment has three separate sites. The hub site is managed and governed by the pathology department, whilst the two satellite sites are managed and governed by the Care After Death team. Whilst the teams have close links and communication to one another, the sites have separate procedural documents, risk assessments, staff training documents, competency assessments and audits for similar activities conducted under the licence as well as different governance frameworks for the management of mortuary documents and records. As the governance frameworks are not aligned, this poses a risk to the DIs ability to oversee licensed activity methodically and ensure consistency in standards across the sites.	Major
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

<p>c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register</p>	<p>During the external premises inspection of the hub site, it was noted that the doors to the body store open out directly opposite to a turning circle used by hospital vehicles and cars of members of the public. The inspection team observed several instances where those in vehicles were able to see directly into the body store when the doors were open. This means there can be oversight of activity in the body store which could compromise the dignity of the deceased leading to a risk of reputational damage to the establishment. This risk has not been assessed or actions identified to ensure oversight of activity is minimised.</p>	<p>Major</p>
<p>PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.</p>		
<p>e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access</p>	<p>The inspection team identified the following risks to the security arrangements of the mortuaries:</p> <ul style="list-style-type: none"> • The decommissioned PM room at the Nevill Hall Hospital satellite site has manual locks to the old changing room area. The changing room has been repurposed to a patient specimen collection area which is now part of pathology. There is a risk should the manual locks not be deployed, of access directly into the mortuary from patients attending this area. • The viewing rooms at the satellite sites do not have systems in place for staff to be able to raise an alarm should this be required. This may pose a risk of visitors accessing the rest of the mortuary if staff security is compromised. Furthermore, the viewing room at the Royal Gwent Hospital satellite site has a door in the waiting area which leads directly to the rest of the mortuary which was not locked at the time of the inspection and is reliant on the deployment of manual locks. 	<p>Major</p>
<p>PFE2 There are appropriate facilities for the storage of bodies and human tissue.</p>		

<p>c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs</p>	<p>The establishment have identified that freezer capacity is frequently not sufficient to meet the demand to move bodies into long term storage. Lack of freezer storage poses significant risk of deterioration to bodies that could otherwise be preventable.</p>	<p>Major</p>
<p>e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range</p>	<p>Following the previous inspection in 2019, manual systems were put in place to regularly monitor local audible fridge and freezer alarms out-of-hours in the body stores at the satellite sites, however, the system adopted has not been effective at the Royal Gwent Hospital site as this monitoring activity ceased in November 2020. This means there is no assurance at this site that an alarm would be responded to within a reasonable timeframe to ensure bodies continue to be stored at an optimal temperature.</p> <p>Whilst the fridges at the Nevill Hall Hospital satellite site are regularly monitored, including out-of-hours, there was no assurance provided that alarms have been tested to ensure they would trigger if temperatures deviated from the acceptable range.</p>	<p>Major</p>
<p>PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored</p>		
<p>b) Equipment is appropriate for the management of bariatric bodies</p>	<p>The establishment do not have appropriately sized concealment trolleys or other suitable alternative arrangements in place for the transfer of bariatric bodies from the wards to the mortuary at the hub site and the satellite site, Nevill Hall Hospital. Currently bariatric bodies are transferred on beds and in a manner which does not provide assurance that the dignity of the deceased is being fully preserved.</p>	<p>Major</p>

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
<p>GQ1 All aspects of the establishment's work are governed by documented policies and procedures</p>		
<p>a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPATH.</p>	<p>Standard Operating Procedures (SOPs) do not always include sufficient detail of the identification checks performed relating to traceability of bodies or describe current practice. These include but are not limited to:</p> <ul style="list-style-type: none"> • Whilst bodies are regularly checked to ensure condition of the body is being maintained, these checks are not recorded or detailed within an SOP. • SOP MO0007 - Procedure for the release of patients from the Mortuary. Whilst this SOP details that three points of identification on the body are checked on release of the deceased against information brought by funeral directors there is no detail of what actions are taken in the event there are discrepancies in the information. • SOP MO0009 - Procedure for the identification and viewing of the deceased. This SOP is not clear how the identifiers received from visitors at the time of a viewing are checked against the body to confirm the correct visitors have arrived to view the correct body. <p>Furthermore, standard operating procedures are not aligned across the sites for similar procedures (see shortfall against standard GQ1(g)).</p> <p>To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies to ensure they contain sufficient details of identification checks performed and are reflective of current practice across the sites.</p>	<p>Minor</p>

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	<p>Whilst the establishment are conducting regular audits, the schedule of audits conducted across all sites is limited. Traceability of bodies in storage audits are only completed yearly and do not cover accuracy of mortuary records relating to the deceased audited. Security audits at the hub site have been completed but do not form part of the audit schedule. The audits have included a review of swipe card access; however, the audit did not include a review of the CCTV in operation.</p> <p>Furthermore, process audits conducted are not aligned across the sites (see shortfall against standard GQ1(g)).</p>	Minor
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents	The SOP for the management of HTA reportable incidents (HTARIs) does not clearly outline responsibilities for investigating incidents or the process for management of HTARIs and follow up to the HTA.	Minor
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	<p>Risk assessments do not sufficiently detail how identified risks are mitigated. Not all risk assessments have been reviewed against the HTARI categories to ensure appropriate mitigation for identified risks.</p> <p>Furthermore, risk assessments are not aligned across the sites for similar procedures. (see shortfall against standard GQ1(g))</p>	Minor
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

a) The premises are clean and well maintained	<p>The inspection team identified the following areas that require maintenance at the satellite sites:</p> <ul style="list-style-type: none"> • There are areas of damage to walls in the body store and mortuary corridors at Royal Gwent Hospital satellite site exposing porous plaster. Furthermore, there are areas of damage to doors, doorframes, and some wooden fittings. This means these areas would be difficult to effectively clean and decontaminate. • Some ceiling tiles in the decommissioned PM room and the viewing room at Nevill Hall Hospital are damaged or not present and require replacement. 	Minor
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The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1(d)	The DI is advised to ensure that procedural documents in place in the mortuaries are detailed with the author and authoriser of the document in the relevant section as currently this is only recorded on QPulse which is not in operation at all sites.
2.	GQ3(c)	The DI is advised to adopt the staff competency framework in use at the hub site at the satellite sites.

3.	GQ5(a)	The DI is advised to place visual Human Tissue Authority reportable incident (HTARI) guidance in the mortuary body stores to assist portering staff to understand the types of incidents which require reporting to the HTA. Details of who should be informed of an incident within the establishment both in and out-of-hours, so timely HTARI reporting can be completed, should also be included.
4.	T1(c)	The DI is advised to ensure that perinatal bodies received are labelled consistently with three points of identification on a label that is attached to the body. The perinatal body audited had three points of identification present and secured with the body but only two identifiers on the band physically attached to the body.
5.	T1(d)	Whilst the systems in place to flag up bodies with a same or similar name appeared effective, the DI is advised to devise a common system for this procedure across all three sites.
6.	T1(g)	The mortuary manager is advised to ensure that the date is clearly recorded of when organs and / or tissue is repatriated to the body prior to release for funeral.
7.	T1(g)	The mortuary manager is responsible for the management of traceability of organs and tissues taken at PM examination and the subsequent compliance with family wishes for retention or disposal. The DI is advised to consider training other mortuary staff members to undertake these procedures to ensure there is resilience in this area.
8.	T2(c)	The DI is advised to liaise with the Coroner's service in regard to the family wishes forms in use. The form has grouped together all the scheduled purposes for which consent can be obtained to retain material. This means those giving consent must consent to retention for all scheduled purposes or to none. Families may not wish to consent to some of the scheduled purposes listed and should be given the option of which scheduled purposes they would like to give consent for.
9.	PFE1(e)	Whilst regular security audits are conducted at the satellite sites which include review of swipe card access and CCTV, the DI is advised to introduce visitor logs at these sites so audits can be reviewed against a documented record of visitors.

10.	PFE2(e)	The DI is advised to review the upper alarm trigger points for the refrigerated units which is currently set at 10 degrees Celsius. This may pose a risk to bodies being stored at suboptimal temperatures for prolonged periods of time prior to the alarm sounding.
11.	PFE2(f)	The mortuary manager is advised to regularly audit the temperature recordings taken by the digital fridge and freezer system in place. This may assist to identify concerning temperature deviations from the optimal range quickly so actions can be taken to prevent a fridge unit failure.
12.	PFE3(a)	The DI is advised to declutter and remove items of equipment no longer in use at both satellite sites. This relates to items being stored in the post mortem rooms which are no longer in use as the activity has ceased and to remove items in storage in the area adjacent to the viewing room at Royal Gwent Hospital.
13.	N/A	The DI is advised to consider if current arrangements are sufficiently sensitive to the needs of patients visiting the specimen collection area directly adjacent to the decommissioned PM room at the Nevill Hall Hospital satellite site.

Background

Grange University Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in February 2019.

Since the previous inspection, the following changes have been made to the licensing arrangements: a change to the list of Persons Designated under the licence was completed in September 2019. In September 2020, the post mortem licence was revoked at the Nevill Hall Hospital satellite site as this activity had ceased. In November 2020, the hub licence was transferred to the newly opened Grange University Hospital, with Royal Gwent Hospital becoming a satellite site of the hub. The post mortem licence was revoked at Royal Gwent Hospital at the same time as all PM activity transferred to the new hub site. There was a change of CLHc in February 2022 and the current CLHc has been in place since September 2022.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary and post-mortem room, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, body and tissue traceability audits, security audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records. Consent seeking policies and procedures, information for relatives giving consent and current consent forms in use for both adult and perinatal PM examination were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises at the hub site and both satellite sites which included the mortuary body storage areas, PM rooms (satellite sites are not licenced for PM activity but have retained the PM suite areas), viewing rooms, the laboratory where tissue retained at PM is processed and the storage area in the gynaecology department for pregnancy remains.

Audit of records

The inspection team undertook audits of traceability for five bodies in storage at the hub site and four bodies in storage at each of the satellite sites. This included bodies with same / similar names, a body stored longer term and a perinatal body. Traceability details were crosschecked between the identification band or toe tag on the body, information on the door of the storage unit, the mortuary register, associated paperwork, and the electronic mortuary database. Whilst no discrepancies with traceability were identified, the inspection team noted that the identification band attached to the perinatal body only contained two points of identification, however, information directly secured with the body contained sufficient identifiers.

Audits were conducted of tissue taken at PM examination for five cases. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, family wishes forms, and the tissue blocks and slides being stored. Whilst no

discrepancies were identified with the traceability of tissue in storage, the inspection team noted that for one case, the date of repatriation of tissue with the body had not been clearly documented.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including the mortuary manager, mortuary staff and laboratory staff during the onsite visual inspection, staff of the Care After Death team, portering staff, staff involved in the consent seeking process for both adult and perinatal PM examination and the DI.

Report sent to DI for factual accuracy: 09 December 2022

Report returned from DI: 23 December 2022

Final report issued: 03 January 2023

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 12 July 2023

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

or

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

- A notice of proposal being issued to revoke the licence
- Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- A notice of suspension of licensable activities
- Additional conditions being proposed
- Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or

- indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	C1a C1b -	Level of Shortfall (major or minor only)	Major (Cumulative)
Short Description	Consent polices and SOPs		
<p>Inspection finding:</p> <p>C1(a) The overarching consent policy is not fully reflective of the requirements of the HT Act or the HTA Codes of practice:</p> <ul style="list-style-type: none"> • Whilst the policy details that consent for post mortem (PM) examination should be obtained from an appropriate person, there is no subsequent detail of who would qualify as the most appropriate person to also include the person in life or a nominated representative of the deceased. • The policy does not detail that those seeking consent should be trained and assessed as competent in the consent seeking procedure. • The policy does not cover the retention of tissue or the scheduled purposes for which consent may be obtained to retain tissue from the deceased. <p>C1(b) The consent SOP in place for the seeking of adult PM examination is not fully reflective of the consent seeking process and does not detail how a change or withdrawal of consent would be communicated to the mortuary.</p> <p>An SOP detailing the process for the seeking of consent for perinatal PM examination was not provided as part of the inspection.</p>			
<p>Corrective and Preventative Action:</p> <p>C1(a)</p> <ul style="list-style-type: none"> • Overarching consent policy added as an agenda item to the ABUHB HTA Governance Group meeting (Executive led) – 18/01/2023 • Updated wording to be agreed <p>C1(b)</p> <ul style="list-style-type: none"> • Consent Post Mortem Procedure, document reference CEP0920 to be reviewed and updated. • Liaise with maternity service colleagues to ensure seeking of consent for perinatal PM examination is accurately documented within the above referenced document. • Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group. 			

OFFICIAL - SENSITIVE

Deadline for completion of corrective and preventative action:

17/03/2023

HTA Use Only

Action for HTA:

Submission of evidence of compliance

Closed ML – 20 April 2023

Compliance information to be submitted:

- Copy of updated consent policy (this could be the draft policy with detail of expected ratification date which can be followed up outside of the CAPA for assurance action completed) – **received and reviewed.**
- Copy of updated consent SOP which includes reference to seeking consent for perinatal PM – **received and reviewed.**
- Evidence updated SOP has been shared with relevant staff undertaking seeking of consent – **received and reviewed.**

APPROVED TEMP

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	C2a C2b C2d -	Level of Shortfall (major or minor only)	Major (Cumulative)
Short Description	Consent - training and competency assessment		
Inspection finding:			
C2(a)			
The mortuary manager, alongside Consultant Pathologists, provides 'just in time' training to clinicians seeking consent for adult PM examination as requests are infrequent. Whilst the mortuary manager has a good understanding of the consent seeking process, he has not undertaken any formal consent training in the last 10 years.			
C2(b)			
The establishment were unable to provide assurance that all staff involved in the adult consent seeking process have up-to-date training as there is no consistent record of training.			
C2(d)			
Competency for those seeking consent for adult PM examination has not been assessed or maintained.			
Corrective and Preventative Action:			
C2(a) & C2(d)			
<ul style="list-style-type: none"> Competency template to be created for consent training refresher sessions. Initial meeting to take place 06/02/2023, 12-1pm. Meeting and review to subsequently be undertaken annually. 			
C2(b)			
<ul style="list-style-type: none"> Form LFMO0001 to be reviewed and updated. Training to be undertaken by all staff involved and documented on form. Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group. 			
Deadline for completion of corrective and preventative action:		17/03/2023	

HTA Use Only

Action for HTA:	Submission of evidence of compliance Closed ML – 20 April 2023
Compliance information to be submitted:	

OFFICIAL - SENSITIVE

- Copy of the competency refresher training template – **received and reviewed.**
- Evidence those seeking consent for adult PM have undertaken the refresher training and competency assessment – **received and reviewed**

APPROVED TEMPLATE

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	GQ1g -	Level of Shortfall (major or minor only)	Major
Short Description	Governance framework		
Inspection finding:			
<p>The establishment has three separate sites. The hub site is managed and governed by the pathology department, whilst the two satellite sites are managed and governed by the Care After Death team. Whilst the teams have close links and communication to one another, the sites have separate procedural documents, risk assessments, staff training documents, competency assessments and audits for similar activities conducted under the licence as well as different governance frameworks for the management of mortuary documents and records. As the governance frameworks are not aligned, this poses a risk to the DIs ability to oversee licensed activity methodically and ensure consistency in standards across the sites.</p>			
Corrective and Preventative Action:			
<p>Plan to be written to document the following:</p> <p>Documents to be held on q-pulse as per all mortuary documentation and aligned as closely as possible with existing mortuary processes. This will be a straightforward method to adopt with current line management of the CAD team falling under the Clinical Support Services Division – Cellular Pathology Department. This temporary transfer of responsibility is in place until 31/03/2023; organisationally we have to yet understand whether this will be permanent or not. Therefore, all processes will fall under the governance structure of UKAS accredited services.</p> <ul style="list-style-type: none"> • Procedural documents – revised as appropriate and distributed to CAD team for acknowledgement. • Risk assessments – review of Mortuary PM service/ CAD risk assessments and plan made as to how to merge assessments. • Staff training documents - revised as appropriate and refresher training given to CAD team and documentation stored. • Competency assessments - revised as appropriate and competency assessments completed to CAD team and documentation stored. • Audit schedules – Mortuary PM service/ CAD audit schedules reviewed and to be combined. Documented on Q-pulse. • Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group. 			
Deadline for completion of corrective and preventative action:	17/03/2023		

Action for HTA:

Submission of evidence of compliance

Closed ML - 20 April 2023

Compliance information to be submitted:

- Action plan detailing timeframes and progress with alignment of governance structure (this could be a copy of the progress tracker) – **received and reviewed.**
- DI to provide assurance that HTA will be updated once alignment of governance structure is complete across the sites and will inform of the governance management structure once agreed – **received and reviewed.**

APPROVED TEMPLATE

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	GQ6c -	Level of Shortfall (major or minor only)	Major
Short Description	Oversight of mortuary activity		
Inspection finding:			
<p>During the external premises inspection of the hub site, it was noted that the doors to the body store open out directly opposite to a turning circle used by hospital vehicles and cars of members of the public. The inspection team observed several instances where those in vehicles were able to see directly into the body store when the doors were open. This means there can be oversight of activity in the body store which could compromise the dignity of the deceased leading to a risk of reputational damage to the establishment. This risk has not been assessed or actions identified to ensure oversight of activity is minimised.</p>			
Corrective and Preventative Action:			
<ul style="list-style-type: none"> Assess the risk, identify the actions to ensure oversight of activity is prevented. Report to ABUHB HTA Governance Group (18/01/2023) and request options appraisal. Identify appropriate funding stream for any revisions required to infrastructure. Submit risk assessment alongside action plan to mitigate risks to HTA. Action plan to cover the two-month time period until 17/02/2023. Following this a realistic exact timescale for corrective action to be in place will likely be available. Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group. 			
Deadline for completion of corrective and preventative action:	17/03/2023		

HTA Use Only

Action for HTA:	Submission of evidence of compliance Closed ML – 29 May 2023
Compliance information to be submitted:	
<ul style="list-style-type: none"> Copy of the risk assessment created to mitigate risk of oversight of activity in the body store in the short-term period detailed – received and reviewed. Copy of action plan created to fully address oversight of activity – received and reviewed. DI to provide assurance that an update will be provided to the HTA once action plan 	

complete to fully mitigate identified risk – **received and reviewed.**

Action:

Please advise once fencing has been erected to the rear of the premises.

APPROVED TEMPLATE

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	PFE1e -	Level of Shortfall (major or minor only)	Major
Short Description	Mortuary security arrangements		
Inspection finding:			
<p>The inspection team identified the following risks to the security arrangements of the mortuaries:</p> <ul style="list-style-type: none"> • The decommissioned PM room at the Nevill Hall Hospital satellite site has manual locks to the old changing room area. The changing room has been repurposed to a patient specimen collection area which is now part of pathology. There is a risk should the manual locks not be deployed, of access directly into the mortuary from patients attending this area. • The viewing rooms at the satellite sites do not have systems in place for staff to be able to raise an alarm should this be required. This may pose a risk of visitors accessing the rest of the mortuary if staff security is compromised. Furthermore, the viewing room at the Royal Gwent Hospital satellite site has a door in the waiting area which leads directly to the rest of the mortuary which was not locked at the time of the inspection and is reliant on the deployment of manual locks. 			
Corrective and Preventative Action:			
<ul style="list-style-type: none"> • Assess the risk, identify the actions to ensure access is minimised. • Report to ABUHB HTA Governance Group (18/01/2023) and request options appraisal. • Identify appropriate funding stream for any revisions required to infrastructure. • Submit risk assessment alongside action plan to mitigate risks to HTA. Action plan to cover the two-month time period until 17/02/2023. Following this a realistic exact timescale for corrective action to be in place will likely be available. • Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group. 			
Deadline for completion of corrective and preventative action:	17/03/2023		

HTA Use Only

Action for HTA:	Submission of evidence of compliance Closed ML – 29 May 2023
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Compliance information to be submitted:

- Copy of the risk assessment created to mitigate identified risks detailed in the shortfall – **received and reviewed.**
- Copy of the action plan created to fully address identified risks to security which includes timeframes for actions to be completed – **received and reviewed.**
- Evidence will be required that identified risks to security have been fully addressed – HTA will require to be updated once all actions complete. – **received and reviewed**

Action:

Please advise when panic alarms and controlled access to relevant doors at the satellite sites have been installed.

APPROVED TEMPLATE

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	PFE2c -	Level of Shortfall (major or minor only)	Major
Short Description	Freezer capacity - long-term storage of the deceased		
Inspection finding:			
The establishment have identified that freezer capacity is frequently not sufficient to meet the demand to move bodies into long term storage. Lack of freezer storage poses significant risk of deterioration to bodies that could otherwise be preventable.			
Corrective and Preventative Action:			
<ul style="list-style-type: none"> Revisit the review of freezer capacity completed in 2022 and update the plan, detailing potential freezer space identified. Report to ABUHB HTA Governance Group (18/01/2023). Identify appropriate funding stream for any revisions required to infrastructure. Submit action plan to mitigate risks to HTA. Action plan to cover the two-month time period until 17/02/2023. Following this a realistic exact timescale for corrective action to be in place will be available. Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group. 			
Deadline for completion of corrective and preventative action:		17/03/2023	

HTA Use Only

Action for HTA:	Submission of evidence of compliance
Compliance information to be submitted:	
<ul style="list-style-type: none"> Copy of the updated freezer capacity plan – received and reviewed. Copy of the meeting minutes ABUHB HTA Governance Group (18/01/2023) – received and reviewed. Copy of the action plan created to address lack of freezer capacity long term – received and reviewed. Evidence will be required that actions to address freezer capacity have been completed – HTA will require to be updated once all actions complete and freezer capacity is 	

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considered sufficient.

Action:

This standard will be reassessed through a CAPA follow up virtual regulatory assessment (VRA) to be scheduled week commencing **09 October 2023** to ensure all actions completed in action plan and freezer storage is sufficient.

APPROVED TEMPLATE

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	PFE2e -	Level of Shortfall (major or minor only)	Major
Short Description	Fridge and freezer alarm testing		
Inspection finding:			
<p>Following the previous inspection in 2019, manual systems were put in place to regularly monitor local audible fridge and freezer alarms out-of-hours in the body stores at the satellite sites, however, the system adopted has not been effective at the Royal Gwent Hospital site as this monitoring activity ceased in November 2020. This means there is no assurance at this site that an alarm would be responded to within a reasonable timeframe to ensure bodies continue to be stored at an optimal temperature.</p> <p>Whilst the fridges at the Nevill Hall Hospital satellite site are regularly monitored, including out-of-hours, there was no assurance provided that alarms have been tested to ensure they would trigger if temperatures deviated from the acceptable range.</p>			
Corrective and Preventative Action:			
<ul style="list-style-type: none"> SOP to be created and implemented to reflect the previous procedures carried out at the RGH when PM licensed activity was undertaken on the premises. The new SOP will cover activity undertaken on all licensed sites and will incorporate procedures for both monitoring and testing of alarms to mitigate risk of deterioration to bodies. Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group 			
Deadline for completion of corrective and preventative action:		17/03/2023	

HTA Use Only

Action for HTA:	Submission of evidence of compliance Closed ML – 20 May 2023
Compliance information to be submitted:	
<ul style="list-style-type: none"> Copy of the temperature and alarm monitoring SOP – received and reviewed. Evidence that relevant staff groups responsible for the monitoring of the units out-of-hours at Royal Gwent Hospital have read and acknowledged the SOP – received and reviewed. Evidence that fridge and freezer alarms have been tested at Neville Hall Hospital – 	

received and reviewed.

Action:

Please provide a copy of the completed time specific action plan for completeness

APPROVED TEMPLATE

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	PFE3b -	Level of Shortfall (major or minor only)	Major
Short Description	Bariatric transfer to mortuary arrangements		
Inspection finding:			
<p>The establishment do not have appropriately sized concealment trolleys or other suitable alternative arrangements in place for the transfer of bariatric bodies from the wards to the mortuary at the hub site and the satellite site, Nevill Hall Hospital. Currently bariatric bodies are transferred on beds and in a manner which does not provide assurance that the dignity of the deceased is being fully preserved.</p>			
Corrective and Preventative Action:			
<ul style="list-style-type: none"> • Create a plan and apply for appropriate capital to ensure that deceased of all sizes can be transported in a dignified way on the Grange and Nevill Hall sites. • Action plan to cover the month time period until 17/02/2023. Following this a realistic exact timescale for corrective action to be in place will be available. • Report to ABUHB HTA Governance Group (18/01/2023). • Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group 			
Deadline for completion of corrective and preventative action:		17/03/2023	

HTA Use Only

Action for HTA:	Submission of evidence of compliance Closed ML – 20 May 2023
Compliance information to be submitted:	
<ul style="list-style-type: none"> • Copy of the action plan created to address suitable transfer of bariatric bodies on the Grange and Nevill Hall sites – received and reviewed. • Meeting minutes of ABUHB HTA Governance Group (18/01/2023) – received and reviewed. • Evidence will be required that actions to address bariatric transfer have been completed – HTA will require to be updated once all actions complete and suitable bariatric transfer arrangements are in place. 	
Action:	

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Please advise if the bariatric transfer arrangements are now in place for completeness.

APPROVED TEMPLATE

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	GQ1a -	Level of Shortfall (major or minor only)	Minor
Short Description	Standard Operating Procedures (SOPs)		
<p>Inspection finding:</p> <p>Standard Operating Procedures (SOPs) do not always include sufficient detail of the identification checks performed relating to traceability of bodies or describe current practice. These include but are not limited to:</p> <ul style="list-style-type: none"> • Whilst bodies are regularly checked to ensure condition of the body is being maintained, these checks are not recorded or detailed within an SOP. • SOP MO0007 - Procedure for the release of patients from the Mortuary. Whilst this SOP details that three points of identification on the body are checked on release of the deceased against information brought by funeral directors there is no detail of what actions are taken in the event there are discrepancies in the information. • SOP MO0009 - Procedure for the identification and viewing of the deceased. This SOP is not clear how the identifiers received from visitors at the time of a viewing are checked against the body to confirm the correct visitors have arrived to view the correct body. <p>Furthermore, standard operating procedures are not aligned across the sites for similar procedures (see shortfall against standard GQ1(g)).</p> <p>To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies to ensure they contain sufficient details of identification checks performed and are reflective of current practice across the sites.</p>			
<p>Corrective and Preventative Action:</p> <ul style="list-style-type: none"> • Create action plan to review relevant SOPs Action plan to cover the three-month time period until 17/04/2023. • SOPs to be aligned across sites as per GQ1(g) • Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group 			
Deadline for completion of corrective and preventative action:		17/05/2023	

HTA Use Only

Action for HTA:	Submission of evidence of compliance Closed ML – 05 June 2023
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Compliance information to be submitted:

- Copy of cross site SOP for condition monitoring of the deceased – **received and reviewed.**
- Evidence relevant staff have read and acknowledged the condition checking SOP – **received and reviewed.**
- Copy of the action plan created to review relevant SOPs and align across sites – **received and reviewed.**
- (I have received the updated viewing SOP) – **received and reviewed.**
- The DI to provide assurance that SOPs reviewed detailing identification procedures of the deceased contain sufficient detail of the identification checks performed relating to traceability of bodies and describe current practice. – **received and reviewed**

APPROVED TEMPLATE

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	GQ2a -	Level of Shortfall (major or minor only)	Minor
Short Description	Mortuary audits		
Inspection finding:			
<p>Whilst the establishment are conducting regular audits, the schedule of audits conducted across all sites is limited. Traceability of bodies in storage audits are only completed yearly and do not cover accuracy of mortuary records relating to the deceased audited. Security audits at the hub site have been completed but do not form part of the audit schedule. The audits have included a review of swipe card access; however, the audit did not include a review of the CCTV in operation.</p> <p>Furthermore, process audits conducted are not aligned across the sites (see shortfall against standard GQ1(g)).</p>			
Corrective and Preventative Action:			
<ul style="list-style-type: none"> • Create action plan to review relevant audits across all sites for Mortuary Post Mortem Service/CAD team • Action plan to cover the three-month time period until 17/04/2023. • Audits to be aligned across sites as per GQ1(g) • Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group 			
Deadline for completion of corrective and preventative action:		17/05/2023	

HTA Use Only

Action for HTA:	Submission of evidence of compliance Closed ML – 29 May 2023
Compliance information to be submitted:	
<ul style="list-style-type: none"> • An audit schedule to be submitted for review and agreement that audits will cover relevant activities and in a timeframe that will allow discrepancies in procedures to be identified – received and reviewed. • Copy of the action plan created to address this shortfall – received and reviewed. 	

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	GQ5b -	Level of Shortfall (major or minor only)	Minor
Short Description	HTARI reporting SOP		
Inspection finding:			
The SOP for the management of HTA reportable incidents (HTARIs) does not clearly outline responsibilities for investigating incidents or the process for management of HTARIs and follow up to the HTA.			
Corrective and Preventative Action:			
<ul style="list-style-type: none"> Review existing document MPMO0003 - Dealing with Errors and Incidents RGH Mortuary. Ensure that the document clearly outlines responsibilities for the investigation of incidents and process management of HTARIs across all sites. Trigger lists to be placed on notice boards within HB sites to act as a reminder to all staff. To be document controlled and held on Q-pulse to ensure up to date versions are available Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group 			
Deadline for completion of corrective and preventative action:		17/05/2023	

HTA Use Only

Action for HTA:	Submission of evidence of compliance Closed ML – 29 May 2023
Compliance information to be submitted:	
<ul style="list-style-type: none"> Copy of the updated HTARI SOP – received and reviewed. Evidence relevant staff have read and acknowledged the updated SOP – received and reviewed. Evidence the trigger lists have been placed in relevant areas (this could be the date completed and area located) – received and reviewed. 	

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	GQ6a -	Level of Shortfall (major or minor only)	Minor
Short Description	Risk assessments		
Inspection finding:			
<p>Risk assessments do not sufficiently detail how identified risks are mitigated. Not all risk assessments have been reviewed against the HTARI categories to ensure appropriate mitigation for identified risks.</p> <p>Furthermore, risk assessments are not aligned across the sites for similar procedures. (see shortfall against standard GQ1(g))</p>			
Corrective and Preventative Action:			
<ul style="list-style-type: none"> • Create action plan to review relevant risk assessments across all sites for Mortuary Postmortem Service/CAD team • Action plan to cover the three-month time period until 17/04/2023. • Risk assessments to be reviewed against HTARI categories • Risk assessments to be aligned across sites as per GQ1(g) • Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group 			
Deadline for completion of corrective and preventative action:		17/05/2023	

HTA Use Only

Action for HTA:	Submission of evidence of compliance Closed ML - 06 June 2023
Compliance information to be submitted:	
<ul style="list-style-type: none"> • Copy of the action plan created to review relevant risk assessments and align across sites – received and reviewed. • Submission of two updated and aligned risk assessments (release of the deceased / viewing of the deceased for example) which demonstrate that sufficient control measure are in place to ensure risks have been mitigated – received and reviewed. • DI to provide assurance that all risk assessments on the action plan will be reviewed and updated as per the action plan produced – received and reviewed. 	

Corrective and preventative action (CAPA) plan

Grange University Hospital - 12036 - Routine on 7/11/2022

Please complete the blanks below

HTA Standard	PFE1a -	Level of Shortfall (major or minor only)	Minor
Short Description	Mortuary maintenance		
Inspection finding:			
<p>The inspection team identified the following areas that require maintenance at the satellite sites:</p> <ul style="list-style-type: none"> • There are areas of damage to walls in the body store and mortuary corridors at Royal Gwent Hospital satellite site exposing porous plaster. Furthermore, there are areas of damage to doors, doorframes, and some wooden fittings. This means these areas would be difficult to effectively clean and decontaminate. • Some ceiling tiles in the decommissioned PM room and the viewing room at Nevill Hall Hospital are damaged or not present and require replacement. 			
Corrective and Preventative Action:			
<ul style="list-style-type: none"> • Raise a request with works and estates response desk to complete restorative work required to be carried out. • Report to ABUHB HTA Governance Group (18/01/2023). • Identify funding stream as appropriate. • Weekly progress review meetings to be held with core team members (DI, Cellular Pathology Department Manager, Mortuary Manager, Pathology Governance Manager, and the Cellular Pathology Senior Quality Lead) and progress tracker to be updated until completion. This can be shared/escalations made with ABUHB HTA Governance Group 			
Deadline for completion of corrective and preventative action:		17/05/2023	

HTA Use Only

Action for HTA:	Submission of evidence of compliance Closed ML – 29 May 2023
Compliance information to be submitted:	
<ul style="list-style-type: none"> • Evidence the identified areas requiring attention have been repaired (this can be completed job request details or photographic evidence – please ensure to include date completed) – received and reviewed. 	



Care after Death Service

Internal Aneurin Bevan University Health Board Review

May 2023



Richard Morgan-Evans
Deputy Director of Operations

Contents of report

- Scope of review
- Background to the CAD service
- Current operating model of the CAD service
- Findings and recommendations of the review
- Summary of recommendations
- Appendix 1 – interviewee list
- Appendix 2 – CAD Assistant key responsibilities

Scope of the review

In March 2023 the Chief Operating Officer requested a review into the Care After Death (CAD) team, which came after a cross-divisional meeting regarding its future within the Health Board.

At the meeting the representatives did not feel they had sufficient information available to make a decision about the placement of the CAD service going forward. There was however a universal agreement that Facilities and Estates was the least preferred option from a placement perspective out of all options discussed.

There was an agreement that a review would be undertaken of the CAD service in terms of form and function to then make an assessment of where the service best sits from a Divisional perspective.

The areas for the review that were felt appropriate included:

- What happens with mass fatalities
- HTA compliance regulation, inspection and considerations
- Role of the Medical Examiner
- Consideration will be PALS service, Winter planning and role of the LRF.

It was also shared that Swansea Bay UHB has a comprehensive CAD service and it was suggested part of the review might take into account a review of the service they deliver. This has been included within this review.

Background to the CAD service

The Health Board's Care After Death (CAD) team was introduced in October 2020 to deliver a co-ordinated approach to Care After Death utilising the learning from both the COVID-19 Pandemic. The team have a front facing CAD office within each main site and also manage the body stores at our hospitals (excluding GUH) with duties such as ensuring dignity and respect of the deceased and releasing to Funeral Directors.

The Health Board's CAD service is unique in its approach and works as an integrated package for families with one team coordinating statutory paperwork, management of the body stores and provision of a single point of access for families. This has provided a consistent and compassionate approach. It is the opinion of this review that the CAD team effectively act as a 'patient flow team for the deceased' by ensuring multiple tasks are carried out and tracked to ensure the safe, respectful and timely movement of deceased patients to meet the needs of families, the Health Board and external organisations.

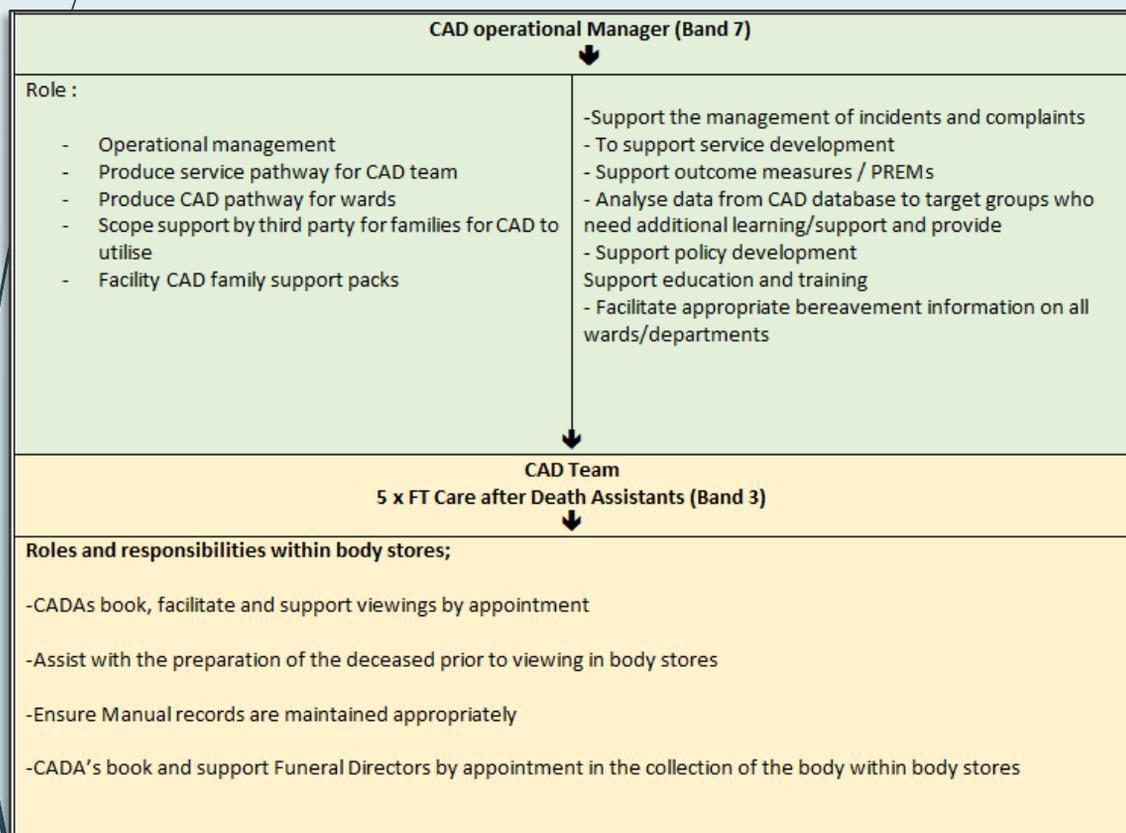
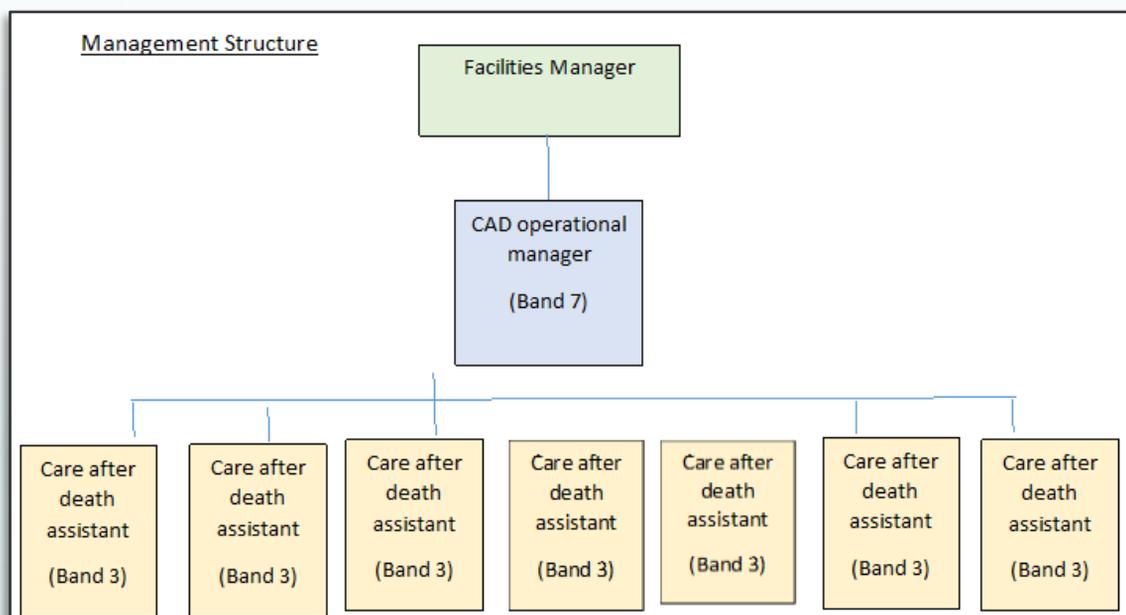
Since their introduction in 2020, the operational requirements of the team expanded with the necessity to provide support to the Medical Examiner (ME) Service. The ME Service is hosted by NWSSP and it provides an independent scrutiny of all deaths that are not investigated by the Coroner.

It was recognised in 2021 that in order to be able to fully support the roll out of the ME Service across the Health Board, an additional 2x WTE CAD assistants were required. This included 1x WTE to support the roll out at Nevill Hall Hospital and a further 1x WTE to provide an uplift to provide cover for natural roster abstractions such as annual leave. In November 2021 this was approved by the Executive Team. This brought the CAD assistant team to 7 x WTE.

The CAD service has sat within the Facilities and Estates Division and recently this had temporarily moved into Clinical Support Services (Pathology) before now being moved back into Facilities and Estates.

Current operating model of the CAD service

The current workforce breakdown of the CAD service is laid out below.



Findings & recommendations of the review

1. Management of the CAD Assistants as a team

Having engaged with members of the CAD team, it is clear that they understandably require a dedicated manager to oversee and develop the service. The period where the current CAD Manager was not in work had a detrimental impact on the team, who described not having someone to be able to escalate to as required. The CAD Assistants perform a vital role for the Health Board acting as a 'one stop shop' for the respectful and efficient management of the deceased including all paperwork, family liaison and tying in with wider stakeholders.

There was wide positive praise for the current CAD Manager who has channelled her passion into the service and its development. The CAD assistants experience difficult circumstances on a regular basis and rightly so they require the careful support and guidance of a manager to oversee and nurture the service.

During this review it has become apparent that the current B7 CAD Manager does not work to a formal / approved 'CAD' job description but instead has a previous primary and community care job description.

Recommendation – A replacement CAD Manager is required to manage the service and to act as an advice and escalation route whilst liaising with the wider organisation. As there is not a current approved JD, it is understood that there is a draft document in existence, which could be banded ready for recruitment.

Alternatively a neighbouring Health Board's JD could be utilised.

Recommendation – Accepting that there will be a gap between when the current manager leaves and a new manager is recruited, there is a requirement to identify an interim management arrangement to ensure the CAD assistants have an escalation route and sufficient oversight during this time. An interim arrangement would also act as a link between the service and where the service is situated. This is something that is missing in the past few months.

Findings & recommendations of the review

2. Split in body store and mortuary ownership at ABUHB and the future siting of the CAD service in ABUHB

Within ABUHB, the ownership and management of the mortuary, located at the GUH, and the body stores, located at local hospitals, is split. The CSS Division (Pathology service) manages the mortuary whilst Facilities and Estates manage the body stores.

Deceased bodies are often transferred between hospital sites (including the GUH) to balance demand and capacity. A contract with a private provider enables this transport and there is a requirement to ensure the accurate tracking and management of deceased patients. It is understood that there are various tracker tools and SOPs to enable this.

As a result of this historical set up, the CAD team manage the body stores and perform a vital multi-functional role. The CAD assistant role is outlined in detail within appendix 2. As part of this review this CAD role and service is considered to be intrinsically linked with 'mortuary services'.

Recommendation – It is therefore recommended by this review that the CAD service (and with it the body store management) be permanently transferred into Mortuary services (Pathology) within the CSS Division. This would unite all deceased patient storage and holistic management within ABUHB under one single structure.

It is recognised that the relationship between the CAD team and Pathology is not a strong one and will need to be improved with the help of a dedicated CAD Manager.

There is no current clear rationale for the CAD service to remain under Facilities and Estates. This current split has the possibility to pose a risk around handoffs between the two services as well as adherence to Human Tissue Authority regulatory oversight.

Findings & recommendations of the review

3. Bereavement component of the CAD Service

There is a great deal of passion and professionalism shown by the CAD service in managing the requirements of the deceased, including regularly liaising with families of the deceased. The service offers signposting to charities and organisations to provide onward support. They also offer a handprint / 'locks of hair' service for all patients as mementos to remember loved ones who have passed away.

The Welsh Government National Framework for delivery of bereavement care outlines the NICE three-component model of bereavement support:

Component 1 (universal): where information is offered regarding the experience of bereavement and people are sign-posted towards further support can be provided as part of a conversation, in written form (leaflets/factsheets) or via on-line resources. Support provided under Component 1 should be available to all those who need it.

Component 2 (selective or targeted): which makes provision for people to access more formal opportunities to reflect upon their grief, and may involve individual or group sessions, peer support, friendship groups, and/or specific groups relating to the type of bereavement, e.g. suicide.

Component 3 (indicated): which encompasses specialist interventions that may involve mental health services, psychological support and specialist counselling.

Findings & recommendations of the review

3. Bereavement component of the CAD Service continued

The current CAD service offers elements of component 1 of this framework by acting to signpost relatives of deceased patients to organisations to be able to provide ongoing support to them.

Recommendation - If ABUHB seeks to want to expand its overall bereavement offer in line with this framework then it is the opinion of this review that the CAD team would not be able to provide this service due to capacity and training requirements. The current offer from the CAD team is considered a positive one, which has been recognised nationally.

Within the Health Board there are wider spectrum of services offered through the use of volunteers. During this review there has been an offer by the Head of Nursing - Person Centered Care within the Health Board to develop further links with the CAD team. This would be to offer more support and advice, including the use of end of life volunteers and family befrienders as part of the pathway. **Recommendation** – Ensure further support is offered to the CAD team with the use of volunteer services.

Findings & recommendations of the review

4. Additional points as set out within the review scope

In order to ensure all aspects of the review scope are covered off the following points are addressed below:

- **What happens with mass fatalities** - if there was a mass fatality event (e.g. lots of people dying or lots of body parts) – There would be an ask from Local Authorities to the NHS to see if we had the capacity to house the deceased bodies. The Health Board answer would very likely be no due to capacity and timelines required (due to a possible criminal element). Each LA has a contract with a company who are able to provide a temporary mortuary (up to the LA to decide where that should be placed). If there was a mass fatality event the LRF would sit and set up a mass fatalities subgroup chaired by the coroner and supported by Newport LA. Ultimately LA's would have to take responsibility but would request technicians from the NHS. They would need to draw from Pathology and the Home office.
- **HTA compliance regulation, inspection and considerations** – HTA responsibilities fall under two overarching areas: The first is the job to make sure that bodies and body parts are looked after in a meticulous way as per strict SOPs. These are checked by regular audits. The second more broader element outlines that we should not do anything that brings the service into disrepute. Both CAD and Mortuary services have a significant role to play in this.
- **Role of the Medical Examiner** – The CAD team work very closely with the Medical Examiner service and during this review a senior representative from the ME office was interviewed. She did not raise any issues with the CAD service or the ongoing rollout plans for the ME requirement.

Findings & recommendations of the review

Additional points as set out within the review scope cont.

Consideration will be PALS service, Winter planning and role of the LRF

- Role of the LRF discussed previously under 'mass fatality' point.
- PALS service will need to decide how it supports and interacts with the CAD team. It is not recommended that the CAD service is placed within a PALS team.
- Winter Planning – The CAD service as part of Pathology will be vital in proactively planning for winter surge requirements. The closer the CAD service works with wider Pathology services will result in a more joined up plan.

It was also shared that Swansea Bay UHB has a comprehensive CAD service and it was suggested part of the review might take into account a review of the service they deliver. This has been included within this review

As part of this review the CAD lead for SBUHB was interviewed. The SB CAD service is an admin team that manages the paperwork and bereavement aspect of the duties. However the team do not interact with the deceased bodies – this is left to Mortuary services. Although the team currently sits within Patient Experience, this is currently being reviewed with a potential view to move under Mortuary services.

The team is made up of:

- Overall Lead for the service
- B6 lead – op management
- CAD Team = B4s = x5 looking to expand to x8.

Summary of recommendations

No.	Recommendation
1	<p>CAD Manager – A replacement CAD Manager is required to manage the service and to act as an advice and escalation route whilst liaising with the wider organisation. As there is not a current approved JD, it is understood that there is a draft document in existence, which could be banded ready for recruitment. Alternatively a neighbouring Health Board's JD could be utilised.</p>
2	<p>Interim arrangements - Accepting that there will be a gap between when the current manager leaves and a new manager is recruited, there is a requirement to identify an interim management arrangement to ensure the CAD assistants have an escalation route and sufficient oversight during this time. An interim arrangement would also act as a link between the service and where the service is situated. This is something that is missing in the past few months.</p>
3	<p>Placement within Pathology - It is recommended by this review that the CAD service (and with it the body store management) be permanently transferred into Mortuary services (Pathology) within the CSS Division. This would unite all deceased patient storage and holistic management within ABUHB under one single structure.</p> <p>It is recognised that the relationship between the CAD team and Pathology is not a strong one and will need to be improved with the help of a dedicated CAD Manager.</p>

Summary of recommendations Continued.

No.	Recommendation
4	Bereavement offer - If ABUHB seeks to want to expand its overall bereavement offer in line with this framework then it is the opinion of this review that the CAD team would not be able to provide this service due to capacity and training requirements. The current offer from the CAD team is considered a positive one, which has been recognised nationally.
5	Person Cantered Care / use of volunteers - Ensure further support is offered to the CAD team with the use of volunteer services.

Appendix 1

List of interviewees:

- **Gwawr Evans** – Assistant General Manager – Clinical Support Services
- **Steve Bonser** – Former Interim-General Manager, Facilities & Estates
- **Julia Hemming** – Cellular Pathology Department Manager
- **Ian West** – Facilities Manager
- **Steve Edwards** – Deputy Medical Director
- **Lorraine Hughes** – Care After Death Manager
- **Kimberley Hampton-Evans** (Swansea Bay UHB) – CAD Manager
- **Wendy Warren** – Head of Emergency Planning
- **Ian Thompson** – Clinical Director, Pathology
- **Melanie Moore** – Medical Examiners Service
- **Tanya Strange** – Head of Nursing - Person Centered Care
- **CAD Assistants (joint Teams discussion):**
 - Carolyn Stephens
 - Emma Clarke
 - Ethan Horsell
 - Alisha Williams

Appendix 2

CAD Assistant B3 JD key responsibilities

- Ensure all relevant paperwork of the deceased patient is recorded and logged as per SOP (Standard Operating Procedures) to ensure compliance with legislation.
- Ensure completion of medical cause of death certificate through liaison with doctors of all grades, pathologists, coroner's officers and risk manager, where appropriate, referring to senior member of staff where required.
- Provide a seamless service for bereaved relatives/registrars to receive Medical Cause of Death Certificate (MCCD) and personal effects.
- Responsible for the safekeeping of deceased patients' property including valuables and money and ensure associated documentation is properly completed and the property is in a condition acceptable to be handed over to the relatives.
- Contact the documented next of kin or first point of contact to inform them when delays are anticipated and to notify them when the certificate is ready.
- Manage and coordinate collection through an appointment system if necessary
- Provide relatives with practical information and sign post to appropriate bereavement support services.
- Support relatives in an empathetic manner if they are distressed when they arrive and escort relatives to view the deceased when a request to visit is made.
- Arrange for the clinical staff to speak to relatives if any concerns or questions about the death are raised.
- Register the death at the Registry Office of a patient who has no next of kin, liaising with the hospital chaplain and the contract funeral directors regarding funeral arrangements in these circumstances.
- Participate in service evaluation using agreed outcome measures.

Appendix 2

- Update and input data into a service database
- Debrief and engage in supervision
- Cover sickness and leave across other hospital sites
- Undertake ongoing training and personal development relevant to the role.
- Undertake basic tasks required to prepare the deceased prior to visiting of relatives, e.g. laying out of the deceased safely using mortuary equipment, brushing hair and ensuring dignity as appropriate
- Following authorised release paperwork received, responsible for releasing the body to an authorised party according to procedures. This will involve using mortuary equipment to transfer the deceased and the cleaning of trays following release.
- At all times, set the example in presenting warmth, compassion, empathy, good manners and diplomacy to grieving family members.
- Take part in rostered telephone on call service on weekends in order to provide advice to HB staff and families in relation to process and paperwork requirements. Working within level of competencies and referring to senior staff where applicable.
- Undertaking basic tasks within the mortuary that ensure no cross contamination, viewing room appropriate for relatives etc. e.g. cleaning of equipment to approved standards etc.



Royal Gwent Hospital
HTA licensing number 11130

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Licensable activities carried out by the establishment

Licensed activities – Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

‘E’ = Establishment is licensed to carry out this activity and is currently carrying it out.

‘TPA’ = Third party agreement; the establishment is licensed for this activity but another establishment (not licensed by the HTA) carries out the activity on their behalf.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Royal Gwent Hospital	E/TPA		E/TPA	E	E		

Tissue types authorised for licensed activities

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal, Bone; Bone	Authorised		Authorised	Authorised	Authorised		

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Royal Gwent Hospital (the establishment) had met the majority of the HTA's standards that were assessed during the inspection, two major and nine minor shortfalls were found against standards for Consent, Governance and Quality, and Premises, Facilities and Equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
<p>GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.</p>	<p>During an audit in 2020, the establishment identified an occasion where an incorrect femoral head was released for human application. This was reported to the HTA as a serious adverse event (SAE). The corrective and preventative actions (CAPAs) undertaken to prevent recurrence of this event included the implementation of a two-person check when transferring FH from the quarantine (F3) freezer to the release (F2) freezer following release by the Medical Director. Although establishment procedures were updated and the check was implemented, it was not maintained. At the time of the inspection, two-person checks at the point of transfer were not being routinely undertaken.</p> <p>During a review of internal incident records, two recent incident records were reviewed in which the record had been signed off as completed before all of the identified CAPAs had been completed. The establishment does not have a separate system to monitor progress of the completion of open CAPAs.</p>	<p>Major</p>
<p>i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.</p>		
<p>GQ7 There are systems to ensure that all adverse events are investigated promptly.</p>		
<p>a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of</p>		

any corrective or preventative actions.		
GQ2 There is a documented system of quality management and audit.		
a) There is a quality management system which ensures continuous and systematic improvement.	<p>During a visit to the Royal Gwent Hospital virology laboratory, it was determined that although donor serological samples are initially received and spun down at the laboratory, serology testing activities have transferred to the Grange Hospital, another hospital within the Trust. The change had not been communicated to, or identified by, the establishment. The new laboratory's premises and procedures have not been audited and no alternative steps have been taken to ensure the arrangements are suitable.</p> <p>The establishment's internal audit records are not sufficiently documented to provide assurance that all CAPAs have been identified and robustly addressed before the audit record is closed.</p>	Major

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.		
a) Staff involved in obtaining consent are provided with training on how to	Consent for donation is taken either in pre-operation clinics or on the day of surgery by trained nurses. A review of records demonstrated that the	Minor

take informed consent in accordance with the requirements of the HT Act and Code of Practice on Consent.	consent training for ward nurses had expired.	
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	Since the last inspection, the establishment has agreed an arrangement with an end user whereby distributed bone can be stored by the end user at -20°C for up to 48 hours before use. The establishment's governance documents, such as agreements and the information provided to end users, have not been updated to reflect this new arrangement and the specific requirements needed to ensure the quality and safety of the distributed bone in this scenario.	Minor
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.	The establishment does not have an agreement in place with the third party testing laboratory that undertakes specialist serological testing of donor samples on occasions where the donor's medical history indicates that additional tests to support the assessment of donor suitability are required.	Minor
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.	The establishment's written agreement with the third party laboratory that undertakes routine HTLV testing does not require the third party to maintain records of raw data in accordance with regulatory requirements.	

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.

e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	The establishment's procedures for documenting staff training, particularly in the context of the reading of updated procedures, do not satisfactorily demonstrate that staff receive such training prior to undertaking the related activity.	Minor
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GQ4 There is a systematic and planned approach to the management of records.

j) Records are kept of products and material coming into contact with the tissues and / or cells.	The establishment does not have a system in place to record the lot numbers of swabs coming into contact with femoral heads during procurement.	Minor
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GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 001/2021.	The establishment's bone donor medical history form requires updating to properly capture donor selection information in accordance with Directions 001/2021. For example, questions relating to diseases of unknown aetiology are limited to inflammatory diseases only, and the form does not explicitly prompt the donor to report medical history that could indicate a risk of immunosuppression or systemic infection.	Minor
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b) The testing of donors by the establishment or a third party on behalf of the establishment is carried	The manufacturers of kits used to undertake serological testing require that samples are spun down within 24 hours of being collected. The laboratory does not record the time at which samples are centrifuged, and was therefore unable to demonstrate that this requirement had been met.	Minor
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out in accordance with the requirements of Directions 001/2021.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.

a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.

The establishment's defined temperature limits for areas in which femoral head storage pots and the swabs used in microbiological testing are stored is not aligned with the storage temperature range stipulated by the manufacturer of the swabs.

The temperature of the St Woolos Hospital theatre area where a stock of swabs and pots are stored is monitored by a stand-alone temperature and humidity probe. The establishment has not provided calibration certification to demonstrate that the probe is suitably calibrated. In addition, a review of records taken using the probe identified several errors and occasions in which only the humidity measurement had been recorded. This indicated that recent staff refresher training had not been successfully embedded. Gaps were also identified in monitoring records relating to the storage area at St Joseph's Hospital.

The temperature monitoring form does not identify the equipment number of the probe used in each location, and examples were reviewed in which the section of the form identifying the location being monitored had not been completed.

Minor

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.	The establishment was unable to provide requested service records for the laminar flow within which microbiological samples are processed, or an incubator within which microbiological plates are incubated.	Minor

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	C1a, GQ5a	The DI is advised to define a maximum time between the taking of consent and donor selection and the day of procurement to ensure the patient's medical history and consent are reconfirmed on occasions where planned surgeries have been postponed for extended periods.
2.	C3a	The establishment is considering whether to restrict the taking of consent to clinic sessions prior to the day of planned surgery. If this change is approved, the DI is advised to ensure standard operating procedures are updated to reflect the change, ensuring arrangements at the third party procurement hospitals are also checked to confirm that they remain suitable and accurately documented.

3.	GQ1c, GQ2b, GQ5b	<p>The DI is advised to appoint Persons Designated (PDs) to represent the establishment's microbiology and virology laboratories and include these representatives in establishment governance meetings. This would help to strengthen lines of communication between the teams so that topics relevant to activities under the licence are reported and discussed.</p> <p>The DI is further advised to put a system in place to circulate governance meeting minutes by email to all invited attendees, to ensure those absent on the day are kept informed of items relevant to activities under the licence.</p>
4.	GQ4f,g	<p>Establishment staff create an entry in the bone bank database for a procured femoral head once the consent form linked to the donation event has been received into the bone bank office. However, the form may not be received until several weeks after the bone has been placed into the quarantine freezer and the serology and microbiology tests have been completed. Although the bone is not released for human application until all the necessary information has been collated and reviewed, the DI is advised to review the current system to ensure that it is suitable and does not create a risk to the security of records or the establishment's ability to manage incidents relating to procured bone that may occur before the database entry is created.</p>
5.	PFE3a	<p>The DI is advised to redesign the temperature monitoring form used to record the temperature and humidity of theatre areas, to assist staff in recording the readings correctly and as a reminder to reset the probe after each daily reading has been taken.</p>

Background

The establishment has been licensed by the HTA since March 2007. This was the establishment's seventh inspection; the last inspection took place in February 2019.

Femoral heads are procured at Royal Gwent Hospital and two other local hospitals, St Woolos Hospital and St Joseph's Hospital, under the terms of third party agreements (TPAs). Consumables, including swabs and storage containers, are supplied by the establishment.

Consent and the donor questionnaire are completed during pre-admission clinics or pre-operatively on the day of procurement. Blood samples for mandatory donor serology testing are taken at the same time as consent and repeated at least 180 days after procurement. Establishment procedures require femoral heads to be placed in quarantine storage at Royal Gwent within four hours of procurement. After receipt of the donor consent form, establishment staff will open a new patient file in the Bone Bank database and generate a unique identification number for the bone to maintain traceability. Microbiological testing of bone swabs and 'nibbles', as well as donor serological testing, is undertaken at the Royal Gwent UKAS-accredited laboratory, with the exception of HTLV testing, which is undertaken under the terms of a TPA.

Release from quarantine is undertaken by the Medical Director following review of the medical history form and the relevant microbiology and serology results.

Since the last inspection mandatory serological testing activities undertaken by the Trust laboratories have relocated to a different hospital within the Trust.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The following areas were covered during the inspection:

Review of governance documentation

The inspection included a review of policies and procedural documents relating to licensed activities, servicing records, agreements, audits, risk assessments, incidents, meeting minutes, temperature monitoring records, and staff training records.

Visual inspection

The inspection included a visual inspection of the establishment's locked and air-conditioned freezer storage area at Royal Gwent Hospital, which is also the room within which the main stock of consumables associated with procurement are stored. The inspection also

included visits to the theatres (within which some consumables are stored) at both Royal Gwent and St Woolos Hospital, and a visit to the establishment's microbiology and virology laboratories, within which donor serological testing and microbiological testing of bone swabs and 'nibbles' are undertaken.

Audit of records

The visual inspection included a review of three selected femoral heads in storage within the quarantine and release freezers against the entries within the associated bone back ledgers. The movement of bone from quarantine storage to release, as documented in the establishment's ledgers, was reviewed. Records of consent, donor selection, microbiology and virology assessment and release by the Medical Director were reviewed for three femoral heads, including one that was used in human application.

Meetings with establishment staff

Round table discussions were held with the DI, who is the establishment's Medical Director, the Deputy Medical Director, the establishment's Governance Manager and the Bone Bank Co-ordinator. The inspection also includes discussions with representatives of the microbiology and virology testing laboratories.

Report sent to DI for factual accuracy: 17 June 2022

Report returned from DI: 28 June 2022

Final report issued: 29 June 2022

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 21 November 2023

Appendix 1: The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, premises and practices are suitable.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

or

A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

- A notice of proposal being issued to revoke the licence
- Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- A notice of suspension of licensable activities
- Additional conditions being proposed
- Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) or the HTA Directions;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by

the HTA either by desk-based review or at the time of the next on-site inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.

Appendix 3: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards (as amended)

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the HTA's Codes of Practice.
b) If there is a third-party procuring tissues and / or cells on behalf of the establishment the third-party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.

C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 001/2021 is included.
b) If third parties act as procurers of tissues and / or cells, the third-party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 001/2021 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.

c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the Medical Devices Regulation 2002 (SI 2002 618, as amended) (UK MDR 2002) and United Kingdom Conformity Assessed (UKCA).
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.

p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.

d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.

e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 001/2021, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 001/2021.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 001/2021.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 001/2021.

c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using UKCA or CE marked diagnostic tests, in line with the requirements set out in Directions 001/2021.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.

d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.

c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure, and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24-hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.

PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2021.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.

c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly, and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.

D2 The reasons for disposal and the methods used are carefully documented.

a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.

b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Corrective and preventative action (CAPA) plan

Royal Gwent Hospital - 11130 - Routine on 17/5/2022

Date final report and CAPA template issued to the establishment: **29 June 2022**

Deadline for completed plan return: **13 July 2022**

Timelines for completion of agreed actions

- Major shortfalls **1-2 months** from date of issue of the final report
- Minor shortfalls **3-4 months** from date of issue of the final report

Please complete the blanks below

HTA Standard	GQ1i GQ7a -	Level of Shortfall (major or minor only)	Major (Cumulative)
Short Description	Implementation of HTA-agreed SAEARs CAPAs, monitoring of open CAPAs		
<p>Inspection finding: During an audit in 2020, the establishment identified an occasion where an incorrect femoral head was released for human application. This was reported to the HTA as a serious adverse event (SAE). The corrective and preventative actions (CAPAs) undertaken to prevent recurrence of this event included the implementation of a two-person check when transferring FH from the quarantine (F3) freezer to the release (F2) freezer following release by the Medical Director. Although establishment procedures were updated and the check was implemented, it was not maintained. At the time of the inspection, two-person checks at the point of transfer were not being routinely undertaken.</p> <p>During a review of internal incident records, two recent incident records were reviewed in which the record had been signed off as completed before all of the identified CAPAs had been completed. The establishment does not have a separate system to monitor progress of the completion of open CAPAs.</p>			
<p>Corrective and Preventative Action:</p> <p>F3 freezer ledger form amended to highlight the section on second person check (version control 3) at the time of transfer.</p> <p>CAPA's derived from non-compliance or SEARs to be reviewed in monthly governance meetings to assess progress of actions taken and documented prior to closing. CAPAs will be audited at 6 monthly intervals to ensure compliance and documented in the internal Audit Check List record.</p> <p>To ensure amendments of SOPs arising from subsequent CAPA's are embedded in practice, a signature of key personnel will be recorded on minutes of governance meeting, once reviewed to acknowledge review of SOP.</p>			
Deadline for completion of corrective and preventative action:		29 th August 2022 Amended form submitted	

HTA Use Only

Action for HTA:	
Compliance information to be submitted:	

Corrective and preventative action (CAPA) plan

Royal Gwent Hospital - 11130 - Routine on 17/5/2022

Please complete the blanks below

HTA Standard	GQ2a -	Level of Shortfall (major or minor only)	Major
Short Description	Change communication and management, management of audit actions		
<p>Inspection finding: During a visit to the Royal Gwent Hospital virology laboratory, it was determined that although donor serological samples are initially received and spun down at the laboratory, serology testing activities have transferred to the Grange Hospital, another hospital within the Trust. The change had not been communicated to, or identified by, the establishment. The new laboratory's premises and procedures have not been audited and no alternative steps have been taken to ensure the arrangements are suitable. The establishment's internal audit records are not sufficiently documented to provide assurance that all CAPAs have been identified and robustly addressed before the audit record is closed.</p>			
<p>Corrective and Preventative Action:</p> <p>The establishment's microbiology department has submitted a DATIX Cymru report to highlight the issue of failure to communicate change.</p> <p>The establishment will apply to HTA to include GUH as a satellite.</p> <p>The DI will risk assess GUH microbiology/serology premises for suitability, in addition will review procedures and amend SOP 4&5, The DI will complete an audit post implementation to ensure procedures are embedded.</p> <p>All internal audits will be completed utilising the Internal Audit Checklist Report (Version 2) (Appendix 14).</p>			
Deadline for completion of corrective and preventative action:		29 th August 2022	

HTA Use Only

Action for HTA:	
Compliance information to be submitted:	

Corrective and preventative action (CAPA) plan

Royal Gwent Hospital - 11130 - Routine on 17/5/2022

Please complete the blanks below

HTA Standard	C3a -	Level of Shortfall (major or minor only)	Minor
Short Description	Staff training in the taking of consent		
Inspection finding: Consent for donation is taken either in pre-operation clinics or on the day of surgery by trained nurses. A review of records demonstrated that the consent training for ward nurses had expired.			
Corrective and Preventative Action: Training for ward nurses to be reviewed and training updated.			
Deadline for completion of corrective and preventative action:		October 29 th 2022	

HTA Use Only

Action for HTA:	
Compliance information to be submitted:	

Corrective and preventative action (CAPA) plan

Royal Gwent Hospital - 11130 - Routine on 17/5/2022

Please complete the blanks below

HTA Standard	GQ1b -	Level of Shortfall (major or minor only)	Minor
Short Description	Agreements and information provided to end users		
<p>Inspection finding: Since the last inspection, the establishment has agreed an arrangement with an end user whereby distributed bone can be stored by the end user at -20°C for up to 48 hours before use. The establishment's governance documents, such as agreements and the information provided to end users, have not been updated to reflect this new arrangement and the specific requirements needed to ensure the quality and safety of the distributed bone in this scenario.</p>			
<p>Corrective and Preventative Action: The establishment will risk assess St Joseph's Hospital premises and facilities for the safe storage of femoral heads < 48hrs prior to use. Following risk assessment findings if suitable will amend the End User Agreement with St Joseph's Hospital to include conditions of storage, use of stored bone and responsibilities.</p>			
Deadline for completion of corrective and preventative action:		October 29 th 2022	

HTA Use Only

Action for HTA:	
Compliance information to be submitted:	

Corrective and preventative action (CAPA) plan

Royal Gwent Hospital - 11130 - Routine on 17/5/2022

Please complete the blanks below

HTA Standard	GQ1p GQ1r -	Level of Shortfall (major or minor only)	Minor
Short Description	Agreements with third parties		
<p>Inspection finding:The establishment does not have an agreement in place with the third party testing laboratory that undertakes specialist serological testing of donor samples on occasions where the donor's medical history indicates that additional tests to support the assessment of donor suitability are required. The establishment's written agreement with the third party laboratory that undertakes routine HTLV testing does not require the third party to maintain records of raw data in accordance with regulatory requirements.</p>			
<p>Corrective and Preventative Action:</p> <p>The establishment is in the process of ascertaining an SLA with our third-party testing laboratory performing malarial testing, but recognises the need for reviewing the necessity for this requirement as so few donors answer an affirmative to the question. We plan on auditing the number of donors who had required malarial testing to ascertain the loss and subsequent requirement to continue.</p> <p>The TPA with our testing laboratory completing HTLV tests for donors has been amended a final draft has been completed and is pending acceptance.</p>			
Deadline for completion of corrective and preventative action:		29 th September 2022	

HTA Use Only

Action for HTA:	
Compliance information to be submitted:	

Corrective and preventative action (CAPA) plan

Royal Gwent Hospital - 11130 - Routine on 17/5/2022

Please complete the blanks below

HTA Standard	GQ3e -	Level of Shortfall (major or minor only)	Minor
Short Description	Documentation of staff training, documented procedures		
<p>Inspection finding:The establishment's procedures for documenting staff training, particularly in the context of the reading of updated procedures, do not satisfactorily demonstrate that staff receive such training prior to undertaking the related activity.</p>			
<p>Corrective and Preventative Action:</p> <p>The establishment has documented training in place for procurement and consenting of staff which provides both information, testing of knowledge and feedback on the quality of the teaching. Amended SOP's relevant to staff involved in procurement and consenting are highlighted and documented as read.</p> <p>The establishment recognise limited evidence of recording of key personnel when they are updated in amendments of SOP's. This is to be recorded on the governance meeting minutes which will record discussed amendments and additional training identified if required or undertaken.</p>			
Deadline for completion of corrective and preventative action:		29 th October 2022	

HTA Use Only

Action for HTA:	
Compliance information to be submitted:	

Corrective and preventative action (CAPA) plan

Royal Gwent Hospital - 11130 - Routine on 17/5/2022

Please complete the blanks below

HTA Standard	GQ4j -	Level of Shortfall (major or minor only)	Minor
Short Description	Recording of consumables and reagents coming into contact with procured tissue		
Inspection finding: The establishment does not have a system in place to record the lot numbers of swabs coming into contact with femoral heads during procurement.			
Corrective and Preventative Action: The lot numbers and expiry date recorded on boxes of swabs are now documented in the 'pot specification' log book along with which site they have been sent.			
Deadline for completion of corrective and preventative action:		completed	

HTA Use Only

Action for HTA:	
Compliance information to be submitted:	

Corrective and preventative action (CAPA) plan

Royal Gwent Hospital - 11130 - Routine on 17/5/2022

Please complete the blanks below

HTA Standard	GQ5a -	Level of Shortfall (major or minor only)	Minor
Short Description	Medical history form		
<p>Inspection finding:The establishment's bone donor medical history form requires updating to properly capture donor selection information in accordance with Directions 001/2021. For example, questions relating to diseases of unknown aetiology are limited to inflammatory diseases only, and the form does not explicitly prompt the donor to report medical history that could indicate a risk of immunosuppression or systemic infection.</p>			
<p>Corrective and Preventative Action: The Bone bank medical history form is being reviewed and amendments planned.</p>			
Deadline for completion of corrective and preventative action:		29 th September 2022	

HTA Use Only

Action for HTA:	
Compliance information to be submitted:	

Corrective and preventative action (CAPA) plan

Royal Gwent Hospital - 11130 - Routine on 17/5/2022

Please complete the blanks below

HTA Standard	GQ5b -	Level of Shortfall (major or minor only)	Minor
Short Description	Donor testing		
<p>Inspection finding:The manufacturers of kits used to undertake serological testing require that samples are spun down within 24 hours of being collected. The laboratory does not record the time at which samples are centrifuged, and was therefore unable to demonstrate that this requirement had been met.</p>			
<p>Corrective and Preventative Action:</p> <p>The establishment acknowledges that the sample spin down time is not directly recorded, but the registration date and time are recorded. The DI is assured that no unspun sample will be issued a registration date or time and therefor this can be used as an indirect record of the spin time. If the registration date is within 24hrs, this complies with the manufacturers of kit recommendations.</p> <p>The DI and PD routinely review serology results prior to release. This will include a check of < 24hrs between 'collect and receive' time and any deviation from this will be individually risk assessed, documented as such and and femoral head discarded if indicated.</p> <p>SOP 7 (Release for use) is currently under review and amendments will be included.</p>			
Deadline for completion of corrective and preventative action:		29 th September 2022	

HTA Use Only

Action for HTA:	
Compliance information to be submitted:	

Corrective and preventative action (CAPA) plan

Royal Gwent Hospital - 11130 - Routine on 17/5/2022

Please complete the blanks below

HTA Standard	PFE3a -	Level of Shortfall (major or minor only)	Minor
Short Description	Temperature monitoring: staff training, completion of records, equipment suitability		
<p>Inspection finding:The establishment's defined temperature limits for areas in which femoral head storage pots and the swabs used in microbiological testing are stored is not aligned with the storage temperature range stipulated by the manufacturer of the swabs.</p> <p>The temperature of the St Woolos Hospital theatre area where a stock of swabs and pots are stored is monitored by a stand-alone temperature and humidity probe. The establishment has not provided calibration certification to demonstrate that the probe is suitably calibrated. In addition, a review of records taken using the probe identified several errors and occasions in which only the humidity measurement had been recorded. This indicated that recent staff refresher training had not been successfully embedded. Gaps were also identified in monitoring records relating to the storage area at St Joseph's Hospital.</p> <p>The temperature monitoring form does not identify the equipment number of the probe used in each location, and examples were reviewed in which the section of the form identifying the location being monitored had not been completed.</p>			
<p>Corrective and Preventative Action:</p> <p>The establishments have amended the Temperature & Humidity recording form to show the defined limits of consumables as per manufacturers stipulation.</p> <p>The establishment has collated evidence provided by the manufacturer that of the stand-alone temperature & humidity probe (Thermo Pro TP – 50) used in monitoring of consumable in both St Joseph's Hospital and St Woolos hospital has no requirement for calibration. The Di is assured of the accuracy and validity of recordings providing the manufacture's guidance is followed.</p>			
Deadline for completion of corrective and preventative action:		Completed – evidence to submit if required	

HTA Use Only

Action for HTA:	
Compliance information to be submitted:	

Corrective and preventative action (CAPA) plan

Royal Gwent Hospital - 11130 - Routine on 17/5/2022

Please complete the blanks below

HTA Standard	PFE5b -	Level of Shortfall (major or minor only)	Minor
Short Description	Equipment servicing and maintenance		
Inspection finding: The establishment was unable to provide requested service records for the laminar flow within which microbiological samples are processed, or an incubator within which microbiological plates are incubated.			
Corrective and Preventative Action: Service records have been provided and ready for submission.			
Deadline for completion of corrective and preventative action:		To submit	

HTA Use Only

Action for HTA:	
Compliance information to be submitted:	



**CYFARFOD BWRDD IECHYD PRIFYSGOLN
ANEURIN BEVAN
ANEURIN BEVAN UNIVERSITY HEALTH BOARD
MEETING**

DYDDIAD Y CYFARFOD: DATE OF MEETING:	02 September 2024
CYFARFOD O: MEETING OF:	Patient Quality, Safety and Outcomes Committee
TEITL YR ADRODDIAD: TITLE OF REPORT:	Research & Development Annual Report
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Dr James Calvert, Medical Director
SWYDDOG ADRODD: REPORTING OFFICERS:	Jeannette Wells, R & D Director Sue Bale, R & D Director Dr David Bosanquet, AMD R & D

**Pwrpas yr Adroddiad (dewiswch fel yn addas)
Purpose of the Report (select as appropriate)**

Er Sicrwydd/For Assurance

**ADRODDIAD SCAA
SBAR REPORT**

Sefyllfa / Situation

The Research and Development Annual Report provides information on the Health Boards key achievements, progress and planned next steps in meeting our research and development strategy – “Research – a core activity” (published December 2022).

Cefndir / Background

Reports from bodies such as the Academy for Medical Science and the Royal College of Physicians show how NHS organisations benefit from undertaking research as part of its core activity. The Health Board recognises this and to ensure that it meets expectations it requires an Annual Report highlighting the achievements and progress to meet the R & D strategy.

The Annual Report provides this information alongside assurances that the R & D department is financially stable and sustainable.

Asesiad / Assessment

The following provides an overview of the achievements during the past year.

- Clinical trial activity has increased from 57 non-commercial studies to 92 non-commercial studies.
- Relationships developed with commercial partners which has seen an increase in the number of commercial trials from 7 (2022/23) to 16 (2023/24) with a further 4 commercial trials in setup and 3 studies awaiting outcomes of the expressions of interest.
- ABUHB has again exceeded the WG/HRW target of 80% of all trials open to recruitment recruiting to time and target with a performance of 95% - increased from 89%. (The Wales average is 78%).
- Health Board was first Health Board in Wales with non-clinical member of staff gaining research officer accreditation. Individual recognised at HCRW Wales conference. Since then a second non-clinician has gained accreditation.
- Joined Wales working group to establish baseline requirements in developing sustainable commercial research presence in Wales, using UK funds to support hub and spoke model of research activity.
- Appointed Lead Nurse in training and education.
- Extended research activity with funded research leads in pharmacy, radiology and pathology.
- Developed research champions programme.
- ICH GCP facilitators trained.
- Research nurse appointed linking NIHR Associate PI schemes. Nurse provides support Health Board staff gain accreditation.
- Enhanced training created for all PI's.
- Positive feedback from students
- Support Advanced Nurse Practitioners to meet requirements set out in the pillars of advanced clinical practice.
- Working in partnership with Cardiff University, University of South Wales and Torfaen Local Authority to share activity, strategies and capability improving the Health Board evidence base.

Argymhelliad / Recommendation

The Committee is asked to receive the report for assurance.

Amcanion: (rhaid cwblhau) Objectives: (must be completed)	
Cyfeirnod Cofrestr Risg Corfforaethol a Sgôr Cyfredol: Corporate Risk Register Reference and Score:	
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	3.1 Safe and Clinically Effective Care 3.3 Quality Improvement, Research and Innovation Choose an item. Choose an item.
Blaenoriaethau CTCI IMTP Priorities Link to IMTP	Not Applicable Choose an item.
Galluogwyr allweddol o fewn y CTCI Key Enablers within the IMTP	Choose an item. Experience Quality and Safety
Amcanion cydraddoldeb strategol Strategic Equality Objectives Strategic Equality Objectives 2020-24	Not Applicable Choose an item. Choose an item. Choose an item.

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	
Rhestr Termau: Glossary of Terms:	
Partion / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol: Parties / Committees consulted prior to University Health Board:	

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Resource Assessment:	Please confirm you have completed the following:
• Workforce	Not Applicable
• Service Activity & Performance	Yes, outlined within the paper
• Financial	Not Applicable
Asesiad Effaith Cydraddoldeb Equality Impact Assessment (EIA) completed	No does not meet requirements

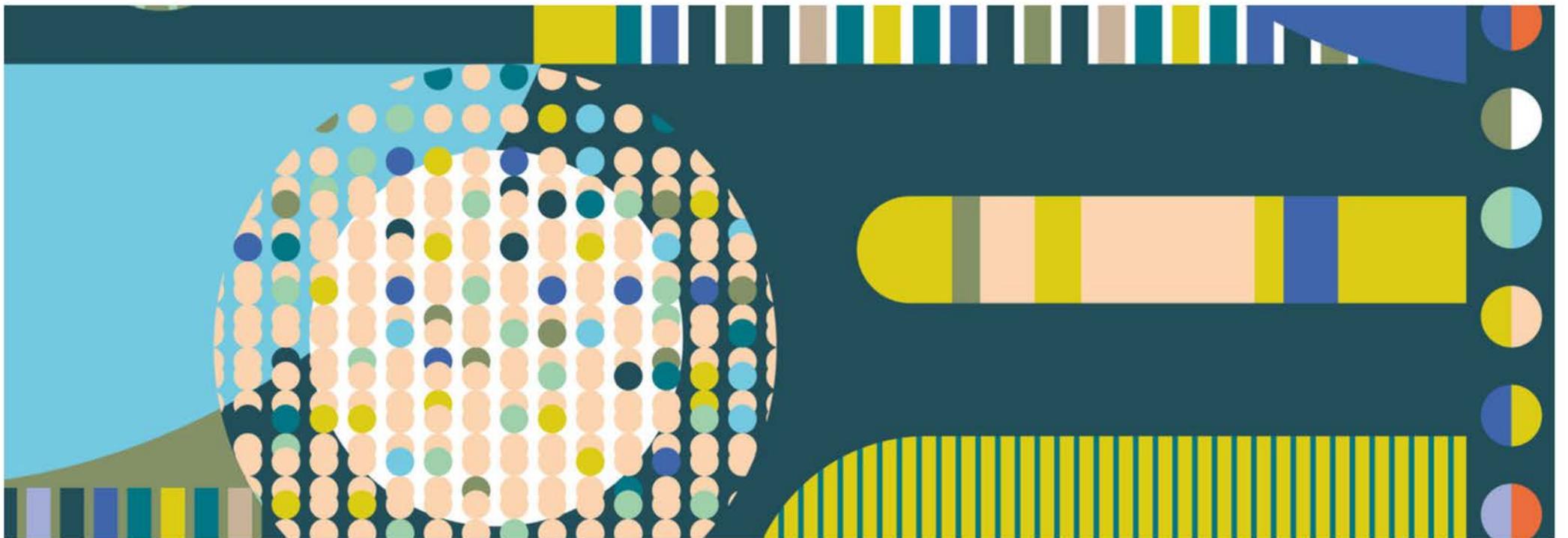
**Deddf Llesiant Cenedlaethau'r
Dyfodol – 5 ffordd o weithio
Well Being of Future
Generations Act – 5 ways of
working**

<https://futuregenerations.wales/about-us/future-generations-act/>

Not Applicable
Choose an item.



Research and Development Annual Report - 2023



Research and Development Strategy: Research – A Core Activity 2022 – 2027

Foreword

We are pleased to present the Aneurin Bevan University Health Board (ABUHB) annual research and development report which summarises key achievements, progress and planned next steps for the implementation of our research and development strategy: *“Research – a core activity”*.

Reports from bodies such as the Academy for Medical Sciences^[1] and the Royal College of Physicians^[2] show that NHS organisations which are research active benefit from the ‘research effect’. Those benefits include a better care experience, improved outcomes for patients and increased recruitment and retention of staff.

A core theme of our strategy is to ensure that the research infrastructure in ABUHB is financially stable and sustainable. During 2023 Health and Care Research Wales (HCRW), for the first time, set a cost pressure against the Research & Development (R&D) allocation. This resulted in the loss of bank nurses and two nurses were redeployed. Whilst HCRW have a cost pressure for 2024, assurances have been given that this will not affect the NHS. This reinforces the importance of the Health Board generating its own research income to support our patients and clinical services.

Despite external pressure the Health Board has achieved and maintained financial autonomy for its R&D allocation. Welsh Government allow Health Boards financial autonomy where they achieve the all-Wales standard ‘80% of all trials open to recruitment will recruit to time and target’: ABUHB performance has increased from 89% to 95% with the all-Wales average currently at 78%. The annual report summarises key achievements and progress over the last year and planned next steps, including for the coming year and beyond.

Published in December 2022, our Research Strategy aims to achieve a sustainable, streamlined, efficient and innovative research infrastructure built on three strategic objectives

- A sustainable and supported research workforce
- Investment in staff and infrastructure
- A streamlined, efficient and innovative research programme

It sets out our ambition to maximise opportunities for staff to get involved in research and for patients to participate in clinical trials or contribute to research studies that will inform future care. To achieve this, we have engaged widely across the Health Board and social media to establish a number of workstreams aligned to the strategic objectives.

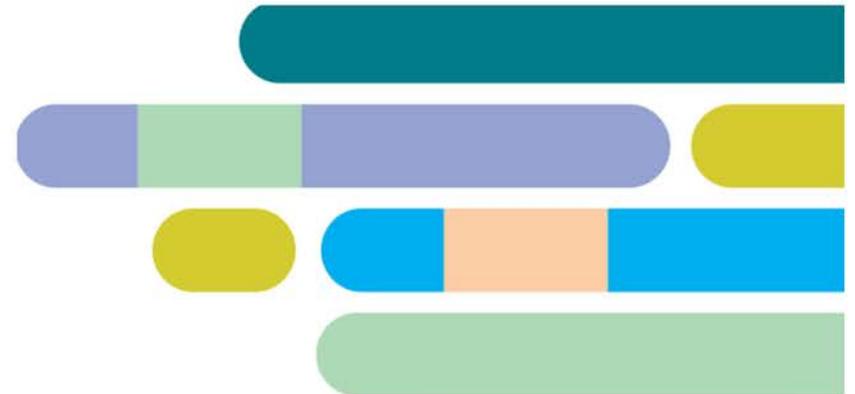
Our vision is to:

- integrate research delivery into operational services
- take research to the patient, regardless of location, wherever possible
- accept referrals from other Health Boards for patients to be included in research offered in ABUHB and vice versa
- build on areas of strength and opportunity
- align strategic plans to Health Board and Welsh Government priorities



To achieve this we will:

- Identify and continually review areas of priority for the Health Board, patients and Welsh Government.
- Work with the Health Board to assess existing referral pathways across organisations and expand to include research.
- Continually review workstream progress, identifying and removing barriers as they arise.
- Continue to identify best practice and share across all workstreams.
- Categorise clinical trials by complexity and risk to determine level of specialist research involvement required to run fully embedded studies.



ABUHB research implementation plan: designed by the workforce for the workforce

A series of engagement workshops were held over the first six months of 2023 to support the development of an implementation plan designed by the ABUHB workforce. As a result, eight workstreams were established.

The workstreams meet monthly and come together quarterly with the research senior management team to discuss progress, risks, barriers and any overlap.



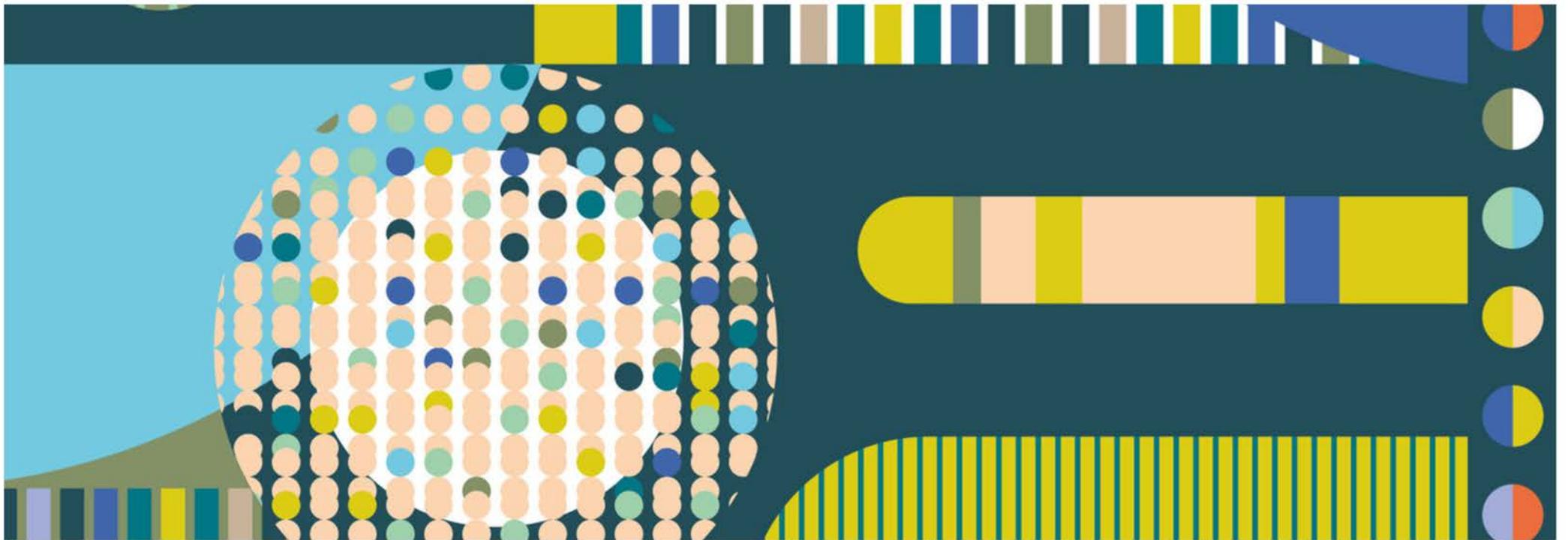
In 2023, HCRW issued WHC/2023/026: NHS Framework for Research and Development – Research Matters – What excellence looks like in NHS Wales. [3]

The framework consists of ten pillars, and in 2023 formed the baseline used by Welsh Government and HCRW for their annual performance review of NHS organisation research and development (R&D) activity.

Workstreams map progress and next steps against the framework to ensure compliance and for ease of reporting.



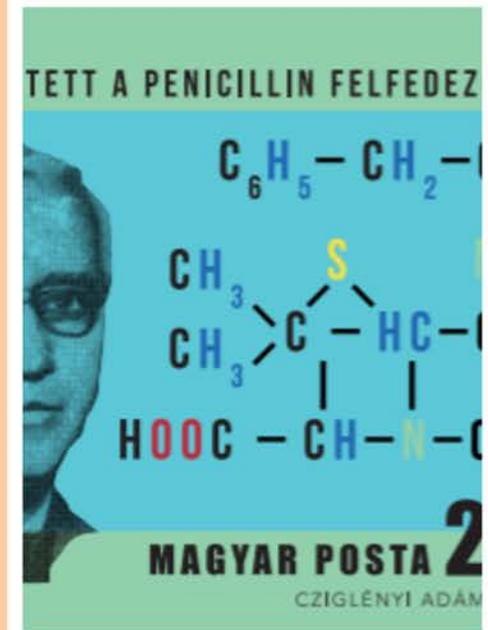
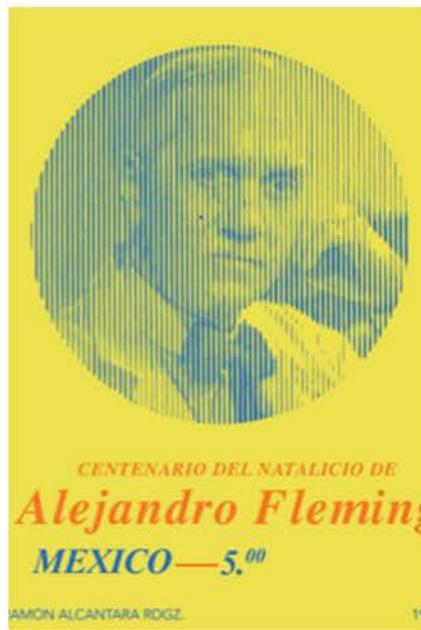
Why we do Research



1928 the discovery of Penicillin

Sir Alexander Fleming was a Scottish physician and microbiologist. He is best known for discovering penicillin, the world's first antibiotic substance.

His discovery in 1928 of what was later named benzyl penicillin (or penicillin G) from the mould *Penicillium Rubens* is described as the "single greatest victory ever achieved over disease." For this discovery, he shared the Nobel Prize in Physiology or Medicine in 1945 with Howard Florey and Ernst Boris Chain.



"One sometimes finds, what one is not looking for. When I woke up just after dawn on September 28, 1928, I certainly didn't plan to revolutionise all medicine by discovering the world's first antibiotic or bacteria killer. But I suppose that was exactly what I did."

Alexander Fleming



Strategic objective 1: a sustainable and supported research workforce



Action

Increase the number of commercial trials

Key publications:

- Lord O'Shaughnessy Review of Commercial Trial activity in the UK. [4]
- UK Government Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) funding: ABPI/NIHR/HCRW opportunity to develop commercial research hubs.

Progress

- Increased the number of commercial trials from 7 (2022/23) to 16 (2023/2024) with a further 4 commercial trials in setup and a further 3 studies awaiting the outcome of expressions of interest.
- A number of relationships have been established with Industry Partners who are keen to work with the Health Board as a preferred partner.
- ABUHB is a member of a group working with HCRW/WG to establish baseline requirements to develop a sustainable commercial research presence in Wales utilising UK Government VPAG funding (anticipated Welsh share: c£20m). The bid will pump prime a commercial hub and spoke model where Health Boards and Trusts in Wales will work together to offer patients the opportunity to take part in commercial clinical trials wherever in Wales the service can be provided. Non-recurrent funding is available from April 2025-March 2029; This will be factored in when bidding for funds to ensure services are sustainable at the end of that period.

Workstream

External Funding

Next steps: 2024

- Work with HCRW to bid for ABPI/NIHR/ VPAG funding to develop a sustainable commercial offering.
- Increase capacity within the research delivery team to set up and oversee the introduction of a commercial hub.
- Work with research active directorates to explore joint research fellow posts part funded by the directorate and part funded by R&D.
- Appoint a clinical research fellow to the clinical trials unit to support sustainable commercial research activity.
- Develop a brochure that will showcase the clinical trials unit. This will be used to build collaborative relationships with commercial companies.

Next steps: 2025

- Establish a commercial portfolio in phases. Phase one will include five clinical areas where there is expertise within the existing department and where commercial companies are already working with R&D and an established PI:
 - Haematology
 - Rheumatology
 - Older adult psychiatry
 - Interventional cardiology
 - Vascular wound healing

- Consolidate relationships with Innovation to support the development of new and innovative ideas through research, utilising HEI and Industry links.
- Manage the risk of the Sponsorship role. Commercial research should always have an external experienced Sponsor.
- Identify and remove barriers to commercial trial set up to ensure rapid study set up becomes a USP that attracts commercial companies to the Health Board as a preferred partner.
- Set up times for commercial trials (from receipt of the local information pack (LIP) to recruitment of 1st patient)
- NB: Metrics are only collected once a patient is recruited and when the recruitment target is less than 2
- 22/23 no data
- 23/24 152 days
- Prepare ABUHB bid for national VPAG funding.

RISKS:

- Commercial spend beyond five years will need to be sustained through commercial capacity building income.
- Inability to support services to continue research activity where a research active service is moved to a site with no research space. e.g. breast services relocation to YYF.

Action

Develop and deliver a training programme for all research active staff and those aspiring to become research active

Established training opportunities:

- ICH GCP (Good Clinical Practice) training.
- Principal Investigator (PI) training.
- Phase 2 trial training.
- Consent to research training.
- Student placement training opportunities.
- National Institute for Health Research (NIHR) Associate PI Scheme.
- NIHR Clinical Research Practitioner registration programme.
- Enhancement of the research team skills to ensure preparedness to accept earlier phase trials (commercial and non-commercial).

Progress

- Lead Nurse specialising in training and education has been appointed.
- In-house ICH GCP facilitators have received training from HCRW. As well as delivering full ICH GCP training the facilitators can deliver study specific ICH GCP training and ICH GCP training tailored to working environments.
- There is now a research nurse linked to the NIHR Associate PI Scheme. The nurse is able to offer all Health Board staff the opportunity to gain this accreditation. This work has already realised benefits by enabling the opening of studies with both medical and nursing associate PIs. The offer is also open to AHPs and non-clinical staff. Currently all AHPs involved in trials have been able to step straight into the PI role.
- In addition to the standard PI training offered, enhanced phase training has now been developed and is available for all PIs. This supports PIs embarking on more intensive complex trials, including PI oversight and documenting evidence of this.

Workstream

Education

- ABUHB were the first Health Board in Wales to support and successfully achieve a non-clinical staff member gaining research officer accreditation. The individual was recognised for their achievement at the HCRW conference. Since then, a second non clinical member of staff has completed accreditation. The Health Board continues to share this good practice by promoting the scheme locally and nationally.
- Student placements have been increased with positive feedback, including a nomination at the student conference. A previous student has secured a job within a research department in Wales.
- Enhanced skills training has been introduced across the research delivery team including emergency scenario training, complex trial toolkit and ward orientation for non-nursing staff.
- Established links with corporate nursing to support Advanced Clinical Practitioners in meeting the research requirements set out in the pillars of advanced clinical practice.

Next steps: 2024

- Develop research documentation training for all levels.
- Complete a training needs analysis at basic, medium and high level for all research active roles.
- Develop general awareness: how to embed research and basic research knowledge training for all Health Board staff.
- Continue to offer placements for student nurses and explore the opportunity to diversify to other specialties.

Next steps: 2025

- Develop phase 2 complex trial training for Health Board PIs.
- Explore the inclusion of 'research awareness' within the Health Board induction package.

RISK: Currently there is no capacity within the induction package to include research, therefore it is important that we continue to offer education on R&D elsewhere.

Action

*Workforce Opportunities:
Work with university
partners to promote
opportunities - university
collaborations*

Building University Partnerships:

- Re-establish the Health Board partnership Board.
- Develop PIs and Chief Investigators (CIs) through partnership working with HEIs and the HCRW faculty.
- Work with universities to develop low intensity low risk research that is relevant to local teams and whereby research can be embedded with light touch specialist research support.
- Review service evaluation oversight and identify most appropriate approval scrutiny route.

Progress

- Cardiff University is the main partner for ABUHB university Health Board status, although within Wales the Health Board also works closely with the University of South Wales, Cardiff Met University, Bangor and Swansea Universities.
- A meeting was held with the Dean of the Cardiff Medical School and his senior staff to explore additional opportunities.
- Made contact with the lead for the Cardiff University Joint Research Office (JRO) to explore the possibility of developing an ABUHB/CU JRO.

HEI and third sector research currently in development

- Cardiff University Business School/ABUHB Staff Well-Being and OD services. An NHS based research centre.
- Supporting Torfaen Local Authority (LA) to become research active. This will include working in partnership with the University of South Wales (USW) and Public Health Wales (PHW) to share strategies, policies, staff, research governance structures, etc; to develop capacity and capability within Torfaen LA to become an evidence-based and research active organisation.

Workstream

***University
Partnerships***

- The Torfaen partnership has been successful in winning an NIHR grant which will enable properly funded activity and present opportunities for further grant applications for more research across the partners. ABUHB staffs' salaries are built into this grant.

Next Steps: 2024

- Benchmark service evaluation review and approval across Wales and develop an SBAR to amend the current process.
- Re-establish the partnership board. The university partnership board is a forum where the local university partners meet with ABUHB Executives and leads for Research and Education to ensure alignment of vision and strategies and plans to deliver these.

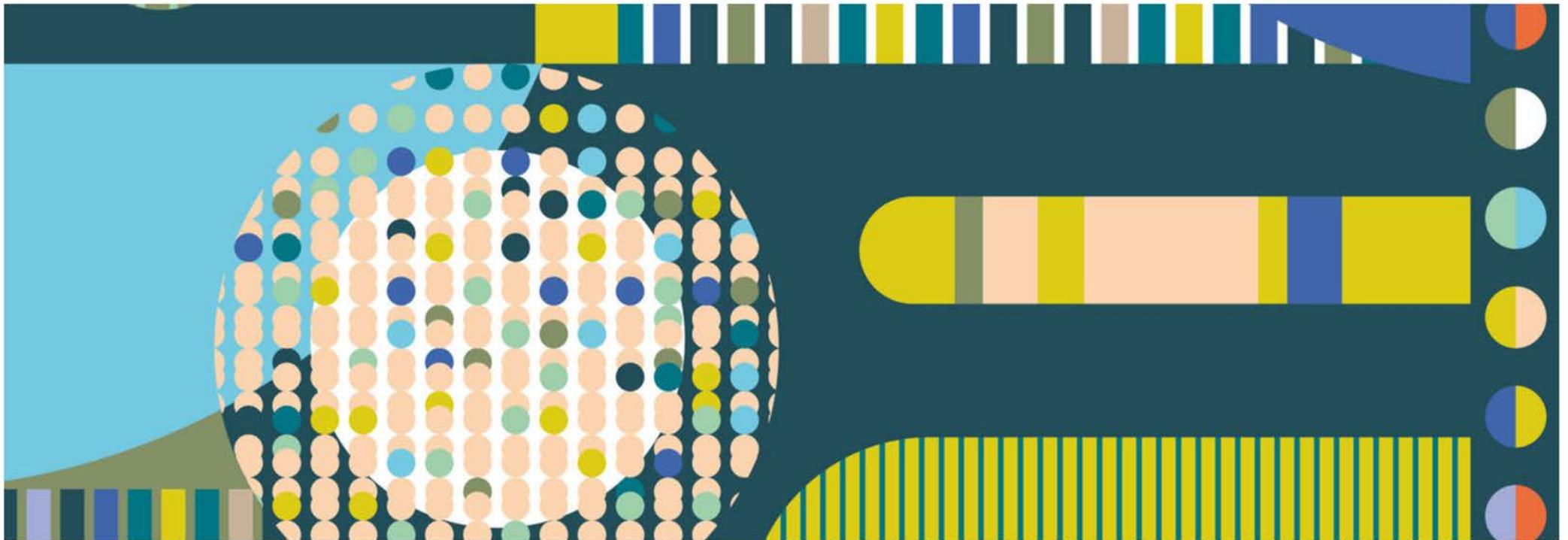
Next steps: 2025

- Establish university partnerships outside of Wales.
- Work with HEI partners to look at ways of being able to prioritise areas of research between ABUHB and its university partners where there is a shared interest and capacity.
- Maximise the potential of embedding low risk research university sponsored research into the core service. There is a continuous flow of research studies in development, funding applications, grants applications and awarded grants where research can be delivered between HEI partners (across a wide variety of schools) and ABUHB (across the diverse clinical and non-clinical Directorates).





Strategic objective 2: Investment in staff and infrastructure



Action

Trial feasibility to include assessments of complexity and risk to determine the level of support required from the research team, and capacity required of the clinical team to run the study

Action

Continue to meet HCRW performance metrics that demonstrate best practice and open doors for preferred partnerships.

Governance Infrastructure:

- Establish a new R&D committee.
- Research Quality committee.
- Research Risk Register.
- Audit programme to ensure compliance with GCP.
- Process for local research Sponsorship (under review).
- MHRA inspection preparedness.
- Continually review staffing levels and requirements to ensure progress in delivering the strategy can be maintained.
- Contracts manager appointed.

Workstream

Research delivery and governance infrastructure

Progress:

- Clinical trial activity has increased from 57 non-commercial and 5 commercial studies open and recruiting in 2022 to 92 non-commercial and 10 commercial studies in 2023.
- WG/HCRW all Wales metric '80% of all trials open to recruitment will recruit to time and target': ABUHB performance has increased from 89% to 95% with the all-Wales average currently at 78%.
- Improvement seen in trial set up and opening times, in line with national guidance this is monitored locally to identify and act on any blocks or delays.
- All studies undergo a complexity assessment to determine the level of support required by the research delivery team. Complexity also determines how much of the study can be embedded within standard care.
- At all complexity levels adequate departmental training is provided before the trial opens with ongoing support remaining under review, including the collection of recruitment metrics and problem solving as required.
- The study set-up system has been streamlined across research delivery and research governance teams with the of reducing/removing duplication.
- A trainee contracts manager has been appointed enabling quicker study set-up including implementation of the national contract value supporting the UK approach to standardised costing for commercial contracts and supporting the HCRW One Wales for research delivery programme which further streamlines the set-up process.
- Planning with the Cancer Directorate has led to increasing cancer trial opportunities and embedding research within standard of care. The work has included aligning the research strategy objectives with those set out in the National CReST strategy.^[5]
 - Studies include QuicDNA where ABUHB are sponsor and the first site to open. ABUHB and C&V are working closely with Cardiff university to open all sites in Wales. It is anticipated that blood biopsies to determine treatment plans for lung cancer will become standard practice in 2025 reducing the time taken to identify and start targeted treatment.
 - Year one has seen a rise in cancer research recruits by 3% and an increase of cancer trials from 9 to 16, compared to previous year.

- The R&D strategy and action plan is aligned to and takes consideration of the NHS Framework for Research and Development: WHC/2023/026 with regular self-assessment and benchmarking undertaken.
- A neonatal study, 'Neogastric' is the first trial where ABUHB have trialled its embedding model. Extensive departmental training was delivered, including meeting with staff on all shifts and delivering training at the cot-side. The first few recruits were overseen by the research delivery team and these were audited. Early indications are that the model has been a success.

Next steps: 2024

- Develop speciality research leads for each cancer area.
- Work with the of cancer services MDT to ensure research activity is discussed and that information is recorded regarding the number patients who enter cancer clinical trials including Velindre early phase trials.
- Review IT Infrastructure to support commercial activity. More worked is needed to comply with the MHRA expectation that all NHS organisations should be able to provide access to electronic health records, to enable quicker screening and easier access for external monitoring: to do this organisations need to have IT systems that reduce the associated with remote monitoring:
 - Monitors should have read only access
 - Site files should be electronic with enabled electronic archiving
 - Monitor access to files should be fully auditable
- Monitors should only be able to access the files of patients who are participants in the relevant trial

RISK: IT Infrastructure is currently the highest risk on the R&D risk register where the risk of an Information Governance Breach through E-Site files is scoring as high (12). The mitigation's being worked through with IT above will have the ability to reduce the risk to low.

Next steps: 2025

- Continue to monitor the embedding model and commence roll out to other areas under strict audit conditions.

Action

Support research active consultants

Research time: Opportunities

- develop role description to support the allocation of additional responsibility sessions for research within job planning.
- research time awards: i.e., HCRW faculty funding.
- work in conjunction with university partners to promote/establish joint working opportunities.
- ensure research is included in directorate activities. To include directorate meetings, quality committees and MDTs.

Progress:

Associate Medical Director for Research & Development Mr David Bosanquet appointed



"With amputation research, you can really change the outcomes for patients, especially when you listen to what they are saying."

Mr David Bosanquet

Ynion Iechyd a Gofal Cyffwrdd
HEALTH AND CARE
RESEARCH WALES

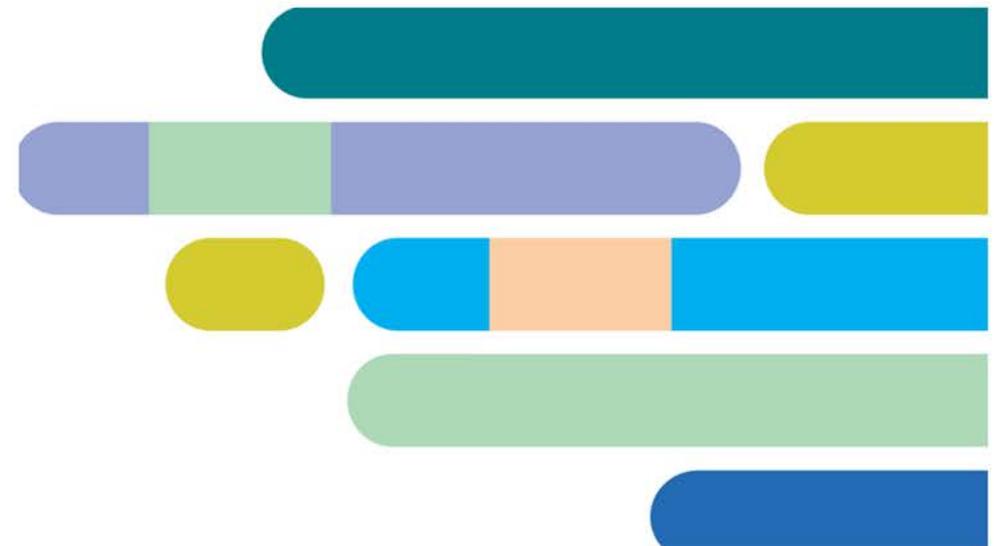
Ynion Iechyd a Gofal Cyffwrdd
HEALTH AND CARE
RESEARCH WALES

Workstream

Workforce Opportunities

Next steps: 2024

- Work with AMD for Job Planning to identify - SPAs and additional responsibility sessions awarded for research and correlate with research activity to validate continuation of paid sessions.
- Support incorporating research additional responsibility sessions into job planning.
- Identify Research Fellows across the organisation and discuss research activity and potential.
- Work with HEIs to progress opportunities for joint appointments.



Next steps: 2025

- Engage with Clinical Directors to ensure they are fully engaged with research activity.
- Engage with Clinical Directors and Directorate Managers to ensure research forms part of their quality agenda, covering research activity, support service engagement and service redesign.

Progress:

- Funded research leads in place in pharmacy, radiology and pathology.
- Funded Histopathologist time to ensure blocks and slides can be accessed in a timely manner for ABUHB patients taking part in clinical trials in ABUHB, Velindre and other sites.
- Regular contact with pharmacy with ongoing discussions to ensure capacity to provide aseptic products required to support the objective to deliver more commercial research as well as many non-commercial studies i.e., rheumatology, neurology
- Research pharmacist now attends all first dosing visits.

Next steps: 2024

- Work with pathology, radiology and pharmacy to identify and address delays in study set-up times.

Next steps: 2025

- Work with pathology, radiology and pharmacy to identify and remove blocks to enable delivery of studies.

RISK: service redesign can result in support services needing additional funding to support research at the new location.

- All Wales R&D directors and HCRW to liaise with Transforming Access to Medicines (TrAMs) coordinators to ensure clinical trials have access to aseptic pharmacy facilities. The aim of TrAMs is to enable access to aseptic pharmacy facilities in three hubs across Wales as part of shared services.

RISK: this is crucial to the success of the national VPAG bid and commercial research aspirations across Wales.

- Work with support services to compliment and streamline the delivery of research trials.
- Reach out to directorate pharmacists to scope ideas to link in with research pharmacists.

Action

Work with estates to enable a research presence across multiple sites

Progress

- Accommodation request made for clinical space in YYF to support surgical and breast cancer clinical trials.

RISK: bid has so far been unsuccessful (under review)

- A meeting has been arranged with the Medical Director, R&D Director and clinical teams in YYF to explore options.

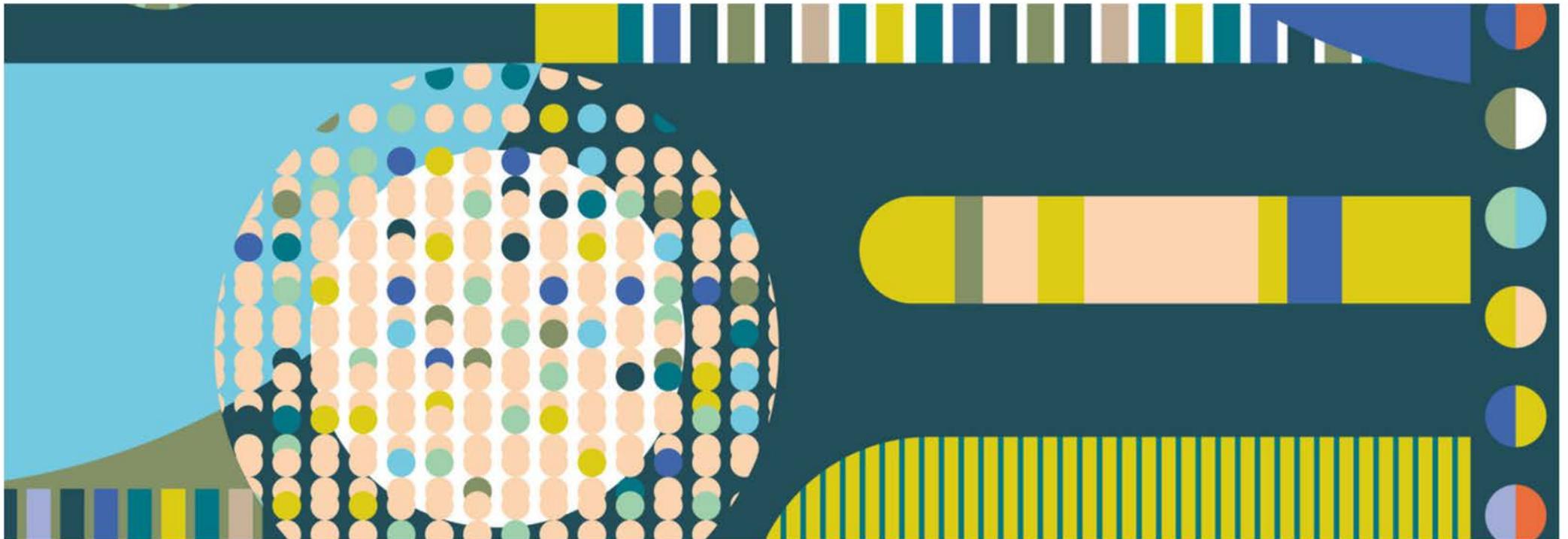
Next steps: 2024/2025

- Work with estates, planning and the Clinical Futures programme to develop new sites to establish clinical trial activity across multiple sites within the Health Board.
- Consider mobile research unit (possibly using VPAG funding).
- Re-submit accommodation request for clinical space in YYF to support surgical and breast cancer clinical trials (maintain communication channels.)
- Explore opportunities in GUH for clinical research space.
- Continue to work with cancer services, planning and Velindre to ensure clinical trial space and support service availability will be present in the proposed cancer centre at NHH.

Workstream
Support Services Estates



Strategic objective 3: A streamlined, efficient, and innovative research programme



Action

Establish a community of practice

Progress

- Communication mechanisms and engagement have been improved through various channels:
- X (formally Twitter)
- New Internet and Intranet pages
- HCRW and Health Board communications team have established links to ensure Intranet and Internet are aligned and that opportunities are not missed (research time, grant funding, education awards etc).
- R&D have established stronger working relationships with the Health Board communications team following the successful launch and open day in the clinical research centre.
- ABUHB research team are members of the National Communication Alliance, this ensures alignment of ABUHB research communication with HCRW and other Health Boards, subsequently increasing research visibility.
- The R&D Directors and Medical Director and the Health Board Independent Member for research meet on a monthly basis.

Next steps

- Engage with research champions through regular meetings and workshops to understand their priorities for research and also their views on study feasibility.
- Further develop and maintain the Intranet and Internet pages, ensuing opportunities are captured and publicised in advance.
- Develop patient experience poster board for public areas.

Workstream

Community of practice

Communications to improve workforce, patient and public awareness of R&D and to better understand research needs and priorities

Action

Establish a research champions programme

Progress

- Significant progress has been made in developing the research champions programme. The first cohort will meet in 2024. They will:
 - establish a terms of reference
 - discuss their priorities for research and also their views on study feasibility.
 - staff who are research champions will promote and encourage research activity
- Through social media patients and public have shown an interest in being research champions. Role descriptions have been developed and applications are being processed through the volunteer service.
- Research champion logo developed and agreed through consultation with staff and patients and the public. Badges, mugs and lanyards purchased in readiness for the launch.

Next steps: 2024

- **Launch research champion's programme**
- **Establish working groups for research champions**



Be a Voice for Research

RESEARCH CHAMPION



Opportunities for patients, carers, and members of the public

Are you:

- over the age of 16
- friendly and reliable?
- interested in research?

Would you like the opportunity to:

- Promote research in the Health Board and the Community?
- Share your views on some of the research studies the Health Board is considering taking on?
- Receive research-related training and education?



ffrind i mi
friend of mine

REGISTER NOW



ABB.Ffrindimi@wales.nhs.uk

Action

Support Principal Investigators

Progress

- PIs are being supported in their roles through development of networking opportunities.
- The PI: randomised coffee trials project launched in 2023 seeks to connect PIs from across the Health Board on a monthly basis regardless of professional background or area of work with the aim of encouraging networking opportunities and peer support.
- Established education sessions.

Next steps: 2024

- Invite external speakers to PI: randomised coffee trials. Record events to share more widely. Increase advertising for events.
- Establish a new open event session on the clinical trials unit where Health Board staff interested in applying for grant awards or research time opportunities can seek advice and guidance. Include university, faculty and HCRW partners as appropriate.

Progress:

Links made with:

- Diversity strategy.
- Communications and engagement strategy – empowering communities to have influence in how we deliver services, tailored to our audiences – utilising staff, community leaders and local trusted voices, listening to staff and patients – identifying correct stakeholders.
- ABUHB nursing strategy
- Clinical futures strategy
- Innovation strategy
- HCRW research framework
- Cancer strategy
- Estates strategy Health Board 10 year strategy

Action
Exploit opportunities to collaborate with internal and external strategy leads

Next steps: 2024

- Continued engagement with cancer board to embed research into all cancer MDTs.
- The Health Board nursing and midwifery strategy aims to embed research and innovation into practice. The workstream will review current and proposed activities to support corporate nursing in realising this aim.

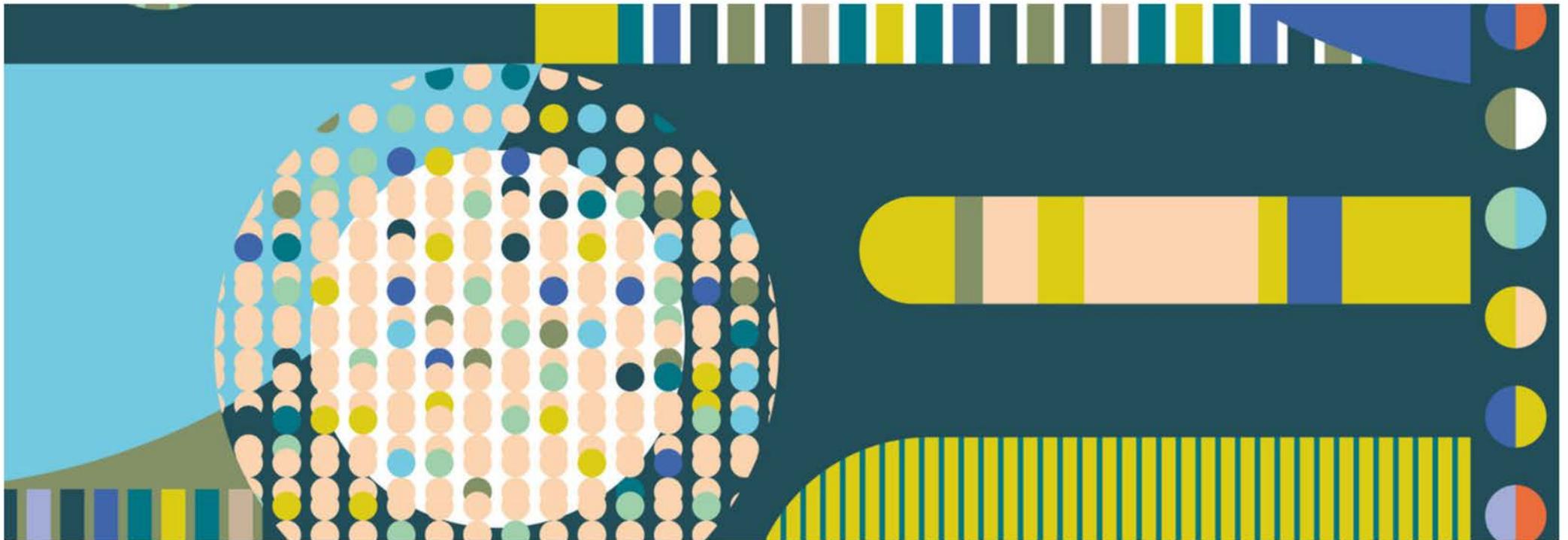
Next steps: 2025

- With executive lead support, work with clinical futures and planning to ensure research activities are inclusive to service redesign.
- With executive lead support, work with estates to establish clinical trials presence in YYF and GUH.



Research Governance

“Today, informed consent is at the heart of medical ethics and regulation to ensure the rights and dignity of research participants is protected”





1920–1951 Henrietta Lacks

Henrietta Lacks was an African-American woman whose cancer cells are the source of the HeLa cell line – the first immortalised human cell line. They reproduce indefinitely under specific laboratory conditions, and continue to be a source of invaluable medical data to the present day.

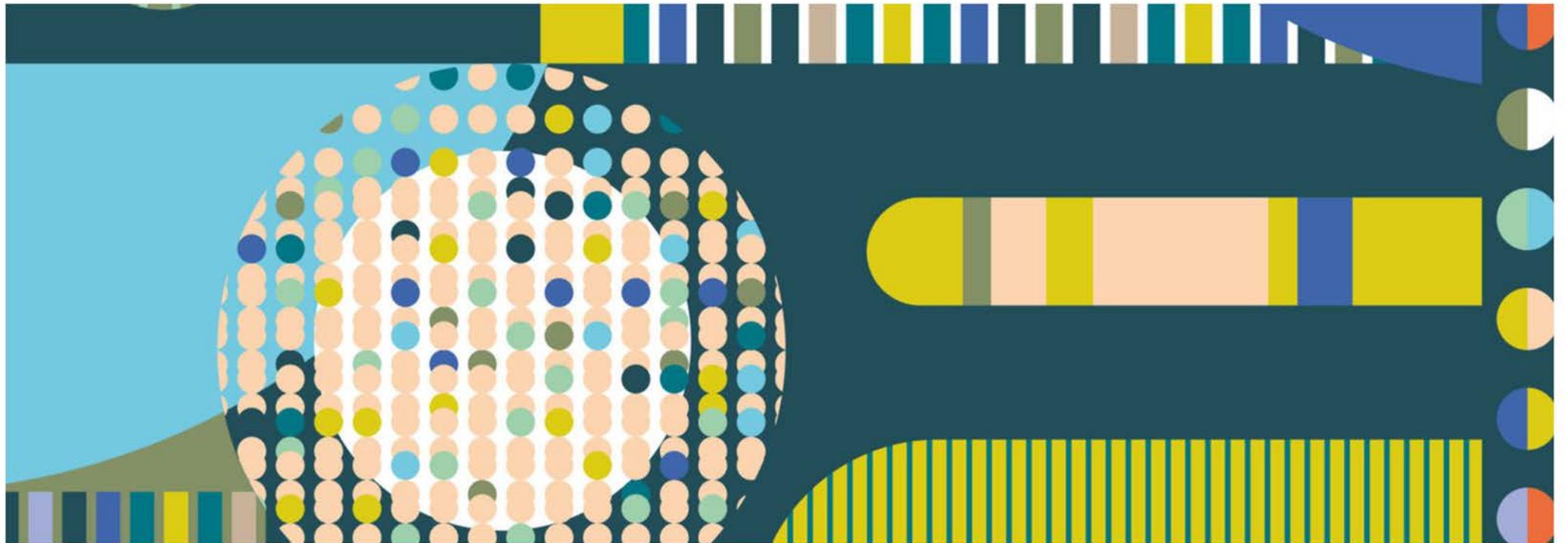
In 1951, Lacks underwent treatment for cervical cancer at Johns Hopkins Hospital in Baltimore. Cells from a tumour biopsy were cultured and the cell line known as HeLa was created. At the time, no consent was required to use the cells for research. It was only later in 1975 that the Lacks family were made aware of the cell line, and in October 2021, Lacks' estate filed a lawsuit against Thermo Fisher Scientific for profiting from the HeLa cell line without Lacks' consent.

The story of Henrietta Lacks, her family, and the creation of HeLa cells has been a catalyst for policy change. In particular emphasising the importance of informed consent.

Today, informed consent is at the heart of medical ethics and regulation to ensure the rights and dignity of participants of research projects are protected. Seeking informed consent properly respects a person's right to determine what happens to them by giving them the information they need to make a decision.



Forward Plan



The R&D strategy and action plan will remain under review to ensure flexibility to incorporate new guidance, changes to practice locally and nationally, and to continue to forge links to local and national strategies.

2023 examples:

- The Lord O'Shaughnessy Review: Commercial Clinical Trials in the UK, sets out 27 recommendations, including both priority actions and longer-term ambitions for UK commercial clinical trials
- UK government VPAG (voluntary scheme for branded medicines pricing, access and growth) in association with the ABPI (Association of the British Pharmaceutical Industry) will invest £300m over five years to bolster the NHS's capacity to deliver commercial clinical research.
- NHS Framework for Research and Development: WHC/2023/026
- CReST: the cancer research strategy for Wales

The Research Champion initiative has been under development throughout 2023. Volunteers from within the Health Board and members of the public have shown an interest in becoming research champions with members of the public currently being enrolled through the Health Board volunteer scheme. There will be a formal launch in 2024.

The Lead Nurse for Research Education has been in post for a year. Training programmes have been developed and delivered enhancing the knowledge and skills of researchers and aspiring researchers. The lead nurse is a member of the PQSOG and aligns that agenda with the R&D quality group including an audit programme and risk register. Next steps will see the introduction of a new R&D Committee that will receive reports from across all areas of research delivery and governance for information, action or escalation as appropriate.

2024 is set to be an exciting year. The appointment of an Associate Medical Director (AMD) for R&D there will bring a focus to supporting and developing research fellows, PIs and current or aspiring CIs.

The AMD will work alongside the current senior management team to further develop relationships with universities to provide opportunities for staff of all grades to work alongside/shadow university colleagues to better understand enablers to joint working.

In addition, the senior management team will consolidate connections with commercial companies interested in working with ABUHB as a preferred partner; this together with the VPAG funding should ensure ABUHB will be ready to meet the recommendations of the Lord O'Shaughnessy review to increase our commercial footprint. Once the UK Governments implement the recommendations of the review there will undoubtedly be new metrics set for commercial activity and those metrics will be performance managed. The strategy implementation team will continue to work flexibly to ensure the new metrics are implemented with immediate effect.

Recommendations

The Executive team are asked to note the contents of the annual report and submit to the PQSOG for information and submission to the Board.

References:

- [1] [Enhancing the NHS-academia interface | The Academy of Medical Sciences \(acmedsci.ac.uk\)](https://www.acmedsci.ac.uk)
- [2] [Research for all: Developing, delivering and driving better research | RCP London](https://www.rcplondon.ac.uk)
- [3] [Research matters - What excellence looks like in NHS Wales \(healthandcarereseearchwales.org\)](https://www.healthandcarereseearchwales.org)
- [4] [Commercial clinical trials in the UK: the Lord O'Shaughnessy review - final report - GOV.UK \(www.gov.uk\)](https://www.gov.uk)
- [5] [CReSt: the cancer research strategy for Wales - Marie Curie Research Centre - Cardiff University](https://www.mariecurie.ac.uk)





**CYFARFOD BWRDD IECHYD PRIFYSGOLN
ANEURIN BEVAN
ANEURIN BEVAN UNIVERSITY HEALTH BOARD
MEETING**

DYDDIAD Y CYFARFOD: DATE OF MEETING:	02 September 2024
CYFARFOD O: MEETING OF:	Patient Quality, Safety and Outcomes Committee
TEITL YR ADRODDIAD: TITLE OF REPORT:	National Organ Donation Report April 2023-March 2024
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Dr James Calvert, Medical Director
SWYDDOG ADRODD: REPORTING OFFICERS:	Dr Matthew Carwardine – Critical Care Consultant ABUHB & Clinical Lead for Organ Donation Sharon Keightley – Specialist Nurse for Organ Donation

**Pwrpas yr Adroddiad (dewiswch fel yn addas)
Purpose of the Report (select as appropriate)**

Er Sicrwydd/For Assurance

**ADRODDIAD SCAA
SBAR REPORT**

Sefyllfa / Situation

The latest NHSBT Report regarding Actual and Potential Deceased Organ Donation for ABUHB covers the period 1 April 2023 – 30 March 2024

The covering letter, full report and summary report is attached as Appendix 1.

Cefndir / Background

- Health Board organ donation performance reports are produced biannually by NHSBT and include a summary report, a detailed report and a covering letter highlighting key figures and issues.
- This latest report will be reviewed at the Health Board Organ Donation Committee (ODC) meeting to be held on 30th August 2024.
- The reports are generated using data from the National Potential Donor Audit (PDA) and the UK Transplant Registry.

- The PDA reviews all deaths in critical care and emergency department of patient's aged 80 and under to investigate the potential for missed opportunities for donation.
- Data from the PDA report also provides information on the quality of care in ABUHB at key stages of organ donation.
- This is then reviewed by the ODC to investigate where there is potential opportunities for care improvement.
- The ODC has input from a number of stakeholders. Key individuals include the Organ Donation Committee Chair (Shelley Bosson – Independent Member ABUHB), the Clinical Lead for Organ Donation/CLOD (Dr Matthew Carwardine – Critical Care Consultant ABUHB) and the Specialist Nurse for Organ Donation/SNOD (Sharon Keightley - NHSBT).
- The ODC Chair, Shelley Bosson, has now retired and stepped down as Chair and the Committee is currently waiting for a new chair to be nominated.

Asesiad / Assessment

Summary of donation activity:

- There were 8 solid organ donors over the 12 months from 13 consented donors which resulted in 19 patients receiving a transplant.
- 80 patients were referred and 24 met criteria for inclusion onto the Potential Donor Audit. This was 100% referral rate.
- There were no missed referrals during this period and there continue to be no missed referrals since 2019. This is a key aim to maintain as low as possible as it has the greatest impact in terms of avoiding missed opportunities for organ donation. The rate is a key indicator of Health Board success and performance.
- Currently ABUHB is classed as exceptional (gold) for referral rates when compared with UK performance and average (bronze) for SNOD presence and consent rates.
- A Specialist Nurse for Organ Donation (SNOD) should be present during every organ donation discussion with families as this has been shown to increase consent rates. This occurred in 18 organ donation discussions but there was 1 occasion where a SNOD was not present. This case has been reviewed by the ABUHB Organ Donation team and consent for organ donation was obtained in and it was believed that there were no specific actions to be learnt from the episode.
- A further target is that neurological death tests should be performed wherever possible in appropriate patients. This was not completed for 3 out of 16 potential patients as it was believed to be inappropriate given the personal circumstances of each case. These have also been reviewed by the Health Board organ donation team who agree with the decisions taken.
- In addition to solid organ donation, tissue donation is a vital part of donation activity. During the 12-month period 31 corneas were donated by ABUHB patients to the NHSBT Eye Banks.

Other notable activity:

- Successful introduction of a protocol for withdrawal of life sustaining treatment in theatres for donation after circulatory death; this has been used successfully for DCD donations.
- Successful in obtaining funds from the regional NHSBT funding stream and commissioned Studio Response to produce an Organ Donation Artwork that will be installed at GUH to commemorate our organ donors.
- ODC members have participated as faculty in a regional Deceased Organ Donation simulation course on the 15th April 2024 and several ABUHB staff also attended as delegates.
- Organ Donation Week in September 2023 saw a number of events take place and the front entrance of GUH was lit up pink to mark the occasion.
- A series of Organ Donation storyboards have been installed in the main corridor in GUH and an opening event was held on the 25th August 2023 with some of the donor families and transplant recipients involved in these stories.
- In July 2024 the GUH Organ Donation Team was awarded the Runner Up prize in the Team of the Year Award at the Health Board staff recognition awards.
- The Organ Donation Team has been well received at several community events in and around ABUHB to promote Organ Donation within the Ethnic Minority Groups, cultures and backgrounds.

Argymhelliad / Recommendation

The Committee is asked to consider the report for assurance.

Appendix 1

NHSBT Reports Apr 2023 – March 2024

Covering Letter



Letter.pdf

Detailed Report



Detailed report.pdf

Summary Report



Summary report.pdf

Amcanion: (rhaid cwblhau) Objectives: (must be completed)	
Cyfeirnod Cofrestr Risg Corfforaethol a Sgôr Cyfredol: Corporate Risk Register Reference and Score:	N/A
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	3.1 Safe and Clinically Effective Care 4.1 Dignified Care 5.1 Timely Access Choose an item.
Blaenoriaethau CTCI IMTP Priorities Link to IMTP	Not Applicable Choose an item.
Galluogwyr allweddol o fewn y CTCI Key Enablers within the IMTP	Choose an item. Experience Quality and Safety
Amcanion cydraddoldeb strategol Strategic Equality Objectives Strategic Equality Objectives 2020-24	Not Applicable Choose an item. Choose an item. Choose an item.

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	N/A
Rhestr Termau: Glossary of Terms:	N/A
Partion / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol: Parties / Committees consulted prior to University Health Board:	N/A

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Resource Assessment:	Please confirm you have completed the following:
• Workforce	Not Applicable
• Service Activity & Performance	Yes, outlined within the paper
• Financial	Not Applicable
Asesiad Effaith Cydraddoldeb Equality Impact Assessment (EIA) completed	No does not meet requirements

**Deddf Llesiant
Cenedlaethau'r Dyfodol – 5
ffordd o weithio
Well Being of Future
Generations Act – 5 ways of
working**
[https://futuregenerations.wales/
about-us/future-generations-act/](https://futuregenerations.wales/about-us/future-generations-act/)

Prevention - How acting to prevent problems occurring or getting worse may help public bodies meet their objectives
Long Term - The importance of balancing short-term needs with the needs to safeguard the ability to also meet long-term needs

May 2024

Dear Mrs Prygodzicz and Mr Calvert,

The number of donors and transplants in the UK have continued to improve and we are returning to pre-pandemic levels. Please accept our recognition and thanks for the effort of your staff.

This letter explains how your Health Board contributed to the UK's deceased donation programme.

Organ and tissue donation and transplantation activity - 2023/24

From 13 consented donors, Aneurin Bevan University Health Board facilitated 8 actual solid organ donors resulting in 19 patients receiving a transplant during the time period. Additionally, 31 corneas were received by NHSBT Eye Banks from your Health Board.

Quality of care in organ donation - 2023/24

The referral of potential organ donors to our Organ Donation Service and the participation of a Specialist Nurse for Organ Donation in the approach to family members to discuss organ donation are key steps in ensuring the success of organ donation.

- Your Health Board referred 80 patients to NHSBT's Organ Donation Services Team; no referrals were missed (100% referral rate) and 24 met the referral criteria for inclusion in the UK Potential Donor Audit.
- A Specialist Nurse participated in 18 organ donation discussions with families of eligible donors. There was 1 occasion when a Specialist Nurse was absent for the donation discussion.
- There was 1 (2%) missed opportunity to follow best practice out of 43 during the time period, compared with 1 (5%) out of 19 in 2022/23.
- In Wales, 44% of the population have registered an NHSBT Organ Donor Register (ODR) opt in decision. This compares to 42% of the population nationally.

Up to date Health Board metrics are always available via our Power BI reports found here:

<https://www.odt.nhs.uk/statistics-and-reports/potential-donor-audit-report/>.

What we would like you to do

- Ensure your Health Board supports your Organ Donation Committee and Clinical Lead for Organ Donation in promoting best practice as they seek to minimise missed donation opportunities.
- Discuss activity and quality data at the Board with support from your Organ Donation Committee Chair.
- Recognise any successes your Health Board has had in facilitating donation or transplantation, especially during the ongoing NHS pressures.
- An opt-in registration on the NHSBT Organ Donor Register results in the highest rates of consent, please support your Organ Donation Committee in their efforts to promote the NHSBT Organ Donor Register where possible.

Deemed Consent Legislation - Wales

Wales introduced deemed consent in December 2015. In Wales, between 1 December 2015 – 31 March 2024, there were 220 occasions when consent was deemed from 346 occasions where deemed consent applied.

Why it matters

In 2023/24, 154 people benefited from a solid organ transplant in Wales. However sadly, 15 people died on the transplant waiting list during this time.

Thank you once again for your vital ongoing support for donation and transplantation.

Yours sincerely,

Anthony Clarkson
Director of Organ and Tissue Donation and Transplantation
NHS Blood and Transplant



Detailed Report
Actual and Potential Deceased Organ Donation
1 April 2023 - 31 March 2024

Aneurin Bevan University Health Board

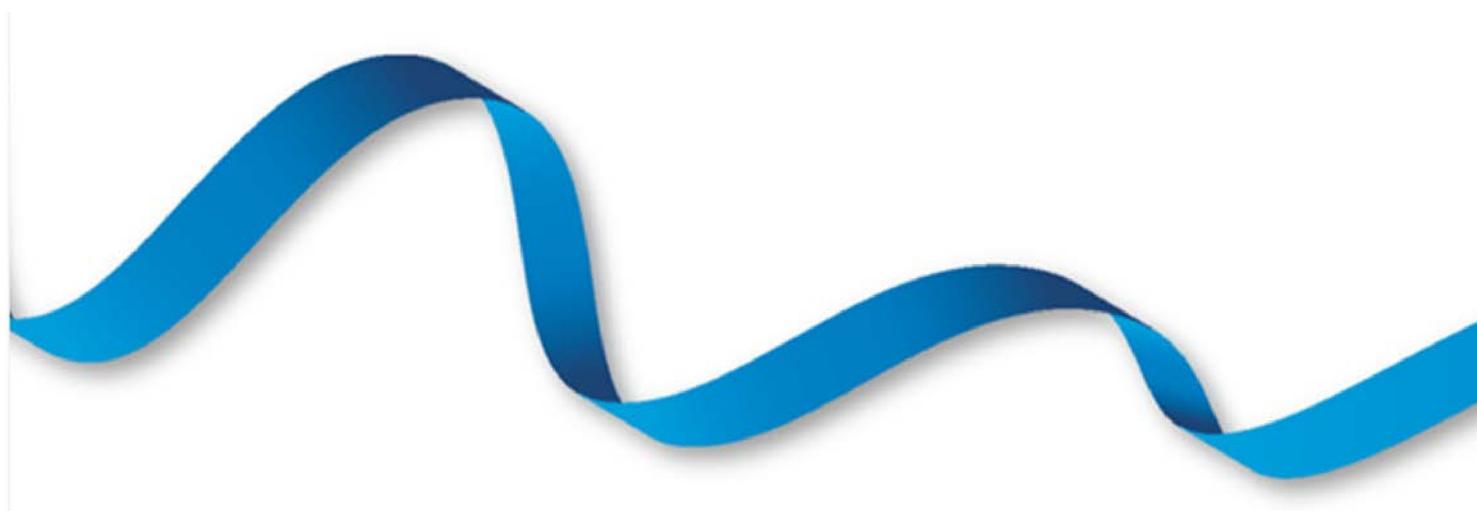


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- 3.5 Consent
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- A.2 Data description
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Further Information

- Appendix A.1 contains definitions of terms and abbreviations used throughout this report and summarises the main changes made to the PDA over time.
- The latest Organ Donation and Transplantation Activity Report is available at <https://www.organdonation.nhs.uk/supporting-my-decision/statistics-about-organ-donation/transplant-activity-report/>
- The latest PDA Annual Report and our Power BI reports with up to date Health Board metrics are available at <https://www.odt.nhs.uk/statistics-and-reports/potential-donor-audit-report/>.
- Please refer any queries or requests for further information to your local Specialist Nurse - Organ Donation (SNOD)

Source

NHS Blood and Transplant: UK Transplant Registry (UKTR), Potential Donor Audit (PDA) and Referral Record.
Issued May 2024 based on data meeting PDA criteria reported at 8 May 2024.

1. Donor Outcomes

A summary of the number of donors, patients transplanted, average number of organs donated per donor and organs donated.

Data in this section is obtained from the UK Transplant Registry

Between 1 April 2023 and 31 March 2024, Aneurin Bevan University Health Board had 8 deceased solid organ donors, resulting in 19 patients receiving a transplant. Additional information is shown in Tables 1.1 and 1.2, along with comparison data for 2022/23. Figure 1.1 shows the number of donors and patients transplanted for the previous ten periods for comparison.

Table 1.1 Donors, patients transplanted and organs per donor, 1 April 2023 - 31 March 2024 (1 April 2022 - 31 March 2023 for comparison)

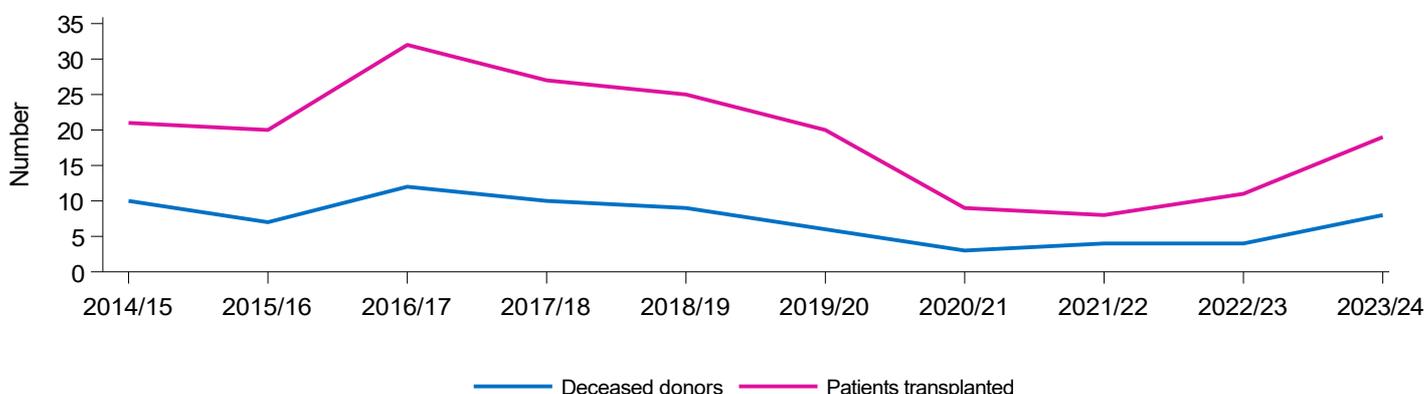
Donor type	Number of donors		Number of patients transplanted		Average number of organs donated per donor Health Board		UK	
DBD	6	(4)	15	(11)	3.2	(3.3)	3.6	(3.4)
DCD	2	(0)	4	(0)	2.0	(-)	2.9	(2.8)
DBD and DCD	8	(4)	19	(11)	2.9	(3.3)	3.2	(3.2)

In addition to the 8 proceeding donors there were 5 additional consented donors that did not proceed, one where DBD organ donation was being facilitated and 4 where DCD organ donation was being facilitated.

Table 1.2 Organs transplanted by type, 1 April 2023 - 31 March 2024 (1 April 2022 - 31 March 2023 for comparison)

Donor type	Number of organs transplanted by type											
	Kidney		Pancreas		Liver		Heart		Lung		Small bowel	
DBD	8	(8)	0	(1)	5	(2)	1	(1)	2	(0)	0	(0)
DCD	4	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)
DBD and DCD	12	(8)	0	(1)	5	(2)	1	(1)	2	(0)	0	(0)

Figure 1.1 Number of donors and patients transplanted, 1 April 2014 - 31 March 2024



2. Key Numbers in Potential for Organ Donation

A summary of the key numbers on the potential for organ donation

Data in this section is obtained from the National Potential Donor Audit (PDA)

This section presents key numbers in potential donation activity for Aneurin Bevan University Health Board. This data is presented in Table 2.1 along with UK comparison data. Your Health Board has been categorised as a level 3 Health Board and therefore percentages in this section are only presented on a national level. A comparison between different level Health Boards is available in the Additional Data and Figures section.

It is acknowledged that the PDA does not capture all activity. There may be some patients referred in 2023/24 who are not included in this section onwards because they were either over 80 years of age or did not die in a unit participating in the PDA.

**Table 2.1 Key numbers comparison with national rates,
1 April 2023 - 31 March 2024**

	DBD		DCD		Deceased donors	
	H. Board	UK	H. Board	UK	H. Board	UK
Patients meeting organ donation referral criteria ¹	16	2029	10	5331	24	6911
Referred to Organ Donation Service	16	2017	10	4949	24	6522
<i>Referral rate %</i>		99%		93%		94%
Neurological death tested	13	1534				
<i>Testing rate %</i>		76%				
Eligible donors ²	13	1426	10	3635	23	5061
Family approached	12	1259	7	1849	19	3108
Family approached and SNOD present	11	1215	7	1672	18	2887
<i>% of approaches where SNOD present</i>		97%		90%		93%
Consent ascertained	7	858	6	1023	13	1881
<i>Consent rate %</i>		68%		55%		61%
- Expressed opt in	4	533	4	637	8	1170
<i>- Expressed opt in %</i>		95%		85%		89%
- Deemed Consent	3	246	0	323	3	569
<i>- Deemed Consent %</i>		58%		47%		51%
- Other*	0	78	2	63	2	141
<i>- Other* %</i>		52%		34%		42%
Actual donors (PDA data)	6	788	2	710	8	1499
<i>% of consented donors that became actual donors</i>		92%		69%		80%

¹ DBD - A patient with suspected neurological death

DCD - A patient in whom imminent death is anticipated, ie a patient receiving assisted ventilation, a clinical decision to withdraw treatment has been made and death is anticipated within 4 hours

² DBD - Death confirmed by neurological tests and no absolute contraindications to solid organ donation

DCD - Imminent death anticipated and treatment withdrawn with no absolute contraindications to solid organ donation

* Includes patients where nation specific deemed criteria are not met and the patient has not expressed a donation decision in accordance with relevant legislation

Note that a patient that meets both the referral criteria for DBD and DCD organ donation is featured in both the DBD and DCD data but will only be counted once in the deceased donors total

3. Best quality of care in organ donation

Key stages in best quality of care in organ donation

Data in this section is obtained from the National Potential Donor Audit (PDA)

This section provides information on the quality of care in your Health Board at the key stages of organ donation. The ambition is that your Health Board misses no opportunity to make a transplant happen and that opportunities are maximised at every stage.

3.1 Neurological death testing

Goal: neurological death tests are performed wherever possible.

Figure 3.1 Number of patients with suspected neurological death, 1 April 2019 - 31 March 2024

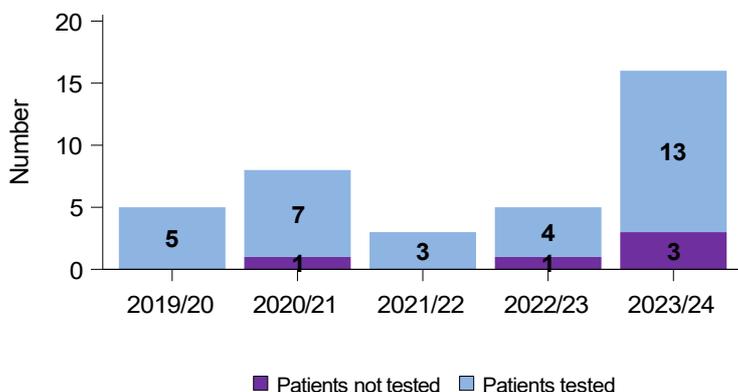


Table 3.1 Reasons given for neurological death tests not being performed, 1 April 2023 - 31 March 2024

	Health Board	UK
Biochemical/endocrine abnormality	-	32
Clinical reason/Clinician's decision	-	72
Continuing effects of sedatives	-	15
Family declined donation	1	40
Family pressure not to test	1	55
Hypothermia	-	1
Inability to test all reflexes	-	20
Medical contraindication to donation	-	5
Other	-	58
Patient had previously expressed a wish not to donate	-	4
Patient haemodynamically unstable	1	151
Pressure of ICU beds	-	1
SN-OD advised that donor not suitable	-	13
Treatment withdrawn	-	20
Unknown	-	8
Total	3	495

If 'other', please contact your local SNOD or CLOD for more information, if required.

3.2 Referral to Organ Donation Service

Goal: Every patient who meets the referral criteria should be identified and referred to the Organ Donation Service, as per NICE CG135¹ and NHS Blood and Transplant (NHSBT) Best Practice Guidance on timely identification and referral of potential organ donors².

Aim: There should be no purple on the following charts.

Note that patients who met the referral criteria for both DBD and DCD donation will appear in both bar charts and both columns of the reasons table.

Figure 3.2 Number of patients meeting referral criteria, 1 April 2019 - 31 March 2024

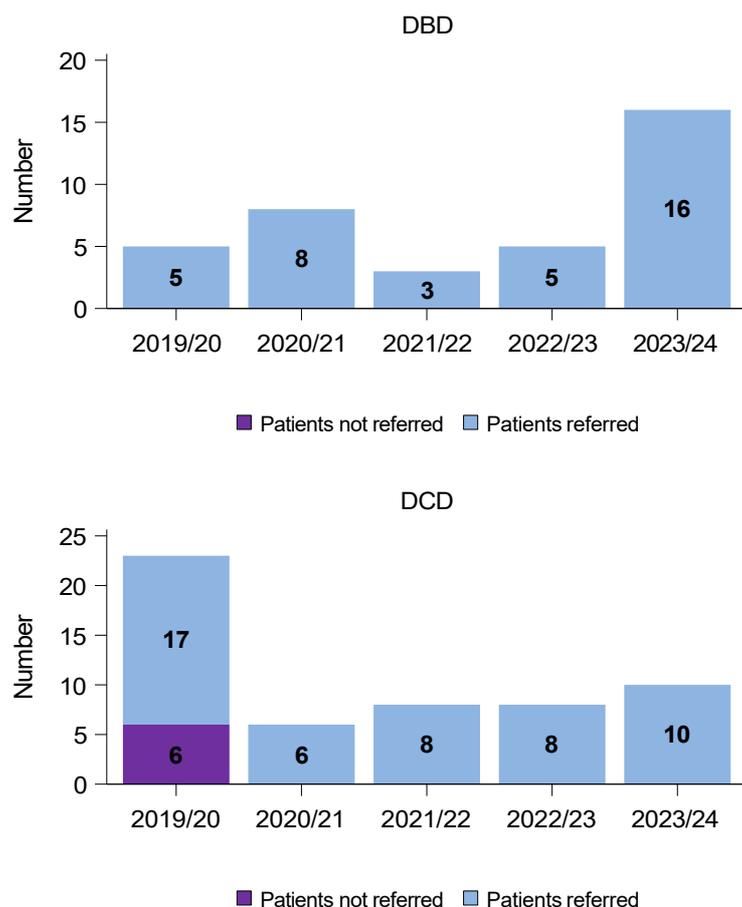


Table 3.2 Reasons given why patient not referred to SNOD, 1 April 2023 - 31 March 2024

	DBD		DCD	
	Health Board	UK	Health Board	UK
Clinician assessed that patient was unlikely to become asystolic within 4 hours	-	-	-	4
Coroner / Procurator Fiscal reason	-	1	-	-
Family declined donation following decision to remove treatment	-	-	-	9
Family declined donation prior to neurological testing	-	-	-	1
Medical contraindications	-	-	-	42
Not identified as potential donor/organ donation not considered	-	8	-	260
Other	-	1	-	9
Patient had previously expressed a wish not to donate	-	-	-	2

If 'other', please contact your local SNOD or CLOD for more information, if required.

**Table 3.2 Reasons given why patient not referred to SNOD,
1 April 2023 - 31 March 2024**

	DBD		DCD	
	Health Board	UK	Health Board	UK
Pressure on ICU beds	-	-	-	5
Reluctance to approach family	-	-	-	2
Thought to be medically unsuitable	-	-	-	42
Uncontrolled death pre referral trigger	-	2	-	6
Total	-	12	-	382

If 'other', please contact your local SNOD or CLOD for more information, if required.

3.3 Contraindications

In 2023/24 there were 16 potential donors in your Health Board with an ACI reported, 16 DBD and 16 DCD donors. Please note, the number of potential DBD and DCD donors with an ACI reported may not equal the total stated as a patient can meet potential donor criteria for both DBD and DCD donation.

3.4 SNOD presence

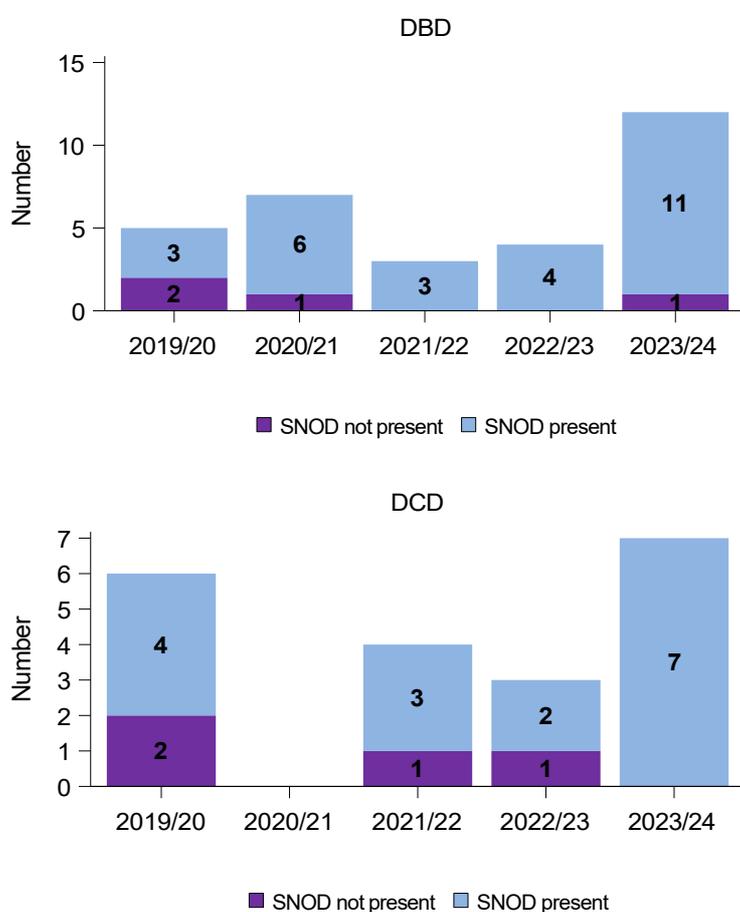
Goal: A SNOD should be present during the formal family approach as per NICE CG135¹ and NHS Blood and Transplant (NHSBT) Best Practice Guidance.³

Aim: There should be no purple on the following charts.

In the UK, in 2023/24, when a SNOD was not present for the approach to the family to discuss organ donation, DBD and DCD consent/authorisation rates were 23% and 14%, respectively, compared with DBD and DCD consent/authorisation rates of 70% and 60%, respectively, when a SNOD was present.

Every approach to those close to the patient should be planned with the multidisciplinary team (MDT), should involve the SNOD and should be clearly planned taking into account the known decision of the patient. The NHS Organ Donor Register (ODR) should be checked in all cases of potential donation and this information must be discussed with the family as it represents the eligible donor's legal consent to donation.

Figure 3.3 Number of families approached by SNOD presence, 1 April 2019 - 31 March 2024



¹ NICE, 2011.
NICE Clinical Guidelines - CG135
[accessed 8 May 2024]

² NHS Blood and Transplant, 2012.
Timely Identification and Referral of Potential Organ Donors - A Strategy for Implementation of Best Practice
[accessed 8 May 2024]

³ NHS Blood and Transplant, 2013.
Approaching the Families of Potential Organ Donors – Best Practice Guidance
[accessed 8 May 2024]

3.5 Consent

In 2023/24 the DBD consent rate in your Health Board was 58%, less than 10 families of eligible DCD donors were approached therefore this consent rate is not presented.

Figure 3.4 Number of families approached, 1 April 2019 - 31 March 2024

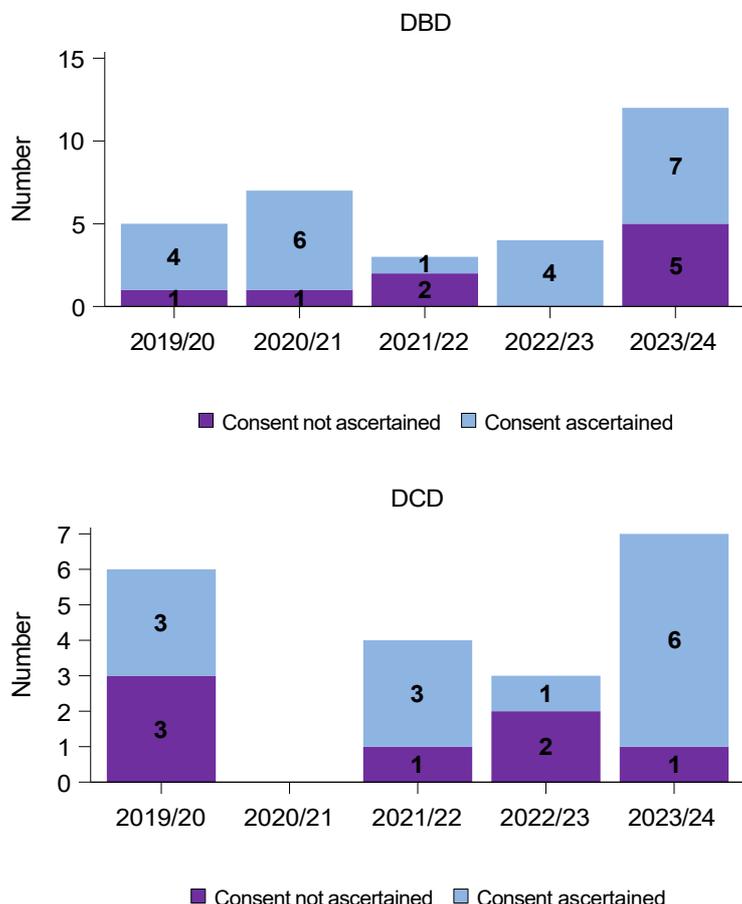


Table 3.3 Reasons given why consent was not ascertained, 1 April 2023 - 31 March 2024

	DBD		DCD	
	Health Board	UK	Health Board	UK
Family believe patient's treatment may have been limited to facilitate organ donation	-	-	-	1
Family concerned other people may disapprove/be offended	-	3	-	4
Family concerned that organs may not be transplantable	-	2	-	8
Family did not believe in donation	-	5	-	9
Family did not want surgery to the body	2	42	-	57
Family divided over the decision	1	12	-	20
Family felt it was against their religious/cultural beliefs	-	49	-	28
Family felt patient had suffered enough	-	24	-	78
Family felt that the body should be buried whole (unrelated to religious/cultural reasons)	-	13	-	17
Family felt the length of time for the donation process was too long	1	30	-	167

If 'other', please contact your local SNOD or CLOD for more information, if required.

**Table 3.3 Reasons given why consent was not ascertained,
1 April 2023 - 31 March 2024**

	DBD		DCD	
	Health Board	UK	Health Board	UK
Family had difficulty understanding/accepting neurological testing	-	3	-	-
Family wanted to stay with the patient after death	-	5	-	17
Family were not sure whether the patient would have agreed to donation	-	49	-	113
Other	-	24	-	57
Patient had previously expressed a wish not to donate	1	94	-	167
Patient had registered a decision to Opt Out	-	21	-	43
Strong refusal - probing not appropriate	-	25	1	39
Total	5	401	1	825

If 'other', please contact your local SNOD or CLOD for more information, if required.

3.6 Solid organ donation

Goal: NHSBT is committed to supporting transplant units to ensure as many organs as possible are safely transplanted.

**Table 3.4 Reasons why solid organ donation did not occur,
1 April 2023 - 31 March 2024**

	DBD		DCD	
	Health Board	UK	Health Board	UK
Clinical - Absolute contraindication to organ donation	-	3	-	5
Clinical - Considered high risk donor	-	4	-	8
Clinical - DCD clinical exclusion	-	-	1	2
Clinical - No transplantable organ	1	7	1	12
Clinical - Organs deemed medically unsuitable by recipient centres	-	17	-	58
Clinical - Organs deemed medically unsuitable on surgical inspection	-	9	-	6
Clinical - Other	-	3	-	7
Clinical - PTA post WLST	-	-	-	164
Clinical - Patient actively dying	-	4	1	7
Clinical - Patient asystolic	-	3	-	1
Clinical - Patient's general medical condition	-	1	-	6
Clinical - Positive virology	-	2	-	-
Clinical - Predicted PTA therefore not attended	-	-	-	1
Consent / Auth - Coroner/Procurator fiscal refusal	-	10	1	8
Consent / Auth - Family placed conditions on donation	-	-	-	1
Consent / Auth - NOK declined organ donation	-	1	-	-
Consent / Auth - NOK withdraw consent / authorisation	-	6	-	22
Consent / Auth - Other	-	-	-	1
Logistical - Other	-	-	-	1
Logistical - Retrieval team not available	-	-	-	1
Logistical - Unit unable to maintain patient	-	-	-	1
Total	1	70	4	312

If 'other', please contact your local SNOD or CLOD for more information, if required.

4. PDA data by hospital and unit

A summary of key numbers and rates from the PDA by hospital and unit where patient died

Data in this section is obtained from the National Potential Donor Audit (PDA)

Tables 4.1 and 4.2 show the key numbers and rates for patients who met the DBD and/or DCD referral criteria, respectively. Percentages have been excluded where numbers are less than 10.

Table 4.1 Patients who met the DBD referral criteria - key numbers and rates, 1 April 2023 - 31 March 2024

Unit where patient died	Patients where neurological death was suspected	Patients tested	Neurological death testing rate (%)	Patients referred	DBD referral rate (%)	Patients confirmed dead by neurological testing	Eligible DBD donors	Eligible DBD donors whose family were approached	Approaches where SNOD present	SNOD presence rate (%)	Consent ascertained	Consent rate (%)	Actual DBD and DCD donors from eligible DBD donors
<i>Llanfrechfa, The Grange University Hospital</i>													
A & E	0	0	-	0	-	0	0	0	0	-	0	-	0
ICU - general	16	13	81	16	100	13	13	12	11	92	7	58	6

Table 4.2 Patients who met the DCD referral criteria - key numbers and rates, 1 April 2023 - 31 March 2024

Unit where patient died	Patients for whom imminent death was anticipated	Patients referred	DCD referral rate (%)	Patients for whom treatment was withdrawn	Eligible DCD donors	Eligible DCD donors whose family were approached	Approaches where SNOD present	SNOD presence rate (%)	Consent ascertained	Consent rate (%)	Actual DCD donors from eligible DCD donors
<i>Llanfrechfa, The Grange University Hospital</i>											
A & E	0	0	-	0	0	0	0	-	0	-	0
ICU - general	10	10	100	10	10	7	7	-	6	-	2

Tables 4.1 and 4.2 show the unit where the patient died. However, it is acknowledged that there are some occasions where a patient is referred in an Emergency Department but moves to a critical care unit. In total for Aneurin Bevan University Health Board in 2023/24 there was 1 such patient. For more information regarding the Emergency Department please see Section 5.

5. Emergency Department data

A summary of key numbers for Emergency Departments

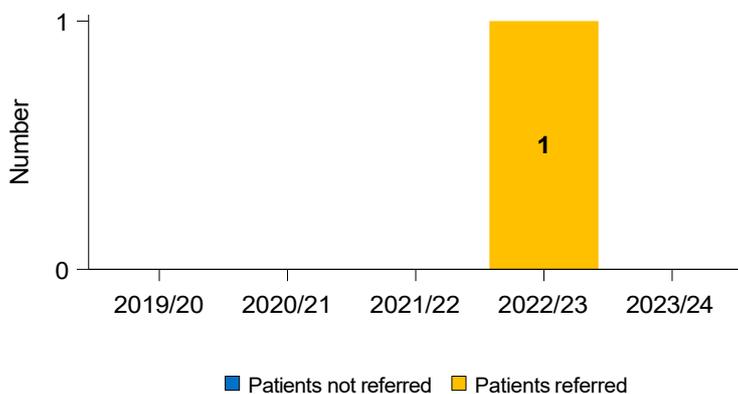
Data in this section is obtained from the National Potential Donor Audit (PDA)

Most patients who go on to become organ donors start their journey in the emergency department (ED). Deceased donation is important, not just for those people waiting on the transplant list, but also because many people in the UK have expressed a decision in life to become organ donors after their death. The overarching principle of the NHSBT Organ donation and Emergency Department strategy is that best quality of care in organ donation should be followed irrespective of the location of the patient within the hospital at the time of death.

5.1 Referral to Organ Donation Service

Goal: No one dies in your ED meeting referral criteria and is not referred to NHSBT's Organ Donation Service.
Aim: There should be no blue on the following chart.

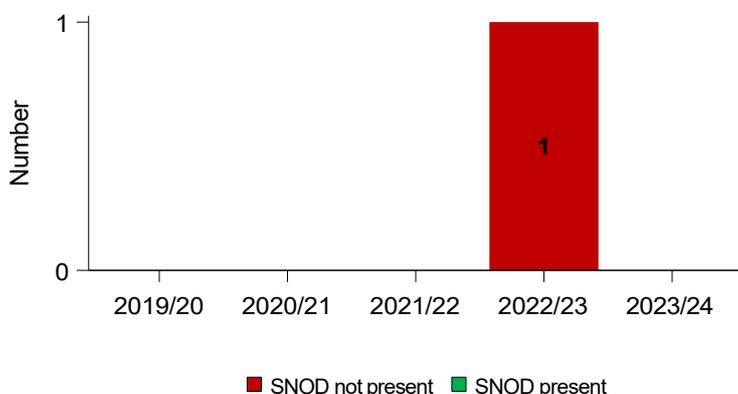
Figure 5.1 Number of patients meeting referral criteria that died in the ED, 1 April 2019 - 31 March 2024



5.2 Organ donation discussions

Goal: No family is approached in ED regarding organ donation without a SNOD present.
Aim: There should be no red on the following chart.

Figure 5.2 Number of families approached in ED by SNOD presence, 1 April 2019 - 31 March 2024



⁴ NHS Blood and Transplant, 2016. *Organ Donation and the Emergency Department* [accessed 8 May 2024]

6. Additional data and figures

Regional donor, transplant, and transplant list numbers

Data in this section is obtained from the UK Transplant Registry

6.1 Supplementary Regional data

Table 6.1 Regional donors, transplants, waiting list, and NHS Organ Donor Register (ODR) data

	Wales*	UK
1 April 2023 - 31 March 2024		
Deceased donors	57	1,510
Transplants from deceased donors	154	3,723
Deaths on the transplant list	15	418
As at 31 March 2024		
Active transplant list	271	7,484
Number of NHS ODR opt-in registrations (% registered)**	1,376,148 (44%)	28,161,705 (42%)
Number of NHS ODR opt-out registrations (% registered)**	189,059 (6%)	2,577,667 (4%)

*Regions are defined using the NHS region definitions

** % registered based on population of 3.11 million, based on ONS 2021 census data

Key numbers and rates on the potential for organ donation

Data in this section is obtained from the National Potential Donor Audit (PDA)

6.2 Trust/Board Level Benchmarking

Aneurin Bevan University Health Board has been categorised as a level 3 Health Board. Levels were reallocated in July 2018 using the average number of donors in 2016/17 and 2017/18, Table 6.2 shows the criteria used and how many Trusts/Boards belong to each level.

Table 6.2 Trust/Board level categories

		Number of Trusts Boards in each level
Level 1	12 or more (≥ 12) proceeding donors per year	36
Level 2	6 or more but less than 12 (≥ 6 to <12) proceeding donors per year	51
Level 3	More than 3 but less than 6 (>3 to <6) proceeding donors per year	31
Level 4	3 or less (≤ 3) proceeding donors per year	39

Tables 6.3 and 6.4 show the national DBD and DCD key numbers and rates for the UK by Trust/Board level, to aid in comparison with equivalent Trusts/Boards. Note that percentages have been excluded where numbers are less than 10.

**Table 6.3 National DBD key numbers and rate by Trust/Board level,
1 April 2023 - 31 March 2024**

Your Trust	Patients where neurological death was suspected	Patients tested	Neurological death testing rate (%)	Patients referred	DBD referral rate (%)	Patients confirmed dead by neurological testing	Eligible DBD donors	Eligible DBD donors whose family were approached	Approaches where SNOD present	SNOD presence rate (%)	Consent ascertained	Consent rate (%)	Actual DBD and DCD donors from eligible DBD donors
Your Trust	16	13	81	16	100	13	13	12	11	92	7	58	6
Level 1	1183	881	74	1174	99	858	814	715	682	95	483	68	451
Level 2	539	414	77	538	100	402	388	344	339	99	242	70	220
Level 3	169	138	82	167	99	138	130	119	116	97	81	68	72
Level 4	138	101	73	138	100	98	94	81	78	96	52	64	45

**Table 6.4 National DCD key numbers and rate by Trust/Board level,
1 April 2023 - 31 March 2024**

Your Trust	Patients for whom imminent death was anticipated	Patients referred	DCD referral rate (%)	Patients for whom treatment was withdrawn	Eligible DCD donors	Eligible DCD donors whose family were approached	Approaches where SNOD present	SNOD presence rate (%)	Consent ascertained	Consent rate (%)	Actual DCD donors from eligible DCD donors
Your Trust	10	10	100	10	10	7	7	-	6	-	2
Level 1	2735	2533	93	2669	1932	1066	965	91	590	55	430
Level 2	1532	1426	93	1494	1039	499	454	91	285	57	187
Level 3	583	547	94	559	353	167	154	92	93	56	54
Level 4	481	443	92	464	311	117	99	85	55	47	39