Patient Safety Incident Management
Final Internal Audit Report

April 2024

Cardiff & Vale University Health Board

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Gwasanaethau Archwilio a Sicrwydd
Shared Services Partnership
Audit and Assurance Services

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

Contents

Review reference:	CVU 2223-29
Report status:	Final Report
Fieldwork commencement:	04 September 2023
Fieldwork completion:	25 January 2024
Debrief meeting:	21 December 2023 and 18 January 2024
Draft report issued:	30 January 2024
Draft report reissued:	12 February 2024/ 4 March 2024
Management response received:	21 March 2024 and 5 April 2024
Final report issued:	5 April 2024
Auditors:	Olubanke Ajayi-Olaoye, Principal Auditor Lucy Jugessur, Interim Deputy Head of Internal Audit Ian Virgill, Head of Internal Audit
Executive sign-off:	Jason Roberts, Executive Nurse Director
Distribution:	Alexandra Scott, Assistant Director of Quality and Patient Safety Tara Cardew, Head of Patient Safety
Committee:	Audit & Assurance Committee

Audit and Assurance Services conform with all Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Chartered Institute of Public Finance & Accountancy in April 2023.

Acknowledgement
NHS Wales Audit and Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

Executive Summary

Purpose

The overall objective of the audit was to review the arrangements in place within the Health Board for the identification, recording, investigation, and management of incidents and learning lessons.

Overview

We have issued reasonable assurance on this area.

The matters requiring management attention include:

- The Health Board's Incident, Hazard and Near Miss reporting policy and procedure have been updated but both require minor amendments to be made to them;
- The Health Board's National Incident Tool Kit requires finalising and being made available for staff; and
- Key stages within the incident reporting cycle are not being completed within reasonable timelines and evidence is not always in place within Datix to support actions taken and lessons learned.

Other recommendations / advisory points are within the detail of the report.

Report Opinion

Reasonable

Some matters require management attention in control design or compliance.

Low to moderate impact on residual risk exposure until resolved.

Assurance summary[1]

Objectives		Assurance
1	The Health Board has an incident management policy and procedures in place which aligns to the Welsh Government policy. The guides are accessible to staff and training is in place for staff.	Reasonable
2	Patient safety incidents (including nationally reportable incidents) are identified and captured, investigated, quality assured, approved and responded to within required timeframes.	Reasonable
3	Monitoring and reporting take place at appropriate forums within the Health Board.	Substantial
4	National Reportable Incidents (NRI) and where applicable local reportable incidents action plans are in place for lessons learnt from patient's safety incidents and learnings and reports are shared across the Health Board.	Substantial

[1]The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.

Key Matters Arising

		Objective	Control Design or Operation	Recommendation Priority
1	Amending of Health Board Incident, Hazard and Near Miss reporting Policy and Procedure	1	Design	Medium
2	Finalise and availability of National Incident Tool Kit Guidance	1	Design	Medium
3	Evidence to support adherence to incident management requirements	2	Operation	Medium

1. Introduction

1.1 Our audit review of Patient Safety Incident management was completed in line with the 2023/24 internal audit plan for Cardiff and Vale University Health Board (the 'Health Board').

1.2 The effective application of appropriate incident management policies and procedures are critical to ensuring patient safety and operating efficiency of all public sector organisations. NHS Wales organisations should maintain policies and procedures setting out the required actions for all staff and independent members to follow when they identify a potential risk, or an incident has occurred.

1.3 NHS Wales National Policy on Patient Safety Incident Reporting & Management[1] is a newly published document with an effective date of 11 May 2023. The purpose of this Policy is to set out clear expectations for patient safety incident reporting and management across NHS Wales. It supersedes and replaces the section on "Serious Incidents" within the 2013 'Putting Things Right' (PTR) guidance document.

1.4 The Health and Social Care (Quality and Engagement) (Wales) Act 2020[2] underpins the statutory Duties of Candour and Quality. The Duty of Candour is intrinsically linked to incident management. The Duty of Candour and Quality came into force in April 2023 and there is a Duty of Candour statutory guidance 2023 and Duty of Candour Procedure (Wales) Regulations 2023[3] in place.

1.5 The duty applies to NHS bodies in Wales and requires them to be open and transparent with people when they come to harm whilst using services. The duty will be triggered when there is an incident that causes harm that is more than minimal, the harm is unexpected or unintended and health care was or could have been a factor in causing the harm[4]. The Duty focusses on the need to be open with patients and service users and anyone acting on their behalf when things go wrong, building on the requirements already set out in the Regulations.

1.6 The relevant lead for this review was the Executive Nurse Director.

Audit Risks

1.7 The potential risks considered for this review were as follows:

- Non-compliance with relevant legislation.
- Patient harm or poor patient experience.
- Financial loss if action is taken against the Health Board.
- Reputational damage with decreased public confidence.

[1] du.nhs.wales/files/incidents/national-policy-on-patient-safety-incident-reporting-2-0-pdf/
[2] The Health and Social Care (Quality and Engagement) (Wales) Act: summary [HTML] | GOV.WALES
[3] The Duty of Candour Procedure (Wales) Regulations 2023 (legislation.gov.uk)
[4] cavuhb.nhs.wales/files/board-and-committees/quality-safety-and-experience-committee-2022-23/2022-01-10-qse-papers-v5pdf/

2. Detailed Audit Findings

Objective 1: The Health Board has an incident management policy and procedures in place which aligns to the Welsh Government policy. The guides are accessible to staff and training is in place for staff that investigate patient safety incidents.

2.1 NHS Wales Executive have produced an NHS Wales National Policy on Patient Safety Incident Reporting & Management in May 2023.

2.2 The Health Board has produced an up-to-date Incident, Hazard and Near Miss Reporting Policy in line with the NHS Wales Executive Policy which is available on the intranet. In addition, there is also an Incident, Hazard and Near Miss Reporting Procedure in place. However, the previous versions of the policy and procedure are also accessible on the intranet. We note that both require minor amendments to be made to them. ***(Matter Arising 1 – Medium Priority)***

2.3 The Health Board's Patient Safety Team have produced a National Incident Tool Kit which is an important procedure detailing the process to follow for NRIs but is not currently available for staff. ***(Matter Arising 2 – Medium Priority)***

2.4 The NHS Executive is working on developing an All-Wales standard approach tool regarding incidents investigation. There is a task and finish group across Wales which involves representatives of the patient and safety teams from each Health Board.

2.5 The Patient Safety Team are responsible for providing training on incident reporting and investigation.

2.6 The Patient Safety team has mandated incident management training for all new Incident Managers.

2.7 Previously, investigations were performed using Root Cause Analysis (RCA), but this has since been replaced by Patient Safety Learning Reviews (PSLRs). PSLR training is available to staff and is carried out in two parts. The first involves virtual/ online training and the second part is face-to-face training which will commence in February 2024.

2.8 SharePoint holds resources for incident managers and reporters. In order to develop into a Datix Incident Manager, staff are required to watch videos on the incident manager training package page and undertake a multiple-choice test to check staff's understanding of the system.

2.9 Facilitators are part of the Patient Safety corporate team allocated to cover specific Clinical Boards. They organise drop-in sessions to assist in managing incidents for their allocated Clinical Boards.

Conclusion:

2.10 The Health Board has produced an Incident, Hazard and Near Miss Reporting Policy in line with the NHS Wales Executive policy but we noted some issues in relation to this document and also the Incident, Hazard and Near Miss Reporting Procedure. There is a Health Board National Incident Tool detailing the process to follow for NRIs, but it is not currently available to staff. Different packages of incident management training are available for staff within the Health Board. We have provided ***Reasonable Assurance*** against this objective.

Objective 2: Patient safety incidents (including nationally reportable incidents) are identified and captured, investigated, quality assured, approved and responded to within required timeframes.

2.11 Incidents are logged onto datix. All incidents have a management review completed, where it is determined whether further investigation is required. In addition, the Patient Safety Team advise the level of investigation required for NRI incidents.

2.12 Datix incidents are assessed by the level of harm, which can be categorised as no harm, low harm, moderate harm, severe harm, or death. Level of harm caused to the patient is rated as a result of action or inaction of the Health Board. A NRI meeting is held between the facilitator, the Clinical Board Director of Nursing and/ or the Clinical Board Quality and Safety leads and relevant clinical facing staff regarding the harm levels for NRIs. As part of the Duty of Candour, key staff are now allocated with the responsibility of reviewing all reported incidents irrespective of the level of harm.

2.13 The Health Board's incidents are classified as Patient Safety incidents, National Reportable Incidents (NRI)/ Potential NRIs and locally reportable incidents:

- Patient Safety incidents: Trained Incident Managers undertake the management review, for pressure damage and falls and this is in the form of a focussed review based on the national pressure damage and injurious falls investigation tools.
- National Reportable Incidents (NRI): Patient Safety corporate team support the Clinical Board in managing the NRIs and will ensure a robust overview of the potential NRIs to determine if they meet external reporting criteria.
- Locally Reportable Incidents (LRIs): Incidents that do not meet the criteria of NRI's but the Patient Safety team consider a more in depth review is required as there will be learnings from them.

2.14 We tested a sample of 20 non NRIs (includes Patient Safety and Locally Reportable incidents) and 5 NRIs that were opened and closed from Integrated Medicine, Adult Mental Health Directorates and Primary Community & Intermediate Care Clinical Board to confirm the process undertaken in relation to meetings, investigations,

approvals and quality review between September 2022 and August 2023. We identified that:

- There was evidence of immediate 'make-safe' actions taking place for both NRI's and non NRI's.
- All 5 NRIs were reported within 2 working days.
- All 5 NRI forms were approved by the Assistant Director of Patient & Safety who signs on behalf of the Executive Nursing Director.

2.15 A review was undertaken to ensure that the 25 sampled incidents are captured, investigated, quality assured and approved, with evidence retained in Datix. Our testing identified a number of exceptions which included delays in the stages of processing incidents. ***(Matter Arising 3 – Medium Priority)***

Conclusion:

2.16 The importance of taking a proactive approach to the documentation and timeliness of the incident reporting process is key. While the timeliness of the majority of the incident reporting stages were appropriate, we identified some stages within the incident reporting for patient safety incidents that were longer than appropriate. Our sample testing confirmed that the process was followed, however, documentation or information was not always present to support each stage in the process. We have provided ***Reasonable Assurance*** against this objective.

Objective 3: Monitoring and reporting take place at appropriate forums within the Health Board

2.17 The Health Board's Quality, Safety and Experience (QSE) Committee monitors the reported incidents via the assurance reports provided by the Clinical Boards which includes the Clinical Boards current NRI position, numbers of open datix incidents, comparisons of trends with the prior month and prior year and possible observations on themes.

2.18 Incident reporting & falls and NRIs are reported as a part of the Quality indicators report to the QSE Committee. It provides a snapshot of NRIs reported in the last 20 months and those reported to NHS Executive by incident type.

2.19 There is a monthly Quality & Safety Lead Forum which discusses ongoing and current incidents with its aim to share relevant information across the Clinical Boards. As part of the forum, the Head of Patient Safety and her team meet the Clinical Boards and provide reports and undertake presentations, they also share learnings and incidents that relate to all areas within the Health Board.

2.20 Each Directorate has a Quality and Safety meeting which reports into the Clinical Board Quality and Safety meeting and upwards to the Health Board's QSE Committee.

2.21 The Clinical Board Directors of Nursing are responsible for chairing the Clinical Board's Q&S meetings. The corporate patient and safety team attend these

meetings and advise on and receive information from dashboard extracts and reports of patient's safety reported incidents.

2.22 Each Clinical Board has a Q&S lead and they co-ordinate the incidents within the Clinical Board. NRIs & incidents are expected to be owned by the Clinical Boards to allow them to learn and help each other. In addition, there are weekly quality meetings where all new NRIs are reported and discussed, and any constraints/ delays are also raised in these meetings.

Conclusion:

2.23 The Health Board has a number of forums in place that provide effective mechanisms for monitoring and reporting of incidents from a localised level up to the Quality, Safety and Experience Committee. We have provided ***Substantial Assurance*** against this objective.

Objective 4: National Reportable Incidents (NRI) and where applicable local reportable incidents action plans are in place for lessons learnt from patient's safety incidents and learnings and reports are shared across the Health Board.

2.24 AMaT is now utilised by the Health Board to store and monitor incident improvement plans. It allows the allocation of actions to appropriate individuals who receive email alerts and are then required to upload evidence of completion of the action. Access is not restricted so areas can view each other's improvement plans and learning.

2.25 Improvement plans are entered into the system based on common themes or datix identifiable references of incidents. The Directorate is responsible for updating and completing the improvement plans on AMaT.

2.26 There are a number of groups whereby lessons are learnt, and actions taken are shared across the Health Board.

- Clinical Boards and Directorate QSE meetings.
- Q&S lead Forum.
- Mental Health lessons learnt forum.
- Clinical Effectiveness Committee.
- Clinical safety group.
- Weekly Executive safety meeting.
- Wards safety briefings.

2.27 Lessons learnt are also communicated across the Health Board via screensavers and patient safety newsletters.

2.28 Learning is shared via the 'learning from sentinel events' bulletin in the Mental Health Clinical Board whilst the Medicine Clinical Board QSE provides safety briefings as a standing agenda at its meetings.

2.29 The Mental Health Clinical Board has a lessons learnt events based on themes and presenting learning to the wider audience. This is new and open to everyone within the Clinical Board.

Conclusion:

2.30 The Health Board has in place a number of mechanisms to capture and share learning from incidents. The AMaT system is a new tool currently in use, which enhances the monitoring of action plans raised as a result of lessons learnt highlighted within datix. We have provided ***Substantial Assurance*** against this objective.

Appendix A: Management Action Plan

Matter Arising 1: Amending of Health Board Incident, Hazard and Near Miss reporting Policy & Procedure (Design)	**Impact**
The Health Board has updated the Incident, Hazard and Near Miss Reporting Policy in line with the updated NHS Wales Executive Patient Safety Incident Policy and it is available on the intranet. The Health Board also has a Health Board Incident, Hazard and Near Miss Reporting Procedure which was produced in October 2021. We noted the following on review of the Health Board's Incident, Hazard and Near Miss Reporting Policy and Procedure: • Reference was made to the Delivery unit (DU) within the procedure, however, the name changed from Delivery Unit to NHS Wales Executive in May 2023. • The policy and procedure highlight the roles and responsibilities of key staff and teams but there is no reference to how monitoring and reporting of incidents takes place at the Board level and other relevant Committees. However, the roles and responsibilities are detailed within the Health Board's National Incident Tool kit. • The procedure makes reference to the Root Cause Analysis (RCA) which is no longer an applicable requirement for the Health Board. • There are out-of-date versions of the Incident, Hazard and Near Miss Reporting Policy and Procedure on the intranet.	Potential risk of: • Non-compliance with the relevant legislation.

Recommendations		**Priority**
1.1	Management should review the Incident, Hazard and Near Miss Reporting Policy and Procedure and update accordingly.	**Medium**

1.2	Management should ensure that the out-of-date Incident, Hazard and Near Miss reporting Policy and Procedure are removed from the intranet and only the current policy and procedure is made available.	**Low**

Agreed Management Action		Target Date	Responsible Officer
1.1	Terminology to be updated as per recommendations. Section 4.1 covers general incident reporting. A paragraph is to be added to include the role of QSE meetings in monitoring and learning from incidents.	June 2024	Tara Cardew
1.2	Out of date policies to be removed from sharepoint – Patient Safety Team to contact Corporate Governance Team to action.	July 2024	Tara Cardew/Nathan Saunders

Matter Arising 2: Finalise and availability of National Incident Tool Kit Guidance (Design)			**Impact**
The Patient Safety team have developed a National Incident Tool Kit, which is a key procedure detailing the National Reportable Incident (NRI) process which is utilised by the Clinical Boards, patient safety team and other members of staff. However, this is not a published document. It was identified from our review of the National Incident Tool Kit and the NRI section of the patient safety team's page on the Health Board's intranet that: • There is reference made to the previous Welsh Government policy published on the 14 June 2021; • The Delivery unit (DU) is referred to; and • Reference is made to phase 1 and phase 2 which is no longer applicable in the current version of the Welsh Government Policy.			Potential risk of: • Non-compliance with the relevant legislation.
Recommendations			**Priority**
2.1	Management should review the National Incident Tool Kit to ensure it is relevant and up to date and should also consider formally publishing it. Management should also ensure the NRI section of the patient safety team's page on the Health Board's intranet is updated with current information.		**Medium**
Agreed Management Action		**Target Date**	**Responsible Officer**
2.1	Toolkit to be updated as above and publish on sharepoint.	June 2024	Cath Evans/Tara Cardew

Matter Arising 3: Evidence to support adherence to incident management requirements (Operation)	**Impact**
We tested a sample of 25 cases (20 non NRIs and 5 NRIs) from Integrated Medicine, Adult Mental Health and Primary Community & Intermediate from September 2022 to August 2023. Our testing reviewed the key stages in the 'incident lifecycle' including investigation, quality assurance and approval process. The following findings were identified: Non NRIs (Note: One of the non NRIs was reclassified and reported as a NRI after the datix report was downloaded for the audit). • 1/19 cases - It took seven months to report an incident after it occurred. • 10/19 cases - Management review did not commence until more than 12 working days after the incident was initially reported, with the longest taking over 11 months to start. • 1/19 cases - It took nearly 120 working days for one incident to be closed on datix after the investigation had been completed. • 3/19 cases had lessons learnt which required an action/ follow up plan, but they were not available on datix or AMaT. NRIs • 1/5 cases - An additional incident occurred during another incident, although it was documented by the reporter when the incident was described. It was not noted if a separate incident was reported to this effect. Datix does not have an interphase system with AMaT. It was observed during the audit that where an improvement plan has been put together following an incident, there is no note made on datix to indicate any information is held on AMaT.	Potential risk of: • Patient harm or poor patient experience.
Recommendations	**Priority**

3.1	Management should ensure that incidents are processed within the expected timeframes and reported as stated in the Welsh Government policy, Welsh Government supporting documents and Health Board policy and procedure. Management should also review the incident process where significant delays are occurring with a view to understanding any reasons behind the delay and revising or refining approaches to help reduce these delays.	**Medium**
3.2	The Health Board should ensure where lessons learnt have occurred improvement plans are completed. With the continuous adoption and use of AMaT by the Health Board, it would be good practice to indicate within datix that the incident has an improvement plan recorded on AMaT. Also, in situations where improvement plans have been developed in themes rather than the identifiable incident ID number, a means of identification would be helpful to link the incident to the initial datix entry.	**Medium**

Agreed Management Action		**Target Date**	**Responsible Officer**
3.1	Quarterly emails to incident managers from the Datix Central Team to highlight overdue incidents.	June 2024	Tara Cardew and Matt McCarthy
	Patient Safety Team and Clinical Board QSE leads with support from Superusers to identify and support incident managers with long standing overdue incidents to support them in managing and closing their incidents.	June 2024	Tara Cardew
	Management of overdue Datix Incidents has been identified as a performance measure for 2024 /2025 with a goal to reduce incidents open for over 90 days by 60% from the April 2024 bench mark by the end of Q3	December 2024	Tara Cardew
	Executive Performance Reviews to include need for assurance on timely incident management within the Clinical Boards, queue position to be added to the assurance report.	August 2024	Alex Scott and Tara Cardew

	Clinical Boards to review availability and utilisation of management days to facilitate timely incident management.		Clinical Boards
3.2	Datix team to explore with Datix Central Team the inclusion of an additional field to reference AMAT entry. Explore with Clinical Assurance Team the inclusion of a Datix reference onto AMAT. Until the above completed, ensure for NRIs that improvement plans are referenced in the progress notes and/or Corporate Section.	August 2024 April 2024	Matt McCarthy Tara Cardew

Appendix B: Assurance opinion and action plan risk rating

Audit Assurance Ratings

We define the following levels of assurance that governance, risk management and internal control within the area under review are suitable designed and applied effectively:

	**Substantial assurance**	Few matters require attention and are compliance or advisory in nature. **Low impact** on residual risk exposure.
	**Reasonable assurance**	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.
	**Limited assurance**	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved.
	**Unsatisfactory assurance**	Action is required to address the whole control framework in this area. **High impact** on residual risk exposure until resolved.
	**Assurance not applicable**	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

Prioritisation of Recommendations

We categorise our recommendations according to their level of priority as follows:

Priority level	Explanation	Management action
High	Poor system design OR widespread non-compliance. Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in system design OR limited non-compliance. Some risk to achievement of a system objective.	Within one month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. Generally issues of good practice for management consideration.	Within three months*

* Unless a more appropriate timescale is identified/agreed at the assignment.

NHS Wales Shared Services Partnership
4-5 Charnwood Court
Heol Billingsley
Parc Nantgarw
Cardiff
CF15 7QZ

Website: Audit & Assurance Services - NHS Wales Shared Services Partnership