

Reference Number: <i>UHB 433</i> Version Number: 2	Date of Next Review: 15 th September 2024 Previous Trust/LHB Reference Number: N/A
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INCIDENT, HAZARD AND NEAR MISS REPORTING PROCEDURE

Introduction and Aim

Cardiff and Vale University Health Board (UHB) is committed to the health, safety and welfare of its staff, patients, visitors, all users of its premises and services, and its impact on the environment by being pro-active in its approach to reduce the number of untoward incidents.

It considers that it is essential that all incidents, near misses and hazards are reported so that appropriate action can be taken with the aim of preventing their reoccurrence, improving staff and patient safety and experience and improving services and the environment where appropriate.

It is the policy of the UHB to ensure that staff feel comfortable to report incidents, hazards and near misses. Therefore, the UHB encourages an open and just culture. The aim of reporting and investigating incidents, near misses and hazards is not to blame but rather to learn from the event and to minimise risk of reoccurrence.

A key aim is to encourage staff to report incidents and for managers to treat staff involved in incidents in a consistent, constructive and fair way. The emphasis is on the "how" and "why" rather than the "who".

However, the UHB will act on information to protect the safety of other staff, patients and visitors where appropriate. Disciplinary action may result from incidents such as those relating to criminal activity, malicious activity and patient care or treatment contrary to the relevant professional code of conduct.

Objectives

- To ensure that all adverse incidents, near misses and hazards are reported and managed appropriately and effectively within a supportive framework.
- To promote a culture in which incidents are reported and investigated appropriately and proportionately to ensure that lessons can be learnt from adverse incidents and near misses to promote the continued improvement of staff and patient safety and well-being.

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- To enable the UHB to comply fully with legislation and mandatory requirements in relation to incident reporting.

Scope

This procedure applies to all of our staff in all locations, including those with honorary contracts.

Equality Health Impact Assessment

An Equality Health Impact Assessment (EHIA) has been completed. The assessment found that there was no adverse impact to the equality groups mentioned.

Documents to read alongside this Procedure

- Incident, Hazard and Near Miss Reporting Policy
 - Health and Safety Policy
 - Policy for Reporting Research Related Adverse Events
 - Being Open Policy
 - Records Management Policy
 - Risk Management Policy
 - Welsh Government Putting Things Right Guidance November 2013
 - NHS Wales National Incident Reporting Policy June 2021
 - Never Events April 2018
 - UHB National Patient Safety Incident process which includes Never Event processes
 - Just Culture guide from NHS Improvement
 - All Wales Root Cause Analysis (RCA) toolkit
 - Statement Writing guidance
 - UHB Coroner's Inquests – A guide for NHS staff
- RIDDOR Guidance September 2016
- Risk Assessment and Risk Register Procedure
 - Process for Undertaking an RCA

Approved by

*Health and Safety Committee
Quality, Safety and Experience Committee*

Accountable Executive or Clinical Board Director

*Director of Corporate Governance
Executive Nurse Director*

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Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the [Governance Directorate](#).

Summary of reviews/amendments			
Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	18.09.18	20.09.18	A new document was created to separate the policy and procedures into two different components.
2			The document was updated to reflect changes in NHS Wales National Incident Reporting policy.

1. DEFINITIONS

- 1.1 An *Adverse Incident* is defined as “any unplanned event that resulted in, or had the potential to result in, an injury or the ill health of any person, or the loss of, or damage to, property”.
- 1.2 A patient safety incident is defined as “any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded care”. (National Patient Safety Agency, 2011).
- 1.3 A hazard is a source of potential harm or damage or a situation with potential for harm or damage.
- 1.4 A near miss is an occurrence, which but for the luck or skilful management would in all probability have become an incident.
- 1.5 A National Patient Safety Incident is defined as: A patient safety incident which caused or contributed to the unexpected or avoidable death, or severe harm, of one or more patients, staff or members of the public, during NHS funded healthcare”.

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The above definition of an incident is applicable to all NHS funded services, regardless of speciality, delivered in all secondary or primary care settings, including community based services

1.6 When considering whether to report a National Patient Safety Incident the following should be applied:

- a patient safety incident will be nationally reported within seven working days from the occurrence, or point of knowledge, if it is assessed or suspected an action or inaction in the course of a service user's treatment or care, in any healthcare setting, has, or is likely to have caused or contributed to their unexpected or avoidable death, or caused or contributed to severe harm.
- as it will not always be possible to determine the extent to which a patient safety incident caused or contributed to the harm or death of a patient within seven working days, responsible bodies should report in line with the criteria where it is known, and/or suspected, that a patient safety incident has caused or contributed to harm or death. In this scenario, for clarity, the responsible body should specify on the form that the position is unclear and/or investigations are ongoing. Incidents can be downgraded at a later date as set out later in this guidance.
- all such incidents must be reported to the Delivery Unit within seven working days from the occurrence, or point of knowledge.

1.7 Specific National Incidents

- In-patient suicides
- Maternal deaths
- Suspected homicides where the alleged perpetrator has been under the care of mental health services in the past 12 months.
- Never Event – all Never Events are defined as National Patient Safety Incidents although not all Never Events necessarily result in severe harm or death;
- Incidents where the number of patients affected is significant such as those involving screening, IT, public health and population level incidents, possibly as the result of a system failure. The key wording in this reporting requirement is “the number of patients affected is significant”.
- Unusual, unexpected or surprising incidents where the seriousness of the incident requires it to be nationally reported and the learning would be beneficial

For more information relating to NHS Wales National Incident Reporting Policy click [here](#).

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1.6 *RIDDOR* is the recognised abbreviation for the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995.

These Regulations specify the accidents, ill health and dangerous occurrences that must be reported to the Health and Safety Executive by the Health and Safety Department. This includes:

- An *over 7-day injury* – an accident that results in an employee being away from work or unable to perform their normal duties for more than seven consecutive days as the result of their injury, not including the day of the incident.
- A *Specified Injury arising out of or in connection with work*, generally more serious injuries for example a fracture or serious burns.
- A *Dangerous Occurrence* is a certain specified near miss event, which may not result in a reportable injury, but have the potential to cause significant harm. A needlestick injury from a known high risk source is reportable as a Dangerous Occurrence.
- A *Reportable Disease* – a disease that may arise from an individual's occupation. They are specified in Schedule 3 of RIDDOR. Such diseases have to be diagnosed by a doctor and the person's job has to involve a specified work activity.
- Should a member of staff advise that they are absent from work, for over 7 days, due to an injury sustained at work, the Manager must ensure that the relevant Health and Safety Advisor is advised of this at the earliest opportunity. This action should be taken even if it is some time after the incident and the information comes to light as part of the sickness review process.

Further information can be found can be found on the Health, Safety and Environment Unit RIDDOR intranet page [here](#):

2. ROLES AND RESPONSIBILITIES

- 2.1 The **Chief Executive** is ultimately responsible for ensuring compliance with the Health and Safety at Work etc Act 1974 and associated legislation including NHS Concerns, Complaints and Redress Arrangements (Wales) Regulations 2011, and that the Incident, Hazard and Near Miss Reporting Policy and these associated procedures are implemented effectively within Cardiff and Vale University Health Board.
- 2.2 The **Executive Nurse Director** is the lead Executive with responsibility for clinical governance/patient safety and quality.

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The Executive Medical Director and Executive Director of Therapies and Health Sciences also have responsibilities in relation to these matters within their professional groups.

- 2.3 The **Executive Director of Governance** has Board level responsibility for health and safety which includes Health and Safety risks and incident management.
- 2.4 The **Assistant Director of Patient Safety and Quality** supports the development of arrangements for incident reporting and is responsible for providing assurance to the Executive Directors that appropriate systems and processes are in place for incident reporting, management and monitoring. The post holder will also ensure that the appropriate level of support is provided to the Clinical/Service Boards to enable timely reporting and investigation of incidents.
- 2.5 The **Head of Health and Safety** supports the development of arrangements for incident reporting and is responsible for providing assurance to the Executive Directors that appropriate systems and processes are in place for health and safety related incident reporting, management and monitoring. The post holder will also ensure that the appropriate level of support is provided to the Clinical/Service Boards to enable timely reporting and investigation of health and safety incidents.
- 2.6 The **Patient Safety Team and Health, Safety and Environment Unit** are responsible for supporting the implementation of this procedure. They will also undertake to raise staff awareness and training on incident reporting and investigation.
- 2.7 The **Clinical/Service Board Management teams** are responsible for ensuring that staff within their Board are briefed on their individual and collective responsibilities within the incident reporting process. They must ensure that all incidents are reported, investigated and analysed, so that learning and improvements can be embedded in practice.
- 2.8 **Department/Line Managers** are responsible for cascading the procedure to staff ensuring that they are fully conversant with the process to be followed for all incidents.

Department/Line Managers are responsible for reviewing, escalating, taking appropriate action and feeding back to incident reporters in a timely manner in line with UHB procedures.

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Significant incidents, for example, those that may require onward reporting to an external agency must be escalated promptly with actions recorded on the electronic incident reporting system. Delivery Unit expects National Patient Safety Incidents to be reported to them via the Patient Safety Team within 7 days of the incident occurring where possible.

There is an expectation that incidents reported on the electronic reporting tool will be reviewed by the relevant manager within 7 days. Where possible, incidents should be concluded within 30 days. More complex incidents, for example National Patient Safety Incidents reported to the Delivery Unit should be concluded within the agreed timeframe (30, 60, 90 or 120 days) in order to comply with the Delivery Unit closure process.

It is imperative that managers review and conclude incidents in a timely manner in order that the UHB fulfils its quality, safety and governance responsibilities, which also includes uploading incident information to the National Reporting and Learning System (NRLS) within prescribed timescales.

Department/Line Managers are responsible for ensuring that an appropriate investigation is undertaken for all incidents that have occurred in their area of responsibility and ensuring that measures to prevent recurrence are implemented within the shortest appropriate timescale. Timeframes regarding general incidents and National Patient Safety Incidents have been outlined in Section 2.8. RIDDOR incidents are to be investigated within 21 days although there will be exceptions for more serious incidents. Incidents which are also investigated by the Health and Safety Executive may result in an extended investigation period.

It is the responsibility of Department/Line Managers to ensure that appropriate disclosure of incidents is made to patients and their families in line with the UHB's Being Open Policy.

It is also important that Department/Line Managers are conversant with the Just Culture Guidance from NHS Improvement in order that the appropriate support can be provided to staff. The guidance can be accessed [here](#)

2.9 **All employees** are responsible for ensuring that the immediate area and staff and patient safety is secured following an adverse incident. The incident must be promptly reported to an

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appropriate senior member of staff if significant harm or injury has occurred. Employees must ensure the incident is reported on the electronic incident reporting tool provided by the UHB, available via the intranet, as soon as it is safe and practical to do so. The incident form can be accessed [here](#).

Employees may be required to provide additional information on incidents during investigations; this may include provision of statements or attendance at interviews.

Under the Safety Representatives & Safety Committees Regulations 1977, **Safety Representatives** are also allowed to investigate: potential hazards, dangerous occurrences, and causes of accidents and occupational ill-health within the area of their responsibility.

- 2.10 **Contractors** such as estates and equipment maintenance contractors and building contractors have a statutory responsibility to report adverse incidents, hazards and near misses that have occurred on UHB sites to the UHB in line with their contract arrangements.

3. TRAINING

- 3.1 Information on incident reporting is provided to all staff on induction and supporting materials are available on the intranet on the incident reporting pages.
- 3.2 Incident reporting is included in Health and Safety mandatory training through an e-learning module or via face to face presentation.
- 3.3 Incident reporting procedures must be included in local departmental induction.
- 3.4 Support for staff is available via a Datix Help Desk, intranet page and Datix Superuser Group.
- 3.5 Training for line managers who require log-in to the electronic incident reporting system will be provided by the Patient Safety Team and Health, Safety and Environment Unit.
- 3.6 Incident investigation (RCA) training is provided by the Patient Safety Team.

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4. ADVERSE INCIDENT, HAZARD AND NEAR MISS REPORTING AND MANAGEMENT

- 4.1 When an incident occurs staff must first ensure the people or area concerned are made safe. The incident must be reported through the recognised UHB incident reporting mechanisms, this being the Datix system available on the intranet; a link is provided in Section 2.9.

All incidents will be graded according to the actual impact on the individual(s) involved using the Grading Framework for Dealing with All Concerns in the Putting Things Right guidance (November 2013) which can be accessed [here](#).

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Grade	Harm
1	None
2	Low
3	Moderate
4	Severe
5	Death

Staff are also able to reflect the potential future risk to individuals and to the organisation on the incident reporting system.

4.2 A duty of candour to tell a patient / Being Open

If adverse events have occurred to patients, the incident should be communicated to the patient or their representative as soon as is practical. There is an expectation that incidents of moderate, severe and catastrophic harm will be disclosed. In exceptional circumstances, if it is deemed that the impact of disclosure will adversely affect the patient's psychological wellbeing, a decision may be taken not to inform the patient. Reasons for this decision must be clearly documented in the patient's health records. Advice can be sought from the Patient Safety Team.

Further guidance on Being Open can be found in the Being Open policy and procedure.

4.3 National Patient Safety Incidents

If a National Patient Safety Incident occurs, supporting information to guide staff can be located within the National Patient Safety Incident flowcharts on the intranet which can be accessed [here](#).

The organisation recognises that National Patient Safety Incidents or incidents requiring investigation may be potentially stressful and difficult for staff, patients and their families. It is

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essential that appropriate and timely support is offered and made available to everyone involved.

4.4 Never Events

Never Events are defined as National Patient Safety Incidents that are wholly preventable because guidance or safety recommendations providing strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.

Each Never Event type has the potential to cause serious patient harm or death. However, serious harm or death does not need to have happened as a result of a specific incident for that incident to be categorised as a Never Event.

Never Events require full investigation under the National Patient Safety Incident framework. This includes the need to fully and meaningfully engage patients, families and carers at the beginning of and throughout any investigation.

Further information on the management of Never Events is provided in the National Patient Safety Incident Flowcharts which can be accessed on the intranet, [here](#).

Further information from Welsh Government on Never Events can be found on the Patient Safety Wales [website](#).

4.5 Supporting staff to report incidents and following an incident occurring

The fair treatment of staff supports a culture of fairness, openness and learning in the NHS by making staff feel confident to speak up when things go wrong, rather than fearing blame. Supporting staff to be open about their concerns allows valuable lessons to be learnt so issues can be dealt with and prevented from being repeated.

The UHB actively encourages staff to raise concerns about safety. If for any reason they feel unable to report an incident in line with this procedure, there are other routes for them to raise their concerns. These would include Freedom to Speak Up, [Safety Valve](#) and Whistleblowing Policy. Click [here](#) for more information about raising a concern.

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The UHB recognises that being involved in an adverse incident can have devastating effects on staff. It is vital that the appropriate supporting mechanisms are put in place.

The Just Culture Guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Further information can be found [here](#).

4.6 Legal Status and Retention of Incident Reports

It is a requirement of WHC 2000(71) that Incident Reports relating to adults will be retained for ten years after the date of the incident, and Incident Reports relating to incidents involving children will be retained until the child is 25 years of age or for eight years after the death of the child (whichever is the sooner).

The electronic incident reporting system fulfils the requirement of the UHB to maintain accident book(s) at strategic locations in accordance with the Social Security (Claims and Payments) Regulations 1979.

4.5 Reporting Information Governance breaches

Events of failure to comply with information governance requirements are considered to be an incident and should be promptly reported using the electronic incident reporting system. These events can be viewed by the Information Governance Department for appropriate further action, monitoring of investigation and remedial actions.

On occasion, onward reporting to the Information Commissioner may be required. Appropriate incidents must be reported to the Information Commissioner within 72 hours of the incident occurring and so prompt incident reporting and review by line managers is of critical importance. Further guidance can be sought from the Information Governance Department.

5. INVESTIGATION

All incidents will be investigated appropriately. Investigations will be proportionate to the incident that has occurred. Investigations may also be undertaken if there is repetition of similar incidents or clusters of incidents.

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Due consideration must be given to the independence of the investigating officer in order that the UHB and its staff, patients and their families can have confidence in the transparency of the investigation process.

Investigation of patient safety incidents will be carried out in line with the All Wales How to Learn Lessons from Concerns Toolkit which can be accessed [here](#).

Information is available on the intranet to support staff who are required to write a statement following an adverse incident by clicking [here](#).

The Patient Safety Team will provide regular Incident investigation/Root Cause Analysis training opportunities and maintain a record of staff who have attended the training.

There is an expectation that staff who attend Incident Investigation/Root Cause Analysis training will support the investigation of patient safety incidents across the UHB.

Timeframes for investigation of incidents are outlined in Section 2.8.

6. REPORTING TO EXTERNAL AGENCIES

Some specified incidents are required to be reported to external agencies. The National Patient Safety Incident Flowchart and standard agenda template prompt attendees at the National Patient Safety Incident meeting to consider whether communication with external agencies is required.

Communication with external agencies will be undertaken through the agreed UHB incident reporting mechanisms by the appointed persons as outlined below. It should be noted that this list is not exhaustive.

External Agency	Requirement	Appointed Department
National Reporting Learning System (NRLS)	All patient safety incidents (irrespective of seriousness and degree of harm) to the National Patient Safety Agency (NPSA) Reporting and Learning System.	Patient Safety Team
Health and Safety Executive - RIDDOR The Reporting of Injuries, Diseases and Dangerous Occurrences	Work related deaths, specified injuries, dangerous occurrences and accidents resulting in over 7 day injury which results in incapacity to undertake normal work duties. Also specified diseases.	The Health and Safety Department Occupational Health Department

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Regulations 1995		
<i>NHS Wales National Incident Reporting Policy June 2021</i>	Reporting of National Patient Safety Incidents to the Delivery Unit should be undertaken within 7 working days and Early Warning Notification (replaces No Surprise/Sensitive Issues) to Welsh Government should be undertaken as soon as is practicable.	Patient Safety Team
Medicines and Healthcare Products Regulatory Agency (MHRA)	Incidents involving a medicine or medical device may be reportable to the MHRA. Breaches to the Blood Safety and Quality Regulations may be reportable to the MHRA as Serious Adverse Blood Reactions or Events.	UHB nominated liaison officer in Pharmacy or Clinical Engineering respectively Blood Transfusion Team
Communicable Diseases	In the event of an infectious disease outbreak and any serious single infection with public health implications.	The Consultant in Communicable Disease Control, Health Protection Agency (HPA) should be contacted
Healthcare Inspectorate Wales – Ionising Radiation Medical Exposure Regulations (IRMER)	Breaches in IRMER to Healthcare Inspectorate Wales. Such incidents will also be reported to the Delivery Unit in line with National Incident reporting if the incident is assessed or suspected an action or inaction in the course of a service user’s treatment or care, in any healthcare setting, has, or is likely to have caused or contributed to severe harm or death	Patient Safety Team
Information Commissioner (ICO)	Breaches of the Data Protection Act may require reporting to the Information Commissioner.	Information Governance Department
Welsh Health Specialised Services Committee (WHSSC)	WHSSC would expect to be informed of any incidents of a catastrophic nature to an individual; any incidents which raise concerns in relation to delivery of a particular commissioned service or emerging themes/trends. The Assistant Director of Patient Safety and Quality and Patient Safety Team representative meet with WHSSC on a regular basis where appropriate concerns are raised for discussion.	Assistant Director of Patient Safety and Quality
Human Tissue Authority (HTA)	Breaches of the Human Tissue Act require reporting to the Human Tissue Authority under the Human Tissue Authority Reportable Incident (HTARI) process https://www.hta.gov.uk/sites/default/files/Guidance_for_reporting_HTARIs.pdf	Designated Individual or Deputy.

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7. IMPLEMENTATION

This procedure reflects existing practice across the UHB and will therefore be implemented with immediate effect. The requirements of this procedure will be re-enforced within Clinical/Service Boards and Directorates/Departments by local risk management, health and safety and quality and safety arrangements.

8. EQUALITY

We have undertaken an Equality Impact Assessment and received feedback on this policy and procedure and the way it operates. We wanted to know of any possible or actual impact that this policy may have on any groups in respect of gender, maternity and pregnancy, carer status, marriage or civil partnership issues, race, disability, sexual orientation, Welsh language, religion or belief, transgender, age or other protected characteristics. The assessment found that there was no adverse impact to the equality groups mentioned. Where appropriate we have taken the necessary actions required to minimise any stated impact to ensure that we meet our responsibilities under the equalities and human rights legislation.

9. MONITORING

It will be necessary to ensure that Clinical/Service Boards are adhering to the requirements of this procedure. This will be monitored via a number of agreed performance indicators.

The Quality, Safety and Experience Committee and Health and Safety Committee will monitor implementation of this policy.

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10. DISTRIBUTION

- 10.1 This procedure will be available on the UHB Clinical Portal, Intranet and Internet Site.
- 10.2 Line Managers/Departmental Managers/Lead Nurses/Directorate Managers/Clinical Directors are responsible for ensuring that all staff have access to this document.

11. REVIEW

This procedure will be reviewed every three years or sooner if required.

12. FURTHER INFORMATION/REFERENCES

HSE (1994), *Management of Health and Safety in the Health Service*, Health Service Advisory Committee, Health and Safety Executive.

HSE (1995) *Reporting of Injuries, Diseases and Dangerous Occurrences Regulations*.

HSE Reporting injuries, diseases and dangerous occurrences in health and social care – Guidance for employer. HSE Health Services Information Sheet No 1 (Revision 2)

Ionising Radiation (Medical Exposure) Regulations 2017

NPSA (2006), *Being open: Communicating patient safety incidents with patients, their families and carers* (Re-launched 2009)

NPSA (2004), *Seven Steps to Patient Safety*

Social Security (1987), Claims and Payments Regulations No 1968
Welsh Government *Putting Things Right/NHS Redress (Guidance November 2013)*

Welsh Government (2015) Health and Care Standards

Welsh Government (2004) *Medical Device Alert 054: Reporting Adverse Incidents – Guidance on New Arrangements for NHS Wales Organisations*