INCIDENT, HAZARD AND NEAR MISS REPORTING POLICY AND
PROCEDURE

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Documents to read alongside this Procedure
The following key documents are recommended to consider along this Policy. Risk Management Policy, Risk Assessment and Risk Register Procedure, Health and Safety Policy, Putting Things Right / NHS Redress Guidance (April 2012). However, a full list of Policies and reference material is provided in Section 22.

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OUT OF DATE POLICY DOCUMENTS MUST NOT BE RELIED ON
### Summary of Amendments

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1. INTRODUCTION

1.1 The Cardiff and Vale University Health Board (UHB) is committed to the health, safety and welfare of its staff, patients, visitors and 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.

1.2 It is essential that all incidents, near misses and hazards are reported so that appropriate action can be taken to try to prevent their reoccurrence, improve the environment, patient experience and services where appropriate.

1.3 Staff must feel comfortable about reporting incidents, hazards and near misses, therefore the UHB encourages an open and fair culture (see section 4). The aim of reporting and investigating incidents, near misses and hazards is not to blame but rather learn from the event and to minimise risk of reoccurrence.

1.4 All managers and staff need to acknowledge that the risks within the UHB will be reduced if everyone adopts an attitude of openness and honesty. All necessary efforts must be made to avoid cover-up of incidents and mistakes. The overall approach within the UHB should be one of help and support to each other, rather than recrimination and blame. The UHB is fully committed to this approach.

1.5 All adverse incidents, near misses and hazards must be investigated appropriately in accordance with the UHB Investigation Procedure.

1.6 All adverse incidents, near misses and hazards must be reported through agreed mechanisms e.g. on a standard UHB Incident Report form or agreed electronic reporting mechanisms. This applies to all incidents relating to UHB premises, employees and facilities.

2. POLICY STATEMENT

The Board has overall responsibility for effective risk management within the UHB and to ensure that statutory duties are complied with. These duties are delegated to the Chief Executive and Executive Directors of the UHB to ensure that organisational requirements are met.

It is the policy of the UHB to ensure that there is an open and fair culture which encourages the reporting and investigation of all adverse incidents, hazards and near misses.
3. AIM

To provide a structure for the reporting, investigation and management of adverse incidents, near misses and hazards that occur within the UHB.

4. OBJECTIVES

4.1 To ensure that all adverse incidents, near misses and hazards are reported and managed appropriately and effectively within a supportive framework.

4.2 To promote a culture in which incidents are reported and investigated appropriately and to ensure that lessons can be learnt from adverse incidents and near misses to promote the continued improvement of staff safety and patient well-being.

4.3 To ensure that the UHB is able to effectively manage the risks to which it is exposed, which may arise from hazards or result in adverse incidents and near misses.

4.4 To enable the UHB to comply fully with legislation and mandatory requirements in relation to incident reporting, there is a requirement to report incident in line with various regulatory guidance, some (but not all) examples are provided:

- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (1995)
- Reporting under Ionising Radiation (Medical Exposure) Regulations (2000, amended 2006);
- the requirements of ‘Putting Things Right/NHS Redress’ Measure (April 2011 Welsh Government);
- The requirements outlined within the Standards for Health Services in Wales “Doing Well, Doing Better” (Welsh Government, 2010);
- The requirements of the National Patient Safety Agency’s (NPSA) National Reporting and Learning System (NRLS);
- Notifiable infectious diseases. A list of notifiable diseases is maintained by and available from the Infection Prevention & Control department or the Consultant Microbiologist.

Note: The above is not a complete list of regulatory / mandatory reporting requirements.

5. SCOPE
This policy applies to all staff employed by the UHB, including those with honorary contracts. It also applies to students and locum/agency staff working within UHB facilities/under contract to the UHB.

This Policy also applies to contractors (such as estates and equipment maintenance contractors and building contractors) who have a statutory responsibility to report accidents that have occurred on UHB sites to the UHB in line with their contract arrangements. Whilst Primary Care Independent Contractors have no absolute requirement to report safety incidents to the UHB, in order to learn lessons and target improvement strategies the UHB would welcome reports of safety incidents from all primary care independent contractors.

6. OPEN AND FAIR CULTURE

6.1 The UHB encourages an open and fair culture, where there is willingness to report incidents, near misses and hazards, so that lessons can be learned and risks reduced as far as is reasonably practicable.

6.2 A key aim is to encourage staff to report incidents without fear of personal reprimand or detriment and for staff to know that by sharing their experiences, others will be able to learn lessons and improve patient safety. The emphasis is on the "how" and "why" rather than the "who".

6.3 To achieve this, the incident investigation process must be:-
- Fair and equitable
- Focused on learning and change
- Focused on identifying contributory factors and root causes.

6.4 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 (e.g. theft, assault)
- Malicious activity (e.g. malicious reporting of untrue allegations against a colleague)
- Patient care or treatment contrary to the relevant professional code of conduct
- Repeated unreported errors
- Repeated violations of policies and procedures or professional codes.

7. DEFINITIONS
7.1 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”.

Or

“Any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded care”. (NPSA 2004)

7.2 A *near miss* is an occurrence, which but for the luck or skilful management would in all probability have become an incident.

7.3 A *hazard* is a source of potential harm or damage or a situation with potential for harm or damage.

7.4 A *risk* is the likelihood that the hazard will cause harm.

7.5 A *Patient Related Serious Adverse Incident* is defined as “an event or situation where one or more patients are involved in an event which is likely to produce serious legal or media interest or the involvement of a statutory body. If not properly managed this may result in serious injury to patients and/or loss of the UHB reputation or assets.” They may be clinical or non-clinical in nature. Examples of Patient Related Serious Adverse Incidents and the procedure to be followed in the event of such an incident occurring is detailed in Appendix 1.

7.6 *RIDDOR* is the recognised abbreviation for the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995. RIDDOR defines the following:

7.6.1 An *over 7 day injury* - an injury in which an employee is unable to perform their normal duties for more than 7 days following an incident, not including the day of the incident.

7.6.2 A *Major Injury* is a more serious injury such as a fracture (see Appendix 3).

7.6.3 A *Dangerous Occurrence* is an event which does not necessarily result in a reportable injury under RIDDOR (Schedule 2), but has the potential to do significant harm (see Appendix 3).

7.6.4 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 (see Appendix 3).

7.7 A *Root Cause Analysis (RCA)* investigation is a recommended investigation methodology used for certain types of reported incidents to help identify the root cause(s) of the incident.
7.8 A Risk Assessment is a calculation of the likely impact of a hazard should it come to fruition.

7.9 Environmental Incident is the release, either accidental or malicious, of a harmful substance to a receiving medium (atmosphere, ground or water) in sufficient quantities to cause environmental pollution or damage.

7.10 Environmental Complaint is a complaint, verbal or otherwise, regarding environmental aspects, performance or their management, to which a resolution is required.

Note: When the term “incident” is used throughout this policy it may also be taken to mean a hazard or near miss for the purposes of reporting and investigation.

8. ROLES AND RESPONSIBILITIES

8.1 The Chief Executive is ultimately responsible for ensuring compliance with the Health and Safety at Work etc Act 1974 and associated legislation, and that this policy is implemented and effective within Cardiff and Vale University Health Board.

8.2 The Executive Director of Nursing, jointly with the Executive Medical Director and Executive Director of Therapies and Health Sciences have Board level responsibility for clinical governance/patient safety and quality, which includes clinical risk and patient safety.

8.3 The Director of Governance has Board level responsibility for corporate governance and risk management which includes health and safety and is responsible for establishing an integrated risk management system for use across the UHB.

8.4 The Assistant Director for Patient Safety and Quality supports the development of arrangements for clinical governance within the UHB including leadership for clinical risk and patient safety.

8.5 The Head of Corporate Risk and Governance supports the development of arrangements for corporate governance within the UHB, including leadership for risk management.

8.6 The Head of Health and Safety supports the development of arrangements for health and safety within the UHB including leadership for health and safety.

8.7 The Clinical Governance Facilitators are responsible in association with the Health and Safety Advisors for supporting the development of this policy. They will also:-


- ensure that the policy is implemented and adhered to including the monitoring of its effectiveness.

- undertake to raise staff awareness and training on incident reporting.

- be responsible for receiving, checking, follow-up and analysis of incidents received, providing reports to Divisions/Directorates and teams as appropriate, to ensure lessons learnt are communicated and changes to practice implemented and overseen by Divisions/Directorates.

- be responsible for ensuring that all incidents reported and additional information received is entered onto the DATIX risk management system.

8.8 The Divisional Directors, Divisional Nurses and Divisional Managers (or equivalent level in non clinical division/directorate/locality areas) are responsible for ensuring that staff within their Division 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.

They are also responsible for ensuring appropriate investigation of any incidents, which have occurred in their area of responsibility and ensure that measures to prevent recurrence are implemented.

They must ensure that the principles of Putting Things Right / NHS Redress Measure (April 2011) and Being Open are followed when dealing with incidents.

8.9 Clinical Directors, Lead Nurses and Directorate Managers are responsible for ensuring that staff 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. They are also responsible for ensuring appropriate investigation of all incidents that have occurred in their area of responsibility and ensure that measures to prevent recurrence are implemented.

They must ensure that the principles of Being Open are followed when dealing with incidents.

8.10 Department/Line Managers are responsible for cascading the policy to staff ensuring that they are fully conversant with the process to be followed for all incidents.
They are also 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.

They are responsible for ensuring that there is an adequate supply of incident forms readily available to staff at all times and that incident forms are processed in a timely manner and sent to the Health, Safety and Environment Unit (HSEU).

For serious incidents affecting patients, staff, visitors it is essential that these are escalated promptly and by telephone notification to the appropriate department i.e. Health, Safety and Environment or Patient Safety. Managers must ensure that the principles of Putting Things Right / NHS Redress Measure (April 2011) and Being Open are followed when dealing with incidents.

8.11 All employees are responsible for reporting incidents in a timely manner and ensuring that the immediate area is made safe and the senior member of staff made aware of the incident. Employees may be required to provide additional information on incidents during investigations; this may include provision of statements or attendance at interviews.

8.12 Although Primary Care Independent Contractors have no absolute requirement to report safety incidents to the UHB, in order to learn lessons and target improvement strategies the UHB would welcome reports of safety incidents from all primary care independent contractors. Primary Care Contractors are therefore encouraged to:

- Undertake Significant Event Audits within their practice;
- Promote safety incident reporting within the practice;
- Engage with the UHB when incidents and near misses have occurred.

Primary Care Contractors are obliged to report Patient-Related Serious Adverse Incidents to the Welsh Government as outlined in Appendix 4

8.13 Other 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.

8.14 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.

Following the investigation of an incident, the Safety Representative should ensure that a copy of their report is given to the Line Manager. The Line Manager shall reply to the Safety Representative advising them of the proposed remedial action or offers of further explanation.

9. TRAINING

9.1 An overview of risk management and incident reporting will be provided to all levels of staff on induction through the e-learning induction module or via the face to face presentation.

9.2 All levels of staff are also required to complete a bi-ennia update for health and safety mandatory e-learning training which includes risk management and incidents.

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

When an incident occurs staff must first ensure the people or area concerned are made safe. The incident should be reported through the recognised UHB incident reporting mechanisms. Staff are encouraged to report any incidents so that recurrence can be prevented and lessons can be learnt.

10.1 Immediate Action Following an Incident

10.1.1 The first priority following an incident is to deal with the immediate needs of the injured/affected individual(s) and others involved e.g. patients, staff, visitors witnessing the incident etc.

10.1.2 Remedial action should be taken to re-establish a safe environment of care. However, it is necessary to have due regard of requirements regarding involvement of the Police, Coroner, Health and Safety Executive etc. for certain serious incidents where it may be necessary to leave the ‘scene’ of the incident undisturbed.

10.1.3 All evidence must be retained intact and kept securely for any subsequent examination. Any defective drugs or medical equipment must be withdrawn from use and kept securely.

10.2 Incident Reporting Mechanisms

10.2.1 Incident Forms
Employees working within UHB premises should report incidents, near misses and hazards using the UHB Incident Form. These forms must be readily available to all staff at all times. However,
for matters relating to the estate/environment, any defects that create an actual / potential hazard must be reported through the established maintenance request processes. Supplies of the UHB Incident Form are available from the Health, Safety and Environment Unit (HSEU) at Denbigh House, University Hospital of Wales.

10.2.2 Patient Safety Incident Reporting Through the National Reporting and Learning System (NRLS)
Employees and contractors are able to report patient safety incidents using the NRLS e-form. This e-form should only be used when there is no timely access to the standard UHB Incident Form.

The information gathered through the NRLS e-form does not include patient identifiable data, as this would breech the Data Protection Act. To ensure that the incident is followed up appropriately, further information may be required. Therefore employees and contractors are strongly encouraged to include contact details in the appropriate section of the NRLS e-form.

On submission of the NRLS e-form, and where the UHB is identified as the responsible organisation, the NRLS will send an email notification of an incident being reported to an agreed email address within the UHB which is accessible by a senior member of the Patient Safety Team. Following receipt, the e-form will be managed in line with the standard UHB incident reporting mechanisms.

10.3 What and how to Report

10.3.1 All incidents, near misses and hazards must be reported on through the agreed reporting mechanisms, however minor.

10.3.2 An indicator list of the different types of incidents that should be reported is specified in Appendix 3. This is not exhaustive, its purpose is to provide guidance.

10.3.3 In addition to these appendices, Divisions and Directorates/Departments may also develop indicator lists for the different types of incidents which may be specific to their area of work. Such lists must be cross referenced to Appendix 3.

10.3.4 The requirements and responsibilities for reporting incidents to external bodies are detailed in section 12.

10.3.5 If a staff member has an accident/near miss they should complete the Incident Form as soon as is practically possible. If they are incapacitated in any way the form may be completed by a
colleague ensuring they accurately relay the circumstances of the incident.

10.3.6 When a patient or visitor is involved in an incident the staff member who first becomes aware of the incident is responsible for ensuring that the incident is reported through the agreed UHB reporting mechanisms.

10.3.7 Incident forms will be returned to the relevant department in the event that any information is missing from the form or the form is illegible.

10.3.8 The Incident Report Form (both white and yellow copies) must be forwarded to the Line/Departmental Manager.

10.3.9 Note: In exceptional circumstances staff may submit an Incident Report Form directly to the Health, Safety and Environment Unit (HSEU). However, to ensure that an effective investigation can be undertaken the Clinical Governance Facilitator/Health and Safety Advisor will discuss the incident with the Line Manager or Senior Manager concerned.

10.3.10 Patient Safety Incidents reported via the NRLS will be forwarded to the appropriate manager for investigation. The investigation will be undertaken as outlined in the UHB Investigation Procedure.

10.3.11 On conclusion of the local investigation, or within 2 working days, (whichever is the shorter) the white top copy of the form must be forwarded to the HSEU at Denbigh House, University Hospital of Wales.

10.3.12 If the investigation has not been completed or is expected to take longer than 2 working days, the form should contain a note to this effect and details of the full investigation should be forwarded once complete, along with a photocopy of the incident form, to the Health and Safety Advisor or Clinical Governance Facilitator.

10.4 Communicating with Patients and/or Relatives, Carers, Advocates

Further information relating to Being Open can be found in the UHB Being Open Policy.

10.4.1 The circumstances of the incident should be communicated to the patient or their representative as soon as is practicable after the incident. In exceptional circumstances, if it is deemed that the impact of disclosure will adversely affect the patient’s psychological well being, a decision may be taken not to inform
the patient; reasons for this decision must be clearly documented in the patient’s health records.

10.4.2 A duty of candour, meaning a duty to tell a patient if adverse events have occurred, must be recognised as owed to patients by all those working in the NHS.

10.4.3 Patients and/or carers should receive an apology as soon as possible after a patient safety incident has occurred and staff should feel able to apologise on the spot. Saying sorry is not an admission of liability and is the right thing to do. Patients have a right to expect openness in their healthcare.

10.4.4 In line with Putting Things Right/NHS Redress (April 2011) patients and/or their carers as appropriate should be informed as to what action has been taken or is intended in response to a reported incident. If the nature of the incident requires further investigation, the patient and or their representative should be asked what involvement if any they would wish to have in the investigation and whether there are any specific questions they would like answered in relation to the reported incident. It is important that the outcome of such discussions is fully recorded on the incident form. Further guidance on being open can be sought from the Patient Safety Team.

10.5 Clinical Examination of Patients Following an Adverse Incident

10.5.1 If the incident involves a patient, the person in charge of the ward/department/work area will make a judgement as to whether an immediate medical examination is required.

10.5.2 The person examining the patient should complete the relevant section of the Incident Report Form along with an appropriate record in the patient’s medical records.

10.6 Incidents occurring in the Community Setting Involving Patients

10.6.1 If an incident involving a patient occurs in a community setting, the person in charge of the work area shall be informed as soon as practicable after the incident and not later than 24 hours (whichever is the shorter period).

10.6.2 If a member of staff feels that a Doctor should be made aware of the incident involving a patient they should either advise the patient/carer to contact their GP or personally notify the GP as soon as practicable after the incident. If the incident is considered to be sufficiently serious, an emergency ambulance should be called.
10.7 Incidents Involving Staff, Volunteers, Visitors, etc.

10.7.1 If a person is injured as a result of an incident an incident form must be completed and they should be offered the appropriate treatment. This may include any of the following:

- First Aid treatment
- Emergency treatment in the Emergency Unit
- Summoning of an ambulance
- Attendance at Occupational Health
- Support from Employee Well-Being Service
- Advice to visit own GP

Some injuries, such as needle-sticks, have a defined protocol that must be followed. If a member of staff is absent from work, as a direct result of their injury, the line manager must inform the relevant Health and Safety Advisor.

10.8 Equipment

10.4.1 If a piece of equipment is involved in the incident it must be retained and where possible/necessary kept secure for later examination. The serial number or any other means of identifying the device should also be recorded on the Incident Report Form.

10.4.2 If medical equipment/devices are involved, the Medical Physics and Clinical Engineering Department and/or Clinical Governance Facilitators must be contacted (as appropriate) as soon as possible for advice before any further action is taken. Examples of medical devices can be found in Appendix 8.

10.4.3 Medical equipment/devices should not be returned to the manufacturer unless this has been agreed with the Medical Physics and Clinical Engineering Department or Clinical Governance Facilitators.

10.4.4 Equipment must also be decontaminated/cleaned to ensure that it does not present a biological hazard to staff inspecting or repairing it (refer to UHB Decontamination and Disinfection Policy). Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled, and retained in a secure location.

10.4.5 Any disposable or reusable accessories related to the device or the procedure e.g. surgical diathermy equipment retaining the return electrode, active electrode and the wires; should be retained and stored safely until the investigation can be undertaken.
10.9 Serious Adverse Events or Reactions during Research

10.9.1 An Incident Report Form must be completed for all serious adverse events or serious adverse reactions which occur within research projects hosted by the UHB (including projects involving Cardiff University).

10.9.2 If an incident is research related then this must be indicated on the Incident Report Form. The Research Unique Identifier should be recorded on the Incident Report Form. This will ensure that the UHB Research and Development (R&D) Office are notified of the incident, as required under the Research Governance Framework for Health and Social Care in Wales (Welsh Government, 2001).

10.9.3 Such events must also be reported to the R&D Office, as described in the UHB Policy for Reporting Research-Related Adverse Events and the corresponding Procedure on Reporting Research-Related Adverse Events. Further details of certain types of incident must be submitted to the R&D Office by the Chief or Principal Investigator using the appropriate report forms (available from the R&D Office via email: research.development@wales.nhs.uk).

10.10 Post Serious Incident Support

The organisation recognises that a serious untoward incident may be potentially stressful and difficult for staff, patients and their families both directly and indirectly involved. It is essential that appropriate and timely support is offered and made available to all who identify that they require it.

10.10.1 Phases for Post Incident Support

There are two phases of support which may be required, immediate and post incident support.

Immediate support may take the form of:
- Provision of guidance and information about the practical steps which need to be taken
- Provision of extra staff to the area where the incident occurred to enable staff involved ‘time-out’ and to talk.
- Checking when staff are next on duty and if appropriate, through discussion with staff involved in the incident, arranging changes to shifts.
- Identifying who may benefit from follow-up telephone calls/support at home.

Post-incident support may take the form of:
- De-briefing
- Involvement of the Chaplaincy Department (spiritual, religious and pastoral support)
Clinical Supervision
- Support by professional colleagues e.g. Employee Well-Being Service, Violence & Aggression Case Manager
- Occupational Health review

10.10.2 Identifying the Need for Support and Provision of Support

It can sometimes be difficult for staff directly involved in an incident to recognise that they need support. Staff should be informed of the support available and the line manager should talk with them about their individual support needs on more than one occasion.

Patients and visitors who may have been involved in, or witness to, a serious untoward incident should also be offered timely and sensitive support and information. The Line Manager of the area involved in the incident should make contact with the patients/visitors as soon as possible after the incident, even if they have already been contacted by the police.

All patients and visitors involved in or witness to the incident must be given a named contact with whom they can discuss any concerns or seek advice. The named contact will usually be the designated person – in charge of the area.

Once the situation has been brought under control the designated person in charge of the area will liaise with the Line Manager for the area (Senior Nurse/Directorate Manager).

The Line Manager will be responsible for ensuring that staff, patients and visitors identified as requiring immediate medical care provided with rapid access to such services.

The Line Manager will be responsible for ensuring that staff immediately involved in the incident are removed from the area and given ‘time-out’ to be debriefed and supported.

The Line Manager will arrange for other staff to be deployed to the area where the incident has taken place whilst the immediate debriefing takes place. Where staff involved in the incident feel unable to continue working the rest of the shift the Line Manager will be responsible for making alternative staffing arrangements.

10.10.3 Provision of Information to External Investigating Bodies

Following certain serious adverse incidents, it may be necessary for an investigation to be undertaken by an external agency e.g. Police, Health and Safety Executive, Healthcare Inspectorate Wales. These agencies may wish to formally interview staff as part of their investigation process.
During these interviews, staff can request that their line manager or other senior member of staff be present at the interview. The role of this person during the interview is to take notes of the information as a record for the individual. This recognises that at times of particular stress individual recall can be difficult.

10.10.4 Media Interest
Some serious incidents attract media interest. All media releases by the organisation will be in line with the organisation’s media arrangements.

It is the responsibility of the designated Executive to ensure that the media team are alerted to the potential for press enquiries and that a press statement is prepared.

11. INVESTIGATION

The organisation is committed to promoting an open and fair culture. The investigation process is focussed on being fair and equitable by identifying the root causes and addressing system failures rather than individuals. The UHB recognises that human error is a contributory factor to some incidents and staff will not as a routine, be disciplined for incidents due to human error. However, staff are accountable for their actions and are expected to be open about incidents they are involved in. However, breaches or violation of policy, procedure, professional codes of conduct, may have to be dealt with under the disciplinary policy following investigation.

All serious incidents will be investigated appropriately. Investigations may also be undertaken if there is repetition of similar incidents or clusters of incidents.

Further information relating to investigation of incidents can be found in the UHB Investigation Procedure.

11.1 Witness Statements and Written Accounts

11.1.1 If an employee witnesses an incident, they should ensure that an Incident Report Form is completed. If the incident is of sufficient severity, a contemporaneous written account should be made by the staff member(s).

11.1.2 Employees may also be asked to provide a formal written statement as part of an investigation into an incident. Guidance on preparing a witness statement and the recommended format is detailed in Appendix 7. The witness should only record what they actually saw or heard in their statement. They must not record what they assumed had happened. A witness statement should only be completed by the member of staff and not any other person i.e. third party.
11.1.3 If a patient/visitor witnesses an accident, their details must be recorded (gaining evidence at a later date could otherwise prove difficult or impossible). Patient/visitor(s) should not normally be asked to complete a witness statement, however if they are insistent that they wish to act in this capacity, they should be given the opportunity to do so.

12. RISK ASSESSMENT

All incidents should be risk assessed using the agreed UHB matrix. Please refer to the Risk Assessment and Risk Register Procedure.

A Post Incident Risk Assessment should be conducted by the Department/Directorate after every incident, as appropriate. Not all Risk Assessments are documented i.e. where a risk is insignificant. In some cases the review will merely result in the existing risk assessment being appropriately amended, signed and dated. In other circumstances it will require a review of the risk assessment documentation and the preparation of an action plan to avoid any similar incidents. These action plans will be reviewed by the Divisional Health and Safety Group or Divisional Quality and Safety Group as appropriate.

Where hazards/risks are identified which present an on-going risk to the organisation, it will be necessary to amend the Directorate/Division/UHB Risk Register as appropriate.

13. REPORTING TO EXTERNAL AGENCIES

All incidents reported to external agencies should also be reported to the UHB through the agreed UHB incident reporting mechanisms.

13.1 National Reporting Learning System (NRLS)

“All NHS organisations are required to report all patient safety incidents (irrespective of seriousness and degree of harm) to the National Patient Safety Agency (NPSA) Reporting and Learning System. This is to inform the prioritisation and development of safety solutions…” (Welsh Government, 2010)

All patient safety incidents reported within the UHB will be shared, electronically via DATIX, to the NRLS. The incident reports will be made anonymous prior to sharing. Sharing patient safety incidents with the NRLS contributes to national learning. Reports received from the NRLS will be distributed through the organisation.

13.2 Health and Safety Executive

13.2.1 RIDDOR

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 came into force on 1st April 1996. The UHB
must report deaths, major injuries, and accidents resulting in over 3 day injury, diseases, dangerous occurrences and gas incidents.

The Health and Safety Advisor(s) are the appointed persons for reporting all RIDDOR events to the HSE, for all of the UHB. When an incident has been identified as RIDDOR reportable, the Health and Safety Advisor should be notified as soon as possible. In serious incidents resulting in major injury or death, the Health and Safety Executive need to be alerted by the Health and Safety Advisor immediately. Outside of normal working hours Switchboard will contact the HSEU via on-call arrangements. If there is an accident connected with work (including an act of physical violence) resulting in an employee suffering an over-seven-day injury, it must be reported in compliance with the above regulations within 10 days. An over-7-day injury is one which is not ‘major’ but results in the injured person being away from work OR unable to do their full range of their normal duties for more than seven days.

It is the manager’s responsibility to ensure that in the event of a major injury, that the Health and Safety Advisor is contacted immediately and in the case of any lost time events within 24 hours (note on call arrangements above when required).

The Health and Safety Executive will require the following information:

- Date and time of incident
- Location of incident
- Name, home address, gender and status of persons involved / affected
- Details of any injuries
- Confirmation as to whether the situation is under control or whether assistance is required
- Brief outline of the circumstances of the incident
- Details of any witnesses.

13.2.2 Health and Safety Executive (HSE) – Exposure to Radiation

Breaches in relation to equipment malfunctions that results in over exposure of radiation will be reported to the HSE by the Health & Safety Advisers.

13.3 Welsh Government

The UHB is required to report Patient-Related Serious Adverse Incidents as defined in the Welsh Government (April 2012) Guidance on the Reporting and Handling of Serious Incidents and Other Patient Related Concerns/No Surprises (see appendix 4). The UHB is required to inform the Welsh Government within 24 working hours of a serious adverse incident.
Reporting of Serious Incidents and No Surprise/Sensitive Issues to the Welsh Government will be coordinated by the Clinical Governance Facilitators. **It is the manager’s responsibility to ensure that the Clinical Governance Facilitator is contacted within 24 hours.**

There are specific forms for reporting Serious Incident and No Surprise/Sensitive Issue Incidents to Welsh Government which are controlled via the Patient Safety Department and must be signed by an Executive Officer prior to submission to Welsh Government.

### 13.4 Medicines and Healthcare Products Regulatory Agency (MHRA)

12.4.1 Where a serious incident involves a medical device the UHB nominated liaison officer with the Medicines and Healthcare Products Regulatory Agency (MHRA) must be contacted within 24 hours. Discussion and agreement must take place between the Clinical Governance Facilitator(s) and the Clinical Engineering Department regarding an appropriate nominated liaison. An appropriate senior manager will be responsible for ensuring that the material evidence is labelled and kept secure. Manufacturers must not be allowed to take the medical device without agreement from the liaison officer and MHRA.

12.4.2 The Prescribing and Medicines Management Team will report adverse reactions to medication to the MHRA.

12.4.3 The Transfusion Team will report appropriate incidents to the MHRA Serious Adverse Blood Reactions and Events (SABRE) mechanisms in accordance with laboratory procedures. This may also include reporting to Serious Hazards of Transfusion (SHOT).

### 13.5 Communicable Diseases

The Consultant in Communicable Disease Control, Health Protection Agency (HPA) should be contacted in the event of an infectious disease outbreak defined as two or more cases connected by time and place and any serious single infection with public health implications. The most senior manager on duty should notify the HPA as soon as an outbreak has been identified.

### 13.6 Estates and facilities

All urgent health and safety estates issues should be reported to the Estates Officer on-call (phone switchboard to connect you to the on-call officer).
Care should be taken to ensure that evidence relating to the incident is not destroyed or removed without authorisation by the Health and Safety Advisor or executive on-call. Out of normal hours, the Executive on-call should be notified via switchboard.

13.7 Healthcare Inspectorate Wales – Ionising Radiation Medical Exposure Regulations (IRMER)

The Clinical Governance Facilitators will report breaches in IRMER to Healthcare Inspectorate Wales in line with their regulatory role in monitoring compliance with IRMER. Such incidents will also be reported to Welsh Government in line with Serious Adverse Incident reporting.

14. FEEDBACK

14.1 The Line/Departmental Manager responsible for the area must provide feedback to the individual that has made the report including action(s) taken to prevent recurrence. Information on changes of practice should be included. Feedback can take a number of different formats and may involve the individual who made the report or a group of staff e.g. where a number of staff have been experiencing difficulties e.g. due to staff shortages, or a challenging patient. Details of any feedback given must be recorded in the relevant section of the incident report form.

14.2 The Health and Safety Advisor will send an acknowledgement letter to each member of staff that has been personally affected by a staff related health and safety incident.

The purpose of sending this letter is to ensure that the staff member is aware that the incident has been reported on the UHB Database and to ensure that they advise the Health and Safety Advisor if they have sustained an injury which is reportable in accordance with RIDDOR.

14.3 The Clinical Governance Facilitators and Health and Safety Advisors will provide a regular report from the DATIX system to Directorates/Divisions. The Directorate will share and disseminate the report as appropriate. Regular reports will also be provided to the appropriate UHB committees and groups on request.

15. LEGAL STATUS AND RETENTION OF INCIDENT REPORT FORMS

15.1 Incident report forms may have to be disclosed under certain circumstances e.g. HM Coroner, Concerns (claims, complaints) etc. It is essential that any information recorded on the form is accurate and factually correct.
15.2 The UHB will ensure that it has mechanisms for storing and retrieving Incident Report Forms. Storage of incident forms may be electronic. It is a requirement of WHC 2000(71) that:
- Incident Report Forms relating to incidents involving adults will be retained for 10 years after the date of the incident, and
- Incident Report Forms relating to incidents involving children will be retained until the child is 25 years of age or for 8 years after the death of the child (whichever is the sooner).

15.3 The yellow copy is a working document and should be retained within the Directorate for no less than one year and not until the incident is closed and all necessary actions have been taken. If additional information is added to the yellow copy this information should be forwarded to the Clinical Governance Facilitators or Health and Safety Advisors for inclusion on DATIX.

15.4 Directorates must ensure that they destroy their copies in line with the UHB retention schedules and in a confidential manner, i.e. shredding. They should retain an index detailing as a minimum, the dates when forms are destroyed, the date range of those forms and the quantity of forms destroyed.

16. SEVERITY RATING OF INCIDENTS

16.1 All incidents will be rated according to the actual impact on the individual(s) involved and/or, dependant on the nature of the incident, the potential future risk to individuals and to the organisation.

16.2 The Clinical Governance Facilitator/Health and Safety Advisor will rate the severity of the incidents entered on DATIX (see Appendix 6).

17. DATA COLLECTION AND ANALYSIS

17.1 Incidents will be recorded on DATIX, the UHB electronic risk management system. Each incident is allocated a unique number to allow for future reference. Security incidents will be forwarded to the security department for entry onto their database – these incidents will not be recorded on DATIX unless personal safety has been affected or where unauthorised access has been gained to confidential information.

17.2 The database 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.
17.3 Reports will be generated from DATIX for discussion at various Divisional and UHB meetings as agreed.

18. **SHARING LESSONS LEARNT**

18.1 Only by learning about the underlying causes of an incident can new ways of working be implemented to minimise the risk of future harm. An incident investigation may reveal action that is required which will have an impact on other areas within the organisation. Lessons learnt should be disseminated via the UHB quality and safety and/or health and safety arrangements to ensure that the UHB can learn from incidents that have occurred to prevent similar occurrences and promote continued improvement in service provision and patient care.

18.2 From time to time it will be appropriate to share lessons learnt with other organisations including; other Welsh Health Boards and Trusts, Welsh Government, HSE, Healthcare Inspectorate Wales, HM Coroner.

18.3 Whilst not necessarily dependent on the UHB reporting an incident associated with the death of a patient or staff member, if a Coroner believes action should be taken to prevent or reduce the risk of a recurrence of fatalities, under Rule 43 of the Coroners’ Rules 1984, it is open to him or her to make a report to the person(s) who may have power to take this action. Appendix 9 outlines the internal arrangements should the UHB receive a Rule 43 Report.

19. **RESOURCES**

19.1 This Policy provides an update of current practices. It is therefore unlikely that any additional resource will be required to ensure that staff report incidents.

19.2 *Database* - the UHB uses the DATIX risk management system for recording incidents. Updating and maintenance of this system has resource implication which at present is managed within the UHB allocated resource.

20. **IMPLEMENTATION**

This Policy and Procedure reflects existing practice across the University Health Board and will therefore be implemented with immediate effect. The requirements of this Policy and Procedure will be re-enforced within Divisions/ Directorates/Departments by local risk management and health and safety arrangements.
21. EQUALITY

Cardiff and Vale UHB is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff, patients and others reflects their individual needs and does not discriminate, harass or victimise individuals or groups. These principles run throughout our work and are reflected in our core values, our staff employment policies, our service standards and our Strategic Equality Plan & Equality Objectives. The responsibility for implementing the scheme falls to all employees and UHB Board members, volunteers, agents or contractors delivering services or undertaking work on behalf of the UHB.

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 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.

22. FURTHER INFORMATION/REFERENCES

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


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

HSE (1977) The Safety Representatives & Safety Committees Regulations


Human Tissue Authority (2012), The Quality and Safety of Organs Intended for Transplantation Regulations.

Department of Health (2006), Ionising Radiation (Medical Exposure) Regulations (amended 2006).

Medicines and Healthcare Products Regulatory Agency (MHRA)

NHSE Controls Assurance Standards (Jan 2000), Risk Management Systems –
Criteria 13,14,15,16 and 17, NHS Executive

NHSME (1993), Risk Management in the NHS, NHS Management Executive

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 April 2012)

Welsh Government (2010) Standards for Health Services in Wales: Doing Well,
Doing Better

Incidents – Guidance on New Arrangements for NHS Wales Organisations

Welsh Government (2001) Research Governance Framework for Health and
Social Care in Wales

Welsh Government (2000) Reporting Arrangements for Serious Adverse
Incidents (71)

Welsh Office (1997), DGM (97)51 – NHS Health and Safety Issues, Welsh
Office Health Department

Associated UHB Policies and Procedures

1 Capability Policy
2 Dignity at Work Policy
3 Disciplinary Procedure
4 Equal Opportunities Policy
5 Sickness Policy
6 Health and Safety Policy
7 Professional Registration Policy
8 Whistleblowing Policy
9 Fire Safety Policy
10 Security Policy
11 Policy for Reporting Research Related Events
13 Procedure on Reporting Research Related Adverse Events
14 Risk Assessment and Risk Register Procedure
   Risk Management Policy
15 Being Open Policy
16 Investigation Procedure
17 Records Management Policy
23. MONITORING

It will be necessary to ensure that Divisions are adhering to the requirements of this policy and its related procedures. This will be monitored via a number of different methods e.g. review of individual incident forms/investigations, review of incident statistics, audits of databases, workplace inspections etc.

Audits may also be undertaken of performance against the timescales and targets set in this procedure.

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

24. DISTRIBUTION

24.1 This Policy will be on the UHB Clinical Portal, Intranet and Internet Site.

24.2 Line Managers/Departmental Managers/Lead Nurses/Directorate Managers/Clinical Directors are responsible for ensuring that all staff have access to this document.

25. REVIEW

This Policy will be reviewed every 3 years or more frequently if required, to ensure continued compliance with risk management guidance and health and safety legislation.

26. ABBREVIATIONS

EMS Environmental Management System
HIW Healthcare Inspectorate Wales
H&S Health & Safety
HSE Health and Safety Executive
HSEU Health, Safety and Environment Unit
IRMER Ionising Radiation and Medical Exposure Regulations
MHRA Medicines and Healthcare Products Regulatory Agency
NHS National Health Service
NPSA National Patient Safety Agency
NRLS National Reporting and Learning Service
RCA Root Cause Analysis
R&D Research and Development
RIDDOR Reportable Injuries, Diseases and Dangerous Occurrences Regulations
SABRE Serious Adverse Blood Reactions & Events
SHOT Serious Hazards of Transfusion
SI Serious Incident
UHB University Health Board
WG Welsh Government
APPENDIX 1

ACTION CHECKLIST TO BE FOLLOWED IN THE EVENT OF A PATIENT RELATED SERIOUS ADVERSE INCIDENT

A. Responsibility of the most senior member of staff present at the event

The immediate handling of the event will be the responsibility of the most senior member of staff present at the incident. He or she must:

1. Ensure the immediate safety and care of people involved.
2. Contact appropriate emergency services, if necessary:
   
   **Acute Hospital setting:**
   - Emergency Service 3333
   - Cardiac Arrest 2222

   **Community/Outlying Service**
   - Emergency Services 999

3. Alert the Consultant and Senior Nurse/Manager. Out of hours, the site manager must be informed.
4. Secure the area, isolate and retain equipment and prevent any unauthorised entry when circumstances deem this action necessary.
5. Note the names and telephone numbers of any witnesses.
6. Document the sequence of events contemporaneously within the patient health records.
7. Complete the UHB Incident Report Form.

B. Responsibility of the Consultant/Senior Nurse/Manager or Site Manager (Out of Hours)

1. Inform the patient, patient’s next of kin, and the patient’s GP (for community patients only) of the incident as soon as possible (NPSA, 2005).
2. Once the immediacy of the situation has been dealt with, the Consultant/Senior Nurse/Manager must inform the Divisional Director, Divisional Nurse, Clinical Director or Directorate Manager or Senior Nurse, and the Clinical Governance Facilitator/Health & Safety Advisor by telephone. Out of normal hours, contact the appropriate manager on call.
3. Ensure that the procedures outlined in A above have been followed.
4. Ensure that all relevant sections of the UHB Incident Report Form have been completed.
5. Ensure that all relevant documents e.g. health records are retained in a secure location.
6. Encourage staff involved with the care of the patient, or witness to the incident, to write a reflective account of events which may later be used to assist the individual in writing their statement, if required.
C. **Responsibility of the Directorate Manager/Clinical Director/Lead Nurse (in normal working hours)**

1. The Directorate Manager/Clinical Director/Lead Senior Nurse will complete the proforma Welsh Government Notification of Patient-Related Serious Adverse Incident Form (see Appendix 4). A blank copy of the form is available from the Patient Safety Department.

2. The completed Patient-Related Serious Adverse Incident Form should be forwarded to a senior member of the Patient Safety team (via e-mail if possible), and a copy sent to the Divisional Director, Divisional Nurse and Divisional Manager. A senior member of the Patient Safety team will share the form with the Assistant Director of Patient Safety and Quality for consideration by the Executive Team and onward reporting to the Welsh Government.

3. To ensure that all relevant patient data is collated and stored in a secure location.

**Responsibility of the Site Manager (outside of normal working hours)**

1. To ensure that the procedures outlined in A and B above have been followed.

2. The Site Manager will inform the On-Call Senior Manager, who will decide whether to escalate through the on-call management structure.

3. To ensure that all relevant patient data is collated and stored in a secure location.

D. **Action Checklist for the Clinical Governance Facilitator/Health and Safety Advisor**

1. Ensure that all appropriate action has been undertaken.

2. Inform the Assistant Director of Patient Safety and Quality.

3. Inform Director of Governance

4. Inform the Press Office of the event as appropriate.

E. **Action Checklist for the Press Office**

1. To set up media handling arrangements as necessary.
“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.” See Appendix 3 for examples.

**IMMEDIATE ACTION**

- Ensure clinical examination of injured party if necessary and advise patient / relatives / carers of incident.
- Report incident to designated person/dept. for onward reporting to External Agency as necessary (see section 11).
- Complete an Incident Report Form and forward to Line/Dept. Manager immediately or within 24 hrs of incident.

**INITIAL INVESTIGATION**

- Line/Dept. Manager/Consultant investigates incident and completes the relevant section of Incident Report.
- Line/Dept. Manager provides appropriate feedback to staff.
- HSEU sorts forms and sends to relevant H&S Advisor/Clinical Governance Facilitator.

**CLINICAL GOVERNANCE FACILITATOR / H&S ADVISER**

- Incidents categorised and graded. Further investigation requested as appropriate.
- Incidents recorded on DATIX. Letters sent to staff personally affected by an H&S incident by relevant H&S Advisor.
- White copy retained by Patient Safety Dept/ HSEU for minimum 10yrs.

- Full investigation report and action plan produced if necessary (see Investigation Procedure).
- Share lessons learnt within / outside Division / UHB as appropriate.
INDICATORS FOR MAJOR INJURIES, DANGEROUS OR UNTOWARD OCCURRENCES, CLINICAL INCIDENTS, MINOR INJURIES AND DISEASES.

1 Some examples of reportable minor injuries / other include:-

- any incident resulting in an injury, including minor cuts or bruises
- all lifting injuries, including sprains and strains not classified in any of the above
- all needlestick/sharps injuries
- all assaults including verbal abuse
- staff member suffering any ill health as a perceived or actual result of working conditions

2 Reportable major injuries are:-

- fracture other than to fingers, thumbs and toes
- amputation
- dislocation other than to, thumbs and toes
- loss of sight (temporary and permanent)
- injury resulting from an electric shock or electrical burn leading to unconsciousness or requiring resuscitation or admittance to hospital for more than 24 hours
- unconsciousness caused by asphyxia or exposure to harmful substance or biological agent
- acute illness requiring medical treatment, or loss of consciousness arising from absorption of any substance by inhalation, ingestion or through the skin
- acute illness requiring medical treatment where there is reason to believe that this resulted from exposure to a biological agent or its toxins or infected material
- chemical or hot metal burn to the eye or any penetrating injury to the eye
- someone not at work is injured in an accident at a hospital, and suffers a major injury

3 Reportable dangerous or untoward occurrences are:-

- collapse, overturning or failure of load-bearing parts of lifts and lifting equipment
- explosion, collapse or bursting of any closed vessel or associated pipework
- failure of any freight container in any of its load-bearing parts
- plant or equipment coming into contact with overhead power lines
- electrical short circuit or overload causing fire or explosion
- any unintentional explosion, misfire, failure of demolition to cause the intended collapse, projection of material beyond a site boundary, injury caused by an explosion
• accidental release of a biological agent likely to cause severe human illness
• malfunction of breathing apparatus while in use or during testing immediately before use
• collapse or partial collapse of a scaffold over five metres high, or erected near water where there could be a risk of drowning after a fall
• unintended collision with any vehicle – Not RIDDOR
• a dangerous substance being conveyed by road is involved in a fire or released, or overturns and the tank is seriously damaged
• unintended collapse of any building or structure under construction, alteration or demolition where over five tonnes of material falls; a wall or floor in a place of work; any false work
• explosion or fire causing suspension of normal work for over 24 hours
• sudden, uncontrolled release in a building of: 100 kg or more of flammable liquid; 10 kg of flammable liquid above its boiling point; 10 kg or more of flammable gas; or of 500 kg of these substances if the release is in the open air
• accidental release of any substance which may damage health

4 Reportable diseases include:

• certain poisonings
• some skin diseases such as occupational dermatitis, skin cancer, chrome ulcer, oil folliculitis/acne
• lung diseases including: occupational asthma, farmer's lung, pneumoconiosis, asbestosis, mesothelioma
• infections such as: leptospirosis, hepatitis, tuberculosis, anthrax, legionellosis and tetanus
• other conditions such as: occupational cancer; certain musculoskeletal disorders; decompression illness and hand-arm vibration syndrome

5 Reportable environmental incidents include:

• spillage of substance / oil / chemical
• spillage of substance / oil / chemical to drainage system
• breakdown of waste collection service
• odours / offensive smells
• nuisance noise - building, plant and equipment
• adverse emissions to atmosphere
• adverse weather conditions resulting in environmental damage

6 Reportable fire incidents

• any incident in which a fire alarm is activated
• any incident in which a fire actually results
7 Reportable security incidents include:-

- loss, damage or theft of any UHB property
- loss, damage or theft of any personal property whilst on UHB property or performing UHB duties (patient and staff)
- unauthorised access to confidential records or computer systems

8 Some examples of reportable clinical incidents are:-

- Unexpected deaths (including post-operative)
- Death/injury as a result of treatment or care
- Unintentional procedure/treatment
- Operations to repair damage due to an invasive or endoscopic procedure
- Pathology / image report to wrong patient
- Equipment failure leading to patient injury
- Wrong patient or wrong site - surgery or radiology
- Attempted/actual suicide while under the care of the UHB
- Any unplanned return to the operating theatre
- Medication error, including infusion pump problems
- Self-harm while under the care of the UHB
- Delay/failure to act upon a test result/report
- Severe extravasation injury
- Breach of patient confidentiality
- Failure to receive informed consent/obtain consent from correct person/invalid consent
- Unlawful treatment
- Unlawful detention – e.g. invalid application of section.5(2) Mental Health Act 1983
- Delay/failure to diagnose or incorrect diagnosis where there is a loss or compromise of chance for successful treatment
- Unexpected admission to Critical Care/Neonatal Unit
- Swab/instrument count incorrect at end of procedure
- Unplanned emergency readmission/re-attendance within 5 days of discharge
- Unsafe discharges
- Missing healthcare records which compromise patient care
- Hospital acquired infection leading to an adverse outcome
- Delay/difficulty in obtaining urgent clinical assistance
- Patient incorrectly identified or specimens/scans mislabelled resulting in (near) patient harm
- Unsafe transfers between clinical areas
- Failure/delay in referral process (child protection/vulnerable adults)
- All incidents of unlawful discrimination and harassment
9 Never Events


"Never events" are very serious, largely preventable patient safety incidents that should not occur if the relevant preventative measures have been put in place.

The Government proposed in last year's White Paper to expand the current list of incidents considered to be "never events". A draft list of "never events" was published in October 2010, and comments were sought on the proposals. Following this engagement process, the list was revised and the policy clarified.

There are 25 "never events" on the expanded list. The list is as follows:

1. Wrong site surgery
2. Wrong implant/prosthesis
3. Retained foreign object post-operation
4. Wrongly prepared high-risk injectable medication
5. Maladministration of potassium-containing solutions
6. Wrong route administration of chemotherapy
7. Wrong route administration of oral/enteral treatment
8. Intravenous administration of epidural medication
9. Maladministration of Insulin
10. Overdose of midazolam during conscious sedation
11. Opioid overdose of an opioid-naïve patient
12. Inappropriate administration of daily oral methotrexate
13. Suicide using non-collapsible rails
14. Escape of a transferred prisoner
15. Falls from unrestricted windows
16. Entrapment in bedrails
17. Transfusion of ABO-incompatible blood components
18. Transplantation of ABO or HLA-incompatible Organs
19. Misplaced naso- or oro-gastric tubes
20. Wrong gas administered
21. Failure to monitor and respond to oxygen saturation
22. Air embolism
23. Misidentification of patients

24. Severe scalding of patients

25. Maternal death due to post partum haemorrhage after elective Caesarean section

This list is an example and Divisions/Directorates may develop their own indicator list which complements the above for reporting of patient safety incidents.

Any incidents resulting in severe harm/death should be reported by telephone to the immediate Line Manager and Clinical Governance Facilitator/Health & Safety Advisor. Out of hours the Site Manager should be informed.

The Fire Safety Advisor and immediate Line Manager must be telephoned if reporting a fire.
1 INTRODUCTION

Arrangements for the reporting and handling of Serious Incidents (SIs) was issued by the Welsh Government (WG) in June 2010. Related guidance was updated in April 2012.

The reporting of SIs to the Welsh Government and National Reporting and Learning System (NRLS) does not exclude the requirement to report to other bodies, e.g. Healthcare Inspectorate Wales, Health & Safety Executive (RIDDOR), Information Commissioner’s Office, Police, Coroner, as appropriate and as required by each individual body.

Each Division must review this Appendix and insert the appropriate titles for the various individuals that have a role in this procedure.

2 DEFINITION

The definition of a SI in this context extends beyond those which impact directly on patients. The NPSA has suggested the following definition which NHS Wales and the UHB has adopted:

A SI requiring investigation is defined as an incident that occurred in relation to NHS funded services and care resulting in:

- the unexpected or avoidable death of one or more patients, staff, visitors or members of the public;
- Severe/permanent harm to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy, or will result in prolonged pain or psychological harm (this includes incidents graded under the NPSA definition of severe harm);
- A scenario that prevents or threatens to prevent an organisation’s ability to continue to deliver health care services, for example, significant disruption to services due to failure of an IM&T system, actual or potential loss or damage to property, reputation or the environment,
- Any death as a direct result of a healthcare associated Infection (D&V, C.Diff, MRSA etc). An outbreak of a healthcare associated infection in a hospital that results in the closure of a ward/bay to admissions and causes signification disruption should be reported as an SI but closure of a bay which doesn’t cause significant disruption to service should be reported as a No Surprise;
- Transmission of infectious diseases;
- An allegation or actual abuse including sexual, physical or psychological;
• Suspected suicide/unexpected death of a mental health patient (including community and in-patient services);
• Self-Harm incidents categorised as severe;
• A child under the age of 18 years admitted to an adult mental health ward;
• Ambulance delays which contribute to the death/severe harm of a patient;
• Data loss and information security;
• Grade 3 or 4 pressure ulcers;
• Absence without leave of a patient subject to the Mental Health Act (please ensure you update the WG once the patient has been found);
• Intrauterine Fetal deaths if there is early indication that the death is linked to midwifery/obstetric practice;
• Maternal death;
• the agreed set of ‘Never events’ as updated on an annual basis (see above list). http://www.nrls.npsa.nhs.uk/resources/collections/never-events/core-list/
• This list is not exhaustive and is meant as a guide. An element of judgement will be inevitable in determining what should be reported. If in doubt - report. Serious incidents can occur in any setting (e.g. community health/services, nursing/care home, primary care or Prison) as long as it is an NHS funded service (either partially or fully funded).

Welsh NHS bodies should ensure that staff and contractors are aware of local policies/processes for reporting incidents. It is important that incidents are reported in a timely manner. All Welsh Government serious incidents should be reported where possible within 24 hours of the incident occurring to improvingpatientsafety@wales.gsi.gov.uk using Appendix W.

If the serious incident may attract significant media attention do not delay in submitting the form. However if this occurs out of hours (i.e. weekdays after 5pm - before 8am or at weekends), the matter should be reported to the most senior person on site, who will need to escalate through recognised on call management arrangements who should consider contacting Welsh Government press office on 029 2089 8099.
SAMPLE IMMEDIATE REPORTING PROCEDURE
(Items in italic and square brackets to be amended as necessary by Divisional Director, Divisional Nurse or Divisional Manager to suit local situation)

Under certain circumstances, incidents need to be reported to outside agencies such as the Welsh Government and/or the Health and Safety Executive. Under these circumstances the appropriate officer within the UHB MUST be contacted to allow them to make the report.

The following areas have internal and external reporting mechanisms and in the event of an Accident/Incident or Dangerous Occurrence the appropriate member of staff listed below must be alerted immediately.

Outside of office hours (i.e. 0900-1700 hrs) the individual listed below, in the out of hours column, should be contacted; they will then contact the appropriate officers as detailed below if necessary.

(The table below should be modified with the appropriate department and titles relevant to the Management Unit - preferably with telephone numbers to aid rapid communication)

<table>
<thead>
<tr>
<th>Type of Incident</th>
<th>0900-1700 hrs Monday-Friday</th>
<th>Department</th>
<th>Out of Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faulty Medicinal Product</td>
<td>Head of Pharmacy</td>
<td>Pharmacy</td>
<td>On-call Pharmacist</td>
</tr>
<tr>
<td>Fault to Structure of Building</td>
<td>[Maintenance Department]</td>
<td>[Estates Department]</td>
<td>On-call Engineer via Switchboard</td>
</tr>
<tr>
<td>Foreign Body Found in Purchased Food Product</td>
<td>[Catering Manager]</td>
<td>[Operational Services Department]</td>
<td>Site Manager</td>
</tr>
<tr>
<td>Faulty Medical Equipment</td>
<td>[Head of Clinical Engineering]</td>
<td>[Medical Physics and Clinical Engineering Department]</td>
<td>Site Manager</td>
</tr>
<tr>
<td>Consumable Product Purchased from Supplier Found to be Faulty</td>
<td>[Supplies Manager]</td>
<td>[Supplies Department]</td>
<td>Site Manager</td>
</tr>
<tr>
<td>Other Faulty Equipment or Services</td>
<td>[Maintenance Department]</td>
<td>[Estates Department]</td>
<td>On-call Engineer via Switchboard</td>
</tr>
<tr>
<td>Incident Type</td>
<td>Officer(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major/Fatal Injury or Specified</td>
<td>Health and Safety Advisor/Clinical Governance Facilitator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dangerous Occurrence (see below)</td>
<td>HSEU/Patient Safety Department</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Site Manager (to be reported onward via on-call management arrangements)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation Incidents</td>
<td>Radiation Protection Supervisor for relevant department</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>As appropriate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>As determined by relevant departments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Security Incidents</td>
<td>[Division specific]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>[Division specific]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Site Manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fire Incidents</td>
<td>Fire Safety Adviser</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Planning and Asset Management</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>On-call Fire Safety Advisor via switchboard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Projects</td>
<td>Research Governance Coordinator</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tel 029 20745053</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fax 029 20745311</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>e-mail - <a href="mailto:research.development@wales.nhs.uk">research.development@wales.nhs.uk</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Research and Development Department</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Via e-mail to <a href="mailto:research.development@wales.nhs.uk">research.development@wales.nhs.uk</a> and return of appropriate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Environmental Incidents *</td>
<td>Health, Safety &amp; Environment Unit</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HSEU</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Estates on-call via switchboard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfusion Related Incidents</td>
<td>Transfusion Practitioner</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood Bank</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Site Manager</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(* If specifically estates related contact Estate Maintenance.)

All of the above officers to whom incidents may be reported are responsible for ensuring that an investigation is carried out. If the incident is sufficiently hazardous then the Senior Manager on call for the UHB must be informed, via established On-Call arrangements.
## INCIDENT RATING METHODOLOGY

All incidents involving patients will be graded according to the actual impact on the person affected/UHB.

<table>
<thead>
<tr>
<th>Severity Rating</th>
<th>Descriptor</th>
<th>Injury/Clinical Outcome</th>
<th>Quality</th>
<th>Reputation/ Publicity</th>
<th>Service/ Environmental Impact</th>
<th>Regulatory/ Legal Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>A**</td>
<td>Serious Patient Related Adverse Event – Death</td>
<td>Death of a patient as a result of the incident</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>A</td>
<td>Catastrophic</td>
<td>Potential fatality, Permanent disability/ harm</td>
<td>Gross failure to meet national/local/professional standards</td>
<td>Public enquiry, National media coverage</td>
<td>The organisation would be rendered dysfunctional. Operational performance would be compromised to the extent that the organisation is unable to meet obligations and liabilities in core activity areas</td>
<td>Severe accountability likelihoods would result in the organisation being unable to meet key regulatory requirements</td>
</tr>
<tr>
<td>B</td>
<td>Major</td>
<td>Multiple injuries</td>
<td>Repeated failure to meet national/local/professional standards</td>
<td>Extensive local coverage and wide spread NHS coverage.</td>
<td>Temporary loss of service provision, Loss of service affecting more than 1 department</td>
<td>Organisation would not be able to comply with the majority of its regulatory requirements effectively</td>
</tr>
<tr>
<td>C</td>
<td>Moderate</td>
<td>Significant adverse effect/harm – medical intervention necessary, some temporary incapacity.</td>
<td>Failure to meet local standards</td>
<td>Coverage throughout organisation and/or some public coverage</td>
<td>Short term disruption</td>
<td>Organisation would experience difficulty in complying with key regulatory requirements, which would jeopardize some external interests</td>
</tr>
<tr>
<td>D</td>
<td>Minor</td>
<td>Minor adverse effect/harm – first aid or self treatment, no capacity.</td>
<td>Minor non-compliance</td>
<td>Coverage limited to elements within the organisation (e.g. trade unions) and/or some external stakeholders</td>
<td>Slight inconvenience/ difficulty in operational performance of function/activity</td>
<td>Some accountability implications for the function/activity area, but would not affect the organisation’s ability to meet key regulatory/ compliance requirements</td>
</tr>
<tr>
<td>E</td>
<td>Insignificant</td>
<td>Minor adverse effect/harm not requiring intervention</td>
<td>Minor non-compliance</td>
<td>Awareness limited to individuals within the organisation</td>
<td>Operational performance of the function/activity would not be materially affected</td>
<td>Organisation would not encounter any significant accountability implications</td>
</tr>
</tbody>
</table>
PREPARING A WITNESS STATEMENT

Introduction

On occasion, staff will be requested to write a witness statement in connection with an incident, accident, near miss, complaint or claim that they have some knowledge about.

Purpose of a Statement

The aim of a statement is to establish the facts about a particular incident(s) so that the UHB can use such evidence when having to deal with a particular complaint, incident or claim that has been made or is being contemplated.

Important Points to Remember when preparing a Statement

- Statements should be full, frank and honest and be confined to the specific facts. They should reflect your account of an incident/event(s) in your own words and be unambiguous.
- Badly written Statements can be confusing, misleading or fail to address many of the crucial aspects of an incident.
- Your full name and job title and brief details of your experience should appear at the top of your statement. At the end of your statement you will be required to print your name, sign and date it.
- The name of any patients, including their hospital references along with any other key witnesses, should be included in the initial part of your statement. Provision of such information for internal use would not breach any confidentiality rules.
- A factual account of your role in the incident(s) should follow. It is helpful if you would make it clear which part of your statement is being recalled from memory as opposed to providing details of your standard or usual practice at the relevant time.
- Statements relating to clinical care should not be written without firstly reading through the relevant medical records if they are available to you as the memory is often unreliable. If the statement is written without access to the records, your statement must reflect this.
- You may wish to attach a sketch plan or diagram to your statement to help describe a situation or establish the location of an incident.
- Take time to compile your account so that you feel confident to rely on it at a later stage.
- Your statement does not form any part of a patient’s medical records. It is a management tool for dealing with any risk issues.
- Most statements are disclosable i.e. there is a duty on the UHB to disclose copies of statements to outside bodies such as the Coroner, UHB Solicitor, Ombudsman, Health Service Commissioner, Police, patient’s representative etc. In the event that you are required to give your evidence at an external enquiry, you will be provided with a copy of your written statement(s) beforehand and given appropriate support and advice by the UHB.
Here is some advice of what to AVOID when preparing your statement

- Do not just regurgitate what you have written in the medical records.
- Do not speculate on what others were doing or thinking. Stick to the facts as you know them.
- It is not advisable to attempt to write a statement without sight of all the relevant medical records. If your statement is prepared without access to the medical records then make this point somewhere in your account.
- Never make up what you cannot recall. If there are gaps in your account, state that you cannot recall what happened during any particular times.

Here is some advice of WHAT TO DO when preparing your statement

- It is important to write a statement as soon after the event as possible because memories will fade. However, following a traumatic incident or busy day, it is not always possible or advisable to write a statement there and then. To ensure that the salient points are not forgotten or distorted, it is a good idea to make bullet points of the important facts on a separate sheet for your own reference before compiling your statement.
- Take sufficient time to think about the incident and the relevant chronology of events and other witnesses.
- A statement is not a list but should expand or explain information that may already be contained in other documentation like incident report forms, medical records etc.
- Some staff may want their union or professional body to see their statement prior to submission. Although there is no problem with this, it can cause delay in the UHB investigation should advice not be available within a few days. In addition, an increasing number of this kind of request will cause a burden for professional bodies to review statements promptly.
- Ideally, statements should be typed and then signed by the person concerned. This ensures that the statement can be read and that any spelling mistakes and erroneous terminology can be identified and corrected. Where you do not have this facility, you should discuss whether arrangements can be made with your Line Manager.
- ALWAYS keep copy of your statement for any later reference. You may well need to refer to it at some future stage.

If in doubt, you can contact the UHB Patient Safety Team for any general advice about statement writing on 029 2074 6228

This recommended format can be used by staff who have been asked to complete an account of their involvement in respect of an incident, near miss, complaint or claim for submission to the UHB as part of an internal investigation. You are advised to check through your statement and only when you are completely satisfied sign and date it.

Please note that your signed statement can be provided to external Agencies such as the Police, Coroner, Ombudsman, Health Service Commissioner, Independent Review and Lay Reviewers, Health and Safety Executive, UHB Solicitor etc.
### 1.1 STATEMENT OF EVENT

<table>
<thead>
<tr>
<th>FULL NAME:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PRESENT JOB TITLE OR GRADE AND A BRIEF SUMMARY OF YOUR EXPERIENCE WITHIN THE UHB / NHS:</td>
<td></td>
</tr>
<tr>
<td>WORK TELEPHONE NO:</td>
<td></td>
</tr>
<tr>
<td>DATE &amp; TIME OF EVENT:</td>
<td></td>
</tr>
<tr>
<td>LOCATION, E.g. Ward, Theatre:</td>
<td></td>
</tr>
<tr>
<td>NAMES OF OTHER PERSONS/WITNESSES INVOLVED: (Any patient must be identified)</td>
<td></td>
</tr>
<tr>
<td>FACTUAL ACCOUNT OF EVENT (Please continue over if necessary)</td>
<td></td>
</tr>
</tbody>
</table>

You may like to begin your statement along the following lines:

I ............................................ am employed by the Cardiff and Vale University Health Board as a .................
On ............... at ......... I was on duty from ..........................
At the time of the incident, I was ..................................................
MEDICAL DEVICES

What is a medical device?

Equipment used for the diagnosis or treatment of disease, or for monitoring of patients.

Some examples are given below (this is not an exhaustive list):

- Anaesthetic equipment
- Blood warming cabinets
- Catheters (e.g. urinary, cardiac)
- Chiropody equipment
- Dental equipment and materials
- Dressings
- Endoscopes
- Examination gloves
- Implants - powered and non-powered (e.g. implantable defibrillators, pacemakers, heart valves, orthopaedic prostheses, bone cements)
- IV administration sets and pumps
- Ophthalmic equipment
- Patient monitoring equipment (e.g. cardiac monitors)
- Physiotherapy equipment
- Radiotherapy equipment (brachytherapy, external beam)
- Sphygmomanometers
- Surgical instruments and equipment
- Syringes and needles
- Thermometers
- Vaginal specula
- X-ray systems, ultrasound imagers and CT/MR scanners

For critical care:
- Defibrillators
- Resuscitators
- Ventilators

For people with a disability:
- Communication aids
- Environmental controls
- Orthotic and prosthetic appliances
- Patient hoists
- Pressure relief equipment
- Walking aids
- Wheelchairs and special support seating

For patient transportation or moving (but not including ambulance vehicles themselves):
- Carry chairs
- Lifting aids
- Stretchers and trolleys

For daily living:
• Bathing and showering equipment
• Commodes
• Hearing aids, dentures and spectacles
• Incontinence products
• Prescribable footwear
• Special chairs
• Urine drainage systems

Medical devices and equipment also include the following in vitro diagnostic medical devices and their accessories:
• Blood gas analysers
• Devices for blood glucose measurement
• Hepatitis and HIV test kits
• Pregnancy test kits
• Specimen collection tubes
• Urine test strips

Also included are:
• Condoms
• Contact lenses and care products
• Intra-uterine devices (IUDs)

MHRA are also interested in products which, whilst not themselves medical devices, are used closely in conjunction with these devices:
• Bench top sterilizers
• Blood and tissue storage systems
• Chemical and biological indicators used in sterilization processes
• Disinfecting and sterilizing equipment

What is not a medical device?

Medical devices do not include ambulances, general workshop equipment such as power or machine tools, or general-purpose laboratory equipment. Pre-filled devices e.g. drug inhalers, syringes and certain other drug/device combinations also fall into this category. MHRA Adverse Incident Centre staff will be happy to provide advice in any cases of doubt.

Further Information
Further information can be found in MDA (2004) 054 (Wales).
Appendix 9  
(new Appendix added to Policy April 2013)

FLOWCHART TO OUTLINE THE PROCESS FOR THE INTERNAL MANAGEMENT OF HM CORONER RULE 43 REPORTS BY THE PATIENT SAFETY TEAM

<table>
<thead>
<tr>
<th>HM Coroner issues a Rule 43 Report to the UHB following an inquest.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chief Executive passes copy of Report to Nurse Director to lead response. (A copy is usually provided direct to the Ass't Director Patient Safety &amp; Quality)</td>
</tr>
<tr>
<td>Rule 43 Report is date stamped, scanned and distributed by Ass't Director of Patient Safety &amp; Quality, to internal interested parties as appropriate. Where required a meeting will be arranged. A record of distribution will be maintained.</td>
</tr>
<tr>
<td>The UHB has 56 calendar days from the date of the Ruling to provide its written response to HM Coroner.</td>
</tr>
<tr>
<td>Within 10 calendar days of response deadline, the Asst Director Patient Safety &amp; Quality will coordinate the compilation of a response for review and Executive Sign off.</td>
</tr>
<tr>
<td>Draft response will be reviewed by Executive Director in advance of Chief Executive ‘sign off’.</td>
</tr>
<tr>
<td>Copy of UHB Final Response shared with interested parties (as directed by HM Coroner) and lead Clinical Board (s) as appropriate to review, monitor and report back, through its Q&amp;S arrangements progress with related corrective action.</td>
</tr>
<tr>
<td>Clinical Board (s) to provide confirmation of actions taken/proposed in response to the Rule 43 and the associated timescales and that related improvement actions feature within the relevant areas audit programme.</td>
</tr>
</tbody>
</table>