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Concerns
Policy & Procedures

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1. Introduction & Purpose

1.1 Cwm Taf Health Board (HB) is committed to the health, safety and welfare of its patients, users, staff, visitors and contractors across the health community by being proactive in its approach to managing Concerns and reducing risks.

1.2 The Concerns Policy and Procedures form part of the Clinical Governance and Risk Management processes of the Health Board, and should be used in conjunction with the following documents:

- Incident Reporting Policy
- Being Open Policy
- Claims Policy
- Claims Procedure
- Child Protection Policy & Procedure
- Vulnerable Adults Policy & Procedure
- Risk Assessment Procedure
- Risk Management Policy
- Risk Management Strategy
- Alerts Procedure

1.3 The term "Concern" is used throughout the document and is used to describe any complaint, claim or reported patient safety incident to be handled under the new *Putting Things Right* arrangements.

1.4 This document is based on the Welsh Government's *Putting Things Right* Guidance (April 2012) produced for the NHS in Wales to enable organisations to effectively handle Concerns according to the requirements set out in the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ("the Regulations"). These Regulations came into force on 1 April 2011. The new arrangements will play a significant role in improving patient safety and experience – there is an explicit requirement to show how services have improved as a result of Concerns that have been notified and dealt with under the arrangements.

Putting Things Right

1.5 The Welsh Government's aim in developing *Putting Things Right* was to provide a single, integrated and supportive process for people to raise Concerns.

1.6 More information about *Putting Things Right* can be found on the Health Board's intranet http://cthb-intranet/SiteDirectory/PCSUnit/default.aspx or the Welsh Government site http://www.wales.nhs.uk/sites3/home.cfm?orgid=932

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

1.7 The Regulations support the process of managing and investigating Concerns by ensuring:

- There is a common method of investigating Concerns which is proportionate to the issue raised;
- The person raising the concern is properly and appropriately

supported, for example, through access to advocacy support at all stages of the process, both from Community Health Council (CHC) advocates and more specialist advocacy services where needed;

- People receive a prompt acknowledgement and a timely response to their concern;
- Concerns are dealt with openly and honestly;
- Concerns are consistently, thoroughly and appropriately investigated;
- People receive a detailed response including clarity about next steps and actions to address their concern;
- The Health Board, in dealing with Concerns, considers how they will investigate and respond to Concerns and consider, in accordance with Regulation 23(i) of the Regulations, the likelihood of a qualifying liability arising and the potential application of the Redress arrangements;
- Arrangements are in place for Redress
    - people are properly informed in relation to any offer of Redress made or if, on investigation, it is determined that there is no qualifying liability, the refusal to make an offer;
    - The Health Board provides free specialist legal advice for people where it is considered there is or may be a qualifying liability for which Redress may be available i.e. in respect of cases where it is estimated that the general damages and special damages that could be awarded would, in total, be £25,000 or less;
- The Health Board demonstrate that learning and improvements have resulted from the process;
- Where a person remains dissatisfied with the outcome of the investigation of a concern, they can refer the matter to the Public Services Ombudsman for Wales;
- Early action is taken so that the likelihood of recurrence is reduced;
- Risks are identified, assessed and minimised, and the Board is alerted to significant risks

Concerns dealt with at the point of service delivery ("on the spot")

1.8 There are some Concerns which will not be handled under the new arrangements, in particular, Concerns which have been raised and dealt with to the satisfaction of the person who notified the concern not later than the next working day after the concern was notified. These Concerns are referred to as having been dealt with "on the spot". It is important for staff to check if the person is satisfied with the immediate actions taken because if they are not, then they should be advised to raise a concern formally.

1.9 The template for recording a concern that has been satisfactorily dealt with "on the spot" is attached at Appendix A. Completed forms should be returned to the Concerns Team, so that themes and lessons can be drawn from them.

1.10 Two Patient Support Officers work as part of the Concerns Team, and

support the management of “on the spot” Concerns - they are based in Prince Charles Hospital and the Royal Glamorgan Hospital and they can be contacted through the switchboard or via the Concerns Team.

Patient Safety Incidents

1.11 This Concerns Policy and Procedure document also incorporates the management of patient safety incidents, to ensure that all patient safety incidents, no matter how minor, are reported, recorded and investigated at an appropriate level if required so that learning lessons leads to reduction in risk and improvements to care and services. This includes incidents where no harm occurred, and ‘near miss’ incidents.

2. Scope

2.1 This guidance applies throughout Cwm Taf Health Board to all staff; the principles also apply to the Independent Contractor Services. However, the Redress elements of the Regulations and the guidance relating to those aspects do not apply to Primary Care practitioners or to independent providers.

2.2 The Health Board has a responsibility to ensure that the care it contracts for patients via the Independent Contractor Services, complies with regulations, is safe and meets required standards. The Health Board therefore has clinical governance systems in place for monitoring compliance by the Independent Contractor services, and for addressing issues of concern and performance.

3. Roles & Responsibilities

3.1 The Health Board staffing structures have been developed to support a comprehensive and effective approach to dealing with Concerns at all levels.

Independent Board Members

3.2 The Health Board has designated an Independent Member of the Board as a Concerns champion to promote, scrutinise, test and challenge the Health Board’s arrangements for dealing with Concerns. Independent Board Members are also part of the membership of the Clinical Governance Committee and the Concerns Scrutiny Panels.

Responsible Officer

3.3 The Chief Executive has delegated the Director of Nursing to be the Responsible Officer, who is charged with overseeing the management of these arrangements and ensuring that they operate in an integrated manner. The Medical Director and Director of Operations / Therapies and Health Science have joint responsibility for quality and safety, and will provide leadership in ensuring that the management of Concerns leads to reduction of risk, and wherever possible, to service improvement.

3.4 The Responsible Officer ensures arrangements are in place to:

- deal with Concerns in line with the Regulations;
- allow for the consideration of qualifying liabilities; and
- provide for incidents, complaints and claims to be dealt with under a single governance arrangement.

Head of Quality & Effective Practice

3.5 Within Cwm Taf Health Board, the responsibilities of the Responsible Officer are delegated through the Assistant Director for Patient Care and Safety to the Head of Quality & Effective Practice for operational purposes. This role involves ensuring that there are systems and processes in place that enable a comprehensive approach to improving standards and services as a result of Concerns involving safety, quality of care, and patient experience. This involves a collaborative approach between Clinical Audit, Research and Development, and medical and nurse education and training.

Senior Manager for Investigations & Quality Improvement

3.6 The day-to-day operational management of Concerns in accordance with the Regulations within Cwm Taf Health Board is the responsibility of the Senior Manager for Investigations & Quality Improvement. The role includes the development of systems to manage Concerns under the Regulations, co-operating with other persons or responsible bodies, e.g. Primary Care providers, to facilitate the handling and investigation of Concerns, and embedding the learning from lessons learnt. This role is supported by specialist staff within the Concerns Team, as part of the integrated arrangements.

Concerns Team Managers / Putting Things Right Facilitators

3.7 The role of Facilitators is incorporated into the roles of the Team Managers as part of the Concerns Team to support the Senior Manager for Investigations & Quality Improvement in the implementation of *Putting Things Right.* Their roles include training of staff, including those in Primary Care; supporting the development of policies and procedures, and providing support and advice to Directorate staff when dealing with Concerns. Senior members of the team carry a caseload of Concerns to ensure continuity for patients, their families, or advocates, as well as for Health Board staff.

Concerns Team

3.8 This corporate team consists of a skill-mix of staff, which includes specialists in dealing with patient safety incidents, compensation claims, and complaints, as well as staff with generic functions. This team will work with other managers and administration staff throughout the organisation to assist and advise in investigations as required, as well as all other aspects of the effective management of Concerns.

Directorate / Locality Leads

3.9 Heads of Nursing, Directorate Managers, and Clinical Directors all have essential roles in the effective management of Concerns within their Directorates. This includes ensuring that:

- a culture of openness is promoted and encouraged to ensure that staff report all patient safety incidents, and that Concerns are investigated and acted upon appropriately;
- effective and practical local arrangements are in place to ensure full implementation of and compliance with the Concerns Policy & Procedures and that these are communicated to staff;
- there is appropriate cross-directorate/locality/hospital co-ordination and liaison to achieve compliance with this policy;
- adequate and appropriate support is made available to staff who are involved in/are the subject of a Concern;
- staff are adequately trained and competent at the appropriate level to implement *Putting Things Right,* and that staff trained in investigations and causal analysis within the Directorate/Locality are released or have their duties appropriately adjusted to enable them to undertake investigations, when requested to do so;
- that all information pertaining to individual Concerns including the outcomes of all investigations are fully and accurately recorded;
- that all necessary actions are taken to address individual Concerns and trends;
- if they undertake the role of Investigating Officer for any concern, they should ensure that copies of the final response sent to the patient, and are shared with all relevant clinicians.
- that risks are identified, assessed, recorded and minimised;
- Action Plans are developed, monitored, and implemented;
- appropriate communication and reporting of relevant information to all necessary groups/committees;
- that improvements are made to systems of care and services following learning from Concerns or escalated if necessary;
- that all risks are appropriately recorded on the organisation's Risk Register.

All Managers

3.10 Every manager in the Health Board should:

- Create and sustain an environment whereby staff feel supported to report Concerns that are patient safety incidents and feel that these will be taken seriously and dealt with appropriately.
- Ensure appropriate feedback is given to the reporters of patient safety incidents and all staff involved with or the subject of any Concern, including any investigation outcomes and actions taken and to ensure that this feedback is clearly documented.
- Identify the training needs of individual members of staff, in relation to the handling of Concerns, through performance review and KSF, and determine a plan to ensure those needs will be met.
- Ensure that volunteers and external sub-contractors are made aware of pertinent aspects of this policy, where their role encompasses responsibility for these groups.
- Ensure their staff are made aware of how to access copies of the Health Board's arrangements for handling Concerns, in all the formats, so that they may satisfy any reasonable request made of them for this information.

Managers who are incident reviewers

3.11 Some managers will be designated to review and investigate incidents; their names will be held by the Datix Administrators. In relation to patient safety incidents, these are likely to be staff responsible for departments, and will include Senior Nurses. Their responsibilities are as follows:

  - o check the adequacy and accuracy of the incident reports on Datix, and complete the DIF2 (Datix incident form 2 - the Datix form for reviewers);
  - o identify where additional reports are necessary and make any appropriate referrals, for example Safeguarding issues to the Health Board Leads; Head of Clinical Engineering of any incidents related to Medical Devices (see full list under 'Internal Reporting section of the Incident Reporting Procedures);
  - o Identify, assess and act on related risks. Consider reviewing existing risk assessment if there is one in place;
  - o Undertake any local investigation, and where appropriate refer to the Directorate Lead or Concerns Team for further investigation / Root Cause Analysis;
  - o Undertake and put monitoring arrangements in place ass required before closure;
  - o Close the incident on the Datix system, when all the investigation is complete and all necessary actions taken;
  - o Feedback to the local reporter of the incident if appropriate;
  - o Share lessons learned.

All Staff

3.12 The Senior Manager for Investigations & Quality Improvement and

Directorate Leads will ensure that staff throughout the organisation know their responsibilities in relation to identifying and reporting Concerns, and supporting patients and their families/advocates to do so.

3.13 In addition:

- All staff must treat persons notifying Concerns with respect and courtesy.
- All staff should ensure that any patient safety incident is reported, no matter how minor they might appear. This ensures that the Health Board has the opportunity to take all appropriate actions under this policy including learning from such events and improving matters for the future.
- Staff should ensure they report patient safety incidents that are brought to their attention by patients and other persons.
- All staff should ensure they are aware of how to access copies of the Health Board's arrangements for handling Concerns, in all the formats, to enable them to satisfy any reasonable request made of them for this information.

4. Organisational Development and Training

General Training – *Putting Things Right*

4.1 Staff at all levels within the Health Board must receive appropriate training to enable them to comply with the Regulations. Levels of competency and staffing numbers must be such as to allow appropriate investigations as well as to be able to consider issues such as liability and settlement of claims in appropriate cases where the Redress arrangements are engaged.

4.2 A mix of training methods will be used, and the delivery of training will be supported by national training resources, which include:

- *PowerPoint* presentations;
- digital stories;
- use of training videos and
- classroom and e-learning methods.

4.3 Existing training and development programmes will be utilised and strengthened, and new ones developed to meet identified needs following training needs analyses. The level of training required by individual staff will also be arranged according to their specific roles and responsibilities, and will be linked to the NHS Knowledge and Skills Framework, and will incorporate:

- Customer Care
- Communication
- Records Management
- Root Cause Analysis
  http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/

  http://www.patientsafetywales.org.uk

- Being Open - NPSA http://www.nrls.npsa.nhs.uk/beingopen/
- Legal training/awareness
- Putting Things Right e-learning training http://www.mle.wales.nhs.uk/
- Safeguarding Children and Vulnerable Adults
- Equality and diversity

  Managing Safely

Learning from Concerns

4.4 Training delivered will also be responsive to local needs identified, for example where specific issues have been identified through trends in Concerns, these will be included. Learning from Concerns is a vital element of organisational development and training. This is covered in Section 11.9

5. Principles and Requirements

Principles that apply to the handling of Concerns

5.1 The Health Board is committed to applying the following Principles (Regulation 3) in the handling of Concerns, whereby people will:

1. *Be able to notify their concern through a single point of entry*
2. *Have their concern dealt with efficiently and openly*
3. *Have their concern investigated properly and appropriately*
4. *Have their expectations and involvement in the process established early on*
5. *Be treated with respect and courtesy*
6. *Be given advice on the availability of assistance to pursue their concern, and where they may obtain it*
7. *If an investigation reveals that there is a qualifying liability, the Health Board must give consideration to the application of the Redress arrangements*
8. *Receive a timely and appropriate response to their concern and be kept informed if there is a delay*
9. *Be informed of the outcome of the investigation*
10. *Be assured that appropriate action has been taken as a result of raising their concern and lessons learnt*
11. *Have their concern managed and investigated in line with the Putting Things Right guidance*

In relation to patient safety incident reporting:

12. *The Health Board seeks to promote an open reporting culture with a focus on learning and not blame.*

Providing Information widely and in accessible ways

5.2 To take account of the needs of individuals when handling and

investigating Concerns, the Health Board publishes and displays information:

- In a variety of formats e.g. leaflets, posters, websites
- Free of charge
- In English and Welsh, and in other languages as required
- In other formats as required e.g. Braille, large print, audio, Easy Read, child-friendly, etc

5.3 Bilingual (English and Welsh) posters and leaflets entitled *Putting Things Right - Raising a concern about the NHS from 1 April 2011* are displayed in public areas and on the Health Board's website detailing how people can raise a concern. Leaflets should be provided by staff on request to individuals when they raise a concern - these are available on the intranet site for staff to access and are also available in PDF format on www.puttingthingsright.wales.nhs.uk **Equality and diversity**

5.4 Staff must also be aware of the need to facilitate access to the Concerns process to those who might feel the process is not accessible to them due to reasons such as sensory impairment, cultural, social, or gender, and should look for ways to assure people that it is safe for them to do so. When Concerns are raised, then people should be provided with information in the format they need and also should be offered support as appropriate.**Welsh Language**

5.5 When dealing with Concerns, the Health Board takes account of its statutory duties in relation to the provision of services in Welsh.

5.6 Staff should be additionally sensitive to the requirements of first language Welsh speakers in the handling of their Concerns and ensure that they are able to raise their Concerns, discuss them and receive a response in Welsh.**Using Interpreters and communication support**

5.7 Where a person expresses the need for an interpreter or communication support, staff should facilitate this, and inform the person of the interpreter's name as soon as possible, so that any conflicts of interest can be identified and an alternative interpreter made available if necessary.**Accessing Advice and Support**

5.8 When information is provided, it must include details about key sources of advice and support, such as:

- Advocacy assistance from the Community Health Councils – this is available to anyone aged 18 or over wishing to raise a Concern. Contact details for patients and families served by Cwm Taf Health Board are: Unit 10 Maritime Offices, Woodland Terrace, Maes-y-Coed, Pontypridd, CF37 1DZ. Phone: (01443) 405830
- Specialist advice and advocacy for people with mental health problems or who lack capacity – this is available for specific issues relating to services provided to people in these groups;
- Advocacy support for children and young people who wish to raise a concern – this is arranged by the Health Board in accordance with the Welsh Government's *'Model for Delivering Advocacy Services to Children and Young People in Wales'*. To access advocacy advice and contact details for advocates, please contact the Children and Young People Advocacy Unit Advocacy mail box:

advocacyinformation@wales.gsi.gov.uk

Safeguarding

5.9 Staff dealing with Concerns must be aware of the potential for any safeguarding issues to apply, in particular in relation to a child or a vulnerable adult. The Health Board's local policies and procedures must be adhered to at all times. Safeguarding means enabling people to live their lives free from harm, abuse and neglect, and to have their health, wellbeing and human rights protected.

5.10 For every Concern, the questions that should be asked are:

- Could this be a safeguarding issue?
- Does the concern involve a child or a vulnerable adult or both?
- Is a referral to another agency necessary?

5.11 All Concerns will be managed in accordance with:

- All Wales Child Protection Procedures 2008
- In Safe Hands 2000

5.12 If there is doubt as to whether a Concern is a safeguarding issue, staff should contact the Health Board's Safeguarding Team for further advice and support.

5.13 Health Board staff need to ensure that Concerns investigations do not prejudice any Safeguarding investigations. Service staff, Safeguarding and Concerns Teams must work together in close collaboration with regards to elements of the investigation, and advice sought from Legal & Risk Services if necessary

Being Open

5.14 A 'Being Open' approach should be applied at all times when dealing with patients or their representative(s). However, when a patient has suffered or is likely to have suffered **Moderate or Severe harm or death as a consequence of a patient safety incident that incident**, the Being Open process must be formally commenced and followed. The Health Board must:

a) notify the patient or his/her representative of the patient safety incident, and

b) engage with the patient and/or their representative during the investigation process.

5.15 The Being Open process will govern all communications with the patient/representative. Where the Reviewer of the patient safety incident has cause to believe that it would not be in the interests of the patient to be informed of the incident or involved in the investigation, the Reviewer must

- make a written record of this decision and the reasons for it against the formal record, and
- keep the decision under review during the investigation of the patient safety incident and act in accordance with the Being Open process if the decision should change.

6. Raising a Concern

How a Concern can be raised

6.1 The single address, phone number, mailbox and fax number for raising a concern is publicised on the Health Board's website: http://www.wales.nhs.uk/sitesplus/865/page/48575

6.2 People can raise Concerns in a variety of ways to any member of staff:

- In writing (by letter, or on a complaint form)
- Electronically (by e-mail or fax)
- Verbally (by telephone or in person)

6.3 If a Concern cannot be dealt with quickly and to the satisfaction of the person raising the Concern, and where the person cannot, or does not wish to put matters in writing, then the details of the Concern will be recorded by the member of staff dealing with the individual, before being managed under the Regulations. A copy of the written record of the Concern will be given to the person who notified the Concern and a copy should also be forwarded to the Concerns Team. A template for recording Concerns that have been made verbally can be found at Appendix B.

6.4 The policies and procedures on record keeping and management of records should be adhered to at all times. Good record keeping is fundamental to the effective handling and investigation of Concerns, and where records exist they must be accurate, complete, understandable and contemporaneous in accordance with professional standards and guidance. This includes any record made on the Datix system.

Who can raise a Concern

6.5 Almost anyone can raise a Concern and the Health Board will be under a duty to consider whether it can be investigated. However, it might not always be possible to share the full details of the investigation with the person raising the Concern, for instance, if they are not the patient or not their next of kin.

6.6 As set out in Regulation 12, Concerns can be raised by:

- People who are receiving or who have received services from the Health Board;
- People affected or likely to be affected by the actions, errors or decisions of the Health Board;
- Staff members;
- Independent Board members;
- A third party acting on behalf of a person who is unable to raise a concern e.g. a young child or someone who lacks capacity to act on their own behalf; or because that person wants someone else to represent them;
- A third party on behalf of a person who has died.

Concerns raised by a third party

6.7 Where a third party acts as a representative on behalf of another e.g. a child or someone who lacks mental capacity - if there are reasonable grounds to conclude that they are not suitable to act on their behalf, for

example because it does not appear to be in the patient's best interests, then they must be advised of this in writing. However, even where the Health Board has made a decision that the third party is not a suitable person to act on behalf of someone else, it may still choose to investigate the Concern – in particular, regard must be had to safeguarding issues. In this instance they are under no obligation to provide a detailed response to the person who raised the Concern, unless it is reasonable to do so.

Concerns raised by or about children and young people

6.8 Where a Concern is notified by a child or young person, he or she must be reasonably supported and assisted to pursue their Concern. There may be a need for specialist advocacy to be offered to assist the child or young person – see Section 4.

6.9 In many cases, someone else (parent/carer/guardian) will raise a Concern on behalf of a child. This does not remove the right of the child to take the Concern forward themselves, with support. The Health Board should therefore satisfy itself as to whether the child wishes to raise a Concern themselves, with assistance or if they are happy for the person who raised the Concern to represent them. If the child is not willing to allow the Concern to be investigated then a decision will need to be taken about proceeding and specialist advice sought if appropriate. Once again, particular regard needs to be given to safeguarding issues, and it may be necessary to proceed with an investigation, even if a child appears unhappy to do so. The Health Board is under no obligation to provide a response to the person who raised the Concern in the first place.

Concerns raised by staff

6.10 These arrangements may be used by members of staff who wish to report that something has gone wrong with care or treatment provided to a patient or patients, with a view to learning lessons. This should be done via in line with the Health Board's Incident Reporting Policy and Procedures. This is not the same as reporting Concerns about another member of staff in terms of suspected wrongdoing, criminal activity or unprofessional behaviour which still need to be dealt with via line management and HR processes or ultimately by using the Whistleblowing Policy and/or the All Wales Dignity at Work Policy when other channels have failed.

Time limits for notification of a Concern

6.11 A Concern can be notified no later than **12 months** from:

- The date on which the Concern occurred, or
- If later, 12 months from the date the person raising the Concern realised they had a Concern.

6.12 To investigate a Concern after the 12 month deadline, the Health Board must consider whether the person raising the concern had good reason not to notify the concern earlier and whether, given the time lapse, is it still possible to investigate the concern thoroughly and fairly.

6.13 The discretion to consider a Concern that has been notified outside the 12 month period referred to above is subject to the provisions of Regulation 15(3) which provides that a concern cannot be notified **3 or more years** from the date the concern occurred or 3 or more years from the date the person became aware of the matter, which the Concern is

about. This time limit is consistent with the limitation period which is in place for the consideration of clinical negligence claims (which is usually three years), but there are exceptions to the rule such as:

- if the person who raised the concern is a child at the time of the injury the three-year period does not begin to run until the individual reaches the age of 18. In these cases, the period will expire on the eve of the person's 21st birthday;
- if the person who raised the Concern lacks capacity under the Mental Capacity Act 2005, the three-year period may never begin to run, or it can start at the date of recovery.

6.14 In some cases where there is an exception to the rule, the Health Board will make it clear to the person raising the Concern, that the investigation may be limited in some aspects, based on the information available, particularly in situations where key staff have left the organisation.

Withdrawal of Concerns

6.15 A Concern may be withdrawn at any time by the patient or by the person who notified the Concern, if they are not the patient. The withdrawal of the Concern can be made;

- in writing
- electronically, or
- verbally in person or by telephone.

6.16 If a Concern is withdrawn verbally, the Health Board must write to the person as soon as possible to confirm their decision.

6.17 However, even if the Concern has been withdrawn, if it is felt that the investigation of the Concern is still appropriate, the Health Board can continue to investigate. In this case, the Health Board will decide whether the outcome of the investigation is shared with the person making the complaint.

7. Handling and Investigating Concerns

Grading Concerns

7.1 At the outset it is important to note that by whichever process a Concern comes to light, i.e. Patient Safety Incident or Complaint they are all subject to the following process of grading for severity and/or levels of harm.

7.2 An initial assessment of the Concern must be undertaken to determine the depth of and parameters of the investigation, which needs to be proportionate to the severity of the Concern notified. It is essential to note at the outset, that an investigation of a Concern identified via a Complaint, does not consist in simply obtaining responses - by email or otherwise, rather, it should be the trigger for an investigation.

7.3 All Concerns must be **graded in terms of severity**. The depth of the investigation will then vary according to the issues under consideration. It is also essential that the assessment of a Concern is kept under review

throughout its investigation in case the nature of the investigation needs to change.

7.4 The number of people participating in an investigation is dependent on the severity and complexity of the Concern.

- Incident resulting in no harm or low harm (grade 1 or 2) should be investigated/reviewed and managed by the Directorate, and it may be sufficient for one person to undertake the investigation;
- Incidents resulting in moderate (grade 3) may require a multidisciplinary team approach supported by the Concerns Team.
- Incidents resulting in severe harm or death (grades 4-5) should be subject to a comprehensive (grade 5) or concise (grade 4) Root Cause Analysis (RCA), be multidisciplinary, and should always involve the Concerns Team, who may support or lead the investigation.

7.5 By accurately grading a Concern, choosing the investigator(s) appropriately, agreeing the terms of reference so they are clear and the use of appropriate investigation tools, the investigation should be carried out thoroughly, speedily and efficiently. The intention is to "*investigate once, investigate well"* and this should remain at the heart of the investigation as it progresses. Further information on grading of Concerns is found at Appendix D.

7.6 The reporter of a patient safety incident and/or their manager will be responsible for assessing both Severity and Future Risk Grade at the time of reporting, using the Grading Matrix and Tables in the Risk Management Framework.

7.7 The assessment of either Severity or Future Risk Grade should not delay completion/submission of the incident report. The reporter should make the most reasonable assessment possible based on the information available at the time. There is always scope for re-grading the incident, if necessary, as facts and issues emerge. An incident Grading should also be re-examined at the time when the risk reduction options are determined. This will also assist in prioritising the actions planned.

7A Concerns highlighted via the compensation Claims process

7.8 It should be noted at the outset, that some Concerns are not immediately recognised or acknowledged by the Health Board through the complaints or patient safety incident route. Instead, they may come to light some time later when the patient or their representative notifies the Health Board via the compensation Claims process - this process is detailed in the Claims Policy and Procedure documents. What is important to highlight, is that the same ethos and principles are applied to these cases, that a proportionate investigation is undertaken, and that if it becomes apparent during that process that a patient safety incident occurred, that the incident is reported retrospectively, and managed with the aim of learning lessons and making improvements.

7B. Concerns reported by Staff as *Patient Safety*

Incidents

7.9 A Patient Safety Incident is defined by the National Patient Safety Agency (NPSA) as “any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care”.

The Immediate Management of Patient Safety Incidents

7.10 Most incidents will be identified at the time of occurrence and the following paragraphs describe the immediate actions that should be taken prior to formally reporting the incident in line with the Incident Reporting Procedures.

Responding to the immediate needs of the persons involved

7.11 Ensure the immediate safety and care of the patient involved. Where the patient has sustained an injury, an appropriate level of examination and treatment must be offered. If the patient is not an inpatient, this might include referral to A&E. Refusal of that offer should be noted in the incident report.

7.12 If the Incident in any way relates to the use of medical equipment, disconnect the equipment from the patient.

7.13 The Consultant or lead professional in charge of the patient's care must be informed, who should consider the communications with the patient/relatives/carers at this time, in line with the Health Board’s Being Open Policy.

7.14 If the Incident occurs in a community setting, and it is considered that the GP should be made aware, the patient should be advised to contact the GP, or the member of staff should personally notify the GP as soon as practicable after the incident. If the incident is sufficiently serious, the GP should be notified immediately and/or an ambulance should be called.

Re-establishing a safe environment

7.15 Appropriate action must be taken to contain the situation, as agreed with the contact person/senior person on duty. There should be notification to or advice sought from specialist advisors/departments, as necessary (e.g. Infection Prevention and Control, Pharmacy etc).

Preservation of Evidence

7.16 It is important that there is a common sense approach and that there is discussion within the Department/Directorate/Locality or with relevant specialists in any given situation.

7.17 Where it is suspected that drugs may be defective/contaminated/out of date etc, they **must** be taken out of use and contact made with Pharmacy for advice.

7.18 If the **incident is serious**, all the relevant evidence must be preserved and kept secure. There may be a police investigation as well as a Health Board investigation. If necessary, secure the area, to ensure that everything is left untouched. Lock doors and put up signs clearly stating that no-one is permitted to enter the area. Explain the reason for the closure to patients, relatives, visitors and staff in the vicinity, ensuring that confidentiality is not breached.

7.19 If the Incident involves the use of **medical equipment**, the item(s) of equipment must be removed from use, appropriately labelled and retained for inspection. All accessories and disposables/consumables must be retained intact. Settings must not be adjusted. The equipment must be clearly labelled as 'Evidence - Not To Be Used' and it must be stored in a place and manner such that it cannot be accidentally or intentionally brought back into use until all investigations are complete and formal approval has been given for the re-introduction of the item. The supplier or manufacturer of an item should **not** be contacted at this particular time.

7.20 If the Incident involves the use of **non-medical equipment**, it must be removed from use, appropriately labelled and retained for inspection by Estates or IT. All accessories and disposables/consumables must be retained intact. Settings must not be adjusted. The equipment must be clearly labelled as 'Evidence - Not To Be Used' and it must be stored in a place and manner such that it cannot be accidentally or intentionally brought back into use in the intervening period until all investigations are complete and formal approval has been given for the re-introduction of the item. The supplier or manufacturer of an item should **not** be contacted at this particular time.

7.21 Equipment must be decontaminated/cleaned in accordance with relevant Health Board procedures, to ensure that it does not present a biological hazard to staff inspecting or repairing it. Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled, and placed in a secure location

7.22 There must be very good reason if any equipment involved in the incident is not to be removed from use. A discussion with the senior manager in charge, relevant specialist department and the Department of Investigations and Redress will be necessary before such a decision is taken. Where an item is not removed from use, a full and accurate description of the state of the device at the time must be recorded and photographs taken.

7.23 Once investigations are complete, should any equipment be identified as requiring service or repair, a works requisition must be submitted as a matter of urgency or any other necessary action taken but it is vitally important that a photograph of the equipment be taken prior to repair taking place.

7.24 Advice can be sought from specialist departments or the Concerns Team if it is considered that photographs of the environment/facility are necessary or would be helpful.

Notifications / Initial Contacts

7.25 Please refer to the Incident Reporting Policy and Procedures for details on this first stage of managing patient safety incidents. A summary of the patient safety incident process, from initial action following the incident, through to reporting, learning and disseminating lessons, is provided at Appendix C.

Completing the on-line incident report

7.26 The Health Board's Incident Reporting Procedures should be referred to for details of the reporting process.

7.27 As far as possible, the person most directly involved in the patient safety incident should complete the incident report.

Reviewing the on-line Incident Report

7.28 Managers that are designated as Incident Reviewers and will review the online incident report.

The purpose of the review is to:

- Ensure that the matter reported constitutes a reportable patient safety incident.
- Ensure that all the information is accurate and comprehensive.
- Ensure that all appropriate actions in response to the incident have been taken or are underway. This includes commissioning an appropriate investigation.
- Ensure that all appropriate communications are undertaken.
- Ensure that appropriate and timely feedback is provided to the incident reporter.

7.29 The review and approval/rejection of the patient safety incident must occur within **3 working days** of the date that the incident is reported.

7.30 The reviewer should ensure that any person who is directly involved in the incident is informed of the report, either directly or through his/her manager, as is deemed most appropriate. If the reviewer believes that this action should not be taken, the reasons for this decision must be fully documented in the Datix record. Advice can be sought from the Concerns Team.

7.31 The feedback provided to the reporter after review will include the following information:

a) the manner in which the incident will be investigated;

b) the period within which the investigation is scheduled to be completed.

7.32 Staff involved in patient safety incidents may require assistance and support. What is appropriate will depend on the nature of what has happened and the outcome. The Reviewer of the incident report will need to consider the involvement of, and advice from, appropriate specialists and departments, Professional Leads, Executive Directors, Personnel, and Occupational Health Department etc.

NB For incidents involving radiation, there is an additional form to support a thorough investigation. This is provided at Appendix E.

7.33 A variety of investigative tools can be accessed via the National Patient Safety Agency website http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/ .

Serious Patient Safety Incident Reporting

7.34 [Operational guidance on reporting patient safety incidents – including serious incidents - is found in the Incident Reporting Procedures document. *Putting Things Right* provides some additional information, which is reflected here. The related forms are found at Appendix F –

Welsh Government Serious Incident Reporting form, and Appendix G – Welsh Government Serious Incident Update / Closure form].

7.35 If the serious incident reported may attract significant media attention report forms should be submitted without delay within 24 hours of the incident occurring. If this occurs out of hours (i.e. weekdays after 5pm, before 8am, or at weekends, then the Welsh Government Press Office should be contacted by the person designated by the Executive on call, on 029 20 898 099).

7.36 The Welsh Government will issue an acknowledgement to the Health Board, which will include a Welsh Government reference number, which must be used in all future correspondence. A grading will also be provided which will indicate the timescale for the investigation.

7.37 The grading that Welsh Government use indicates when the Health Board will be expected to issue a Closure Form for the investigation and should not be confused with the Putting Things Right grading.

7.38 All serious incidents reported to Welsh Government will be subject to a review. This is to establish whether the harm caused was as a result of a patient safety incident in line with NPSA definitions. Those defined as serious patient safety incidents will be subject to a root cause analysis. Once this is completed and approved by the Health Board, a Closure Form should be completed by the Concerns Team and sent to improvingpatientsafety@wales.gsi.gov.uk This should include:

- findings,
- recommendations, and
- associated action plans, and
- learning, and
- should be in-line with the timescales for dealing with Concerns.

7.39 Welsh Government expect most Closure Forms to be sent within 6 months of the incident. Pro-active contact between the Health Board and Welsh Government is vital, and extensions are agreed on an individual case by case basis.

7.40 If the update/closure form relates to a 'joint' serious incident, the email from the lead investigating organisation submitting the form to Welsh Government should also be copied to the other party. The update/closure form should provide as much detail as possible, in particular where an issue has been identified that needs addressing – it should be made clear what action is needed.

7.41 Regular progress reports will be provided to the Director of Nursing throughout the investigation. The final incident report must be also be submitted to the Director of Nursing approval / sign-off prior to closing the investigation.

Public Service Ombudsman for Wales reports

7.42 All Public Service Ombudsman for Wales and Independent Review Panel reports are copied to Welsh Government's Improving Patient Safety Team at the same time they are sent to the Health Board. The Health Board should therefore routinely, share with the Welsh Government, any correspondence/action plans issued to the person who raised the Concern

via improvingpatientsafety@wales.gsi.gov.uk

Media Interest

7.43 The management of any media interests/communications in relation to Incidents, either individually or generally, will be undertaken by the Communications Department in collaboration with the Concerns Team, under the direction of the Director of Nursing. If an incident is expected to attract significant media interest, regardless of the level of harm, a 'No Surprises Form' should be submitted by the Concerns Team. (Appendix H)

Investigations - Selecting the correct level (this section will apply to all Concerns)

7.44 Depending on the circumstances, one of two levels of investigation will be used by the Health Board:

Level 1: Concise Investigation

7.45 For Concerns that resulted in no, low or moderate harm to the patient, but where it has been agreed that an investigation is required.

- Commonly involves completion of a summary or one page structured template.
- Includes the essentials of a thorough and credible investigation, conducted in the briefest terms.
- Involves a select number of tools (e.g. timeline, 5 why's, contributory factors framework).
- Conducted by one or more people, with a multidisciplinary approach if there is more than one investigator, who are experienced and/or trained in incident investigation, human error and effective solutions development.
- Often conducted by staff local to the incident (e.g. ward, department, Directorate, or GP surgery).
- If a patient is directly affected, they/relative/carer should be involved.
- Includes robust recommendations for shared learning, locally and/or nationally as appropriate.

Level 2: Comprehensive Investigation

7.46 Commonly conducted Concerns which resulted in, or had the potential to result in 'severe harm or death'.

- Conducted to a high level of detail, including all elements of a thorough and credible investigation.
- Includes use of appropriate analytical tools (e.g. root cause analysis, tabular timeline, contributory factors framework, change analysis, barrier analysis).
- Led by an investigator who is experienced and/or trained in RCA, human error and effective solutions development.
- Normally conducted by a multidisciplinary team, or involves experts/expert opinion/independent advice or specialist investigator(s).
- Conducted by staff not involved in the incident.

- Overseen at Director level, either as a Chair or Facilitator.
- Includes patient/relative/carer involvement and should include an offer to patient/relative/carer of links to independent representation or advocacy services.
- May require management of the media via the organisation's communications department.
- Includes robust recommendations for shared learning, locally and/or nationally as appropriate.
- Includes a full report with an Executive Summary and appendices

Level 3: Independent Investigation

7.47 This level of investigation would be commonly considered for Concerns of high public interest. They are *commissioned and conducted* by those independent to the provider service and organisation involved, and would be initiated by the Welsh Government.

Root Cause Analysis

7.48 Root Cause Analysis is a technique for undertaking a structured and consistent approach to investigation that enables an understanding of the underlying causes and environmental context in which the incident occurred - there are a selection of RCA tools available to support investigations. RCA is designed to identify the sequence of events, working back from the incident.

Stages	RCA Tools
WHAT happened Chronology	Tabular timeline
HOW it happened Gather data & evidence	Tabular timeline Brainstorming Change Analysis
WHY it happened Contributory factors at each step in sequence of events	Fishbone Classification framework Five Why's Brainstorming

7.49 **Full Root Cause Analysis** should be undertaken for:

- all incidents resulting in moderate or permanent harm;
- unexpected deaths that were directly related to an incident;

7.50 The stages on which the NPSA Root Cause Analysis tool is based are:

1. Identifying which incidents should be investigated
2. Scoping the incident
3. Gathering the information
4. Mapping the events
5. Analysing the information
6. Developing solutions and an action plan for implementation
7. Completing a report

7.51 The investigating officer is responsible for recording the outcome of the investigation in a formal written report. The Health Board report template should be used to support a consistent approach – this is found at Appendix I.

7.52 The time for completion of an RCA will vary according to the complexity of the circumstances, but in order to minimise anxiety for patients, and in order to identify lessons at the earliest stage, staff should aim to complete investigations within 6 weeks of the occurrence of the incident.

7C. Concerns reported by patients or their representatives

7.53 The vast majority of Concerns are likely to be about the services provided by one Responsible Body. However, there will be situations where services provided by more than one Responsible Body form part of a concern. It is also possible under the new arrangements for people to raise Concerns with the Local Health Board about the services provided by Primary Care practitioners, and additionally, for those practitioners to ask the Health Board to undertake investigations for them.

Concerns which involve more than one Responsible Body
(Regulation 17)

7.54 In practice it is likely that the person has only raised the Concern with one of the responsible bodies. However, checks should be undertaken to ensure that there is no duplication of effort on the part of any organisation. If it seems clear to the Health Board that the matters involve another Responsible Body, then it must **within 2 working days** of first receipt:

- inform the person raising the Concern that another Responsible Body is, or may be, involved in their Concern, and

- seek consent from the person raising the Concern to contact and notify the other Responsible Body that they are involved in the Concern.

7.55 Once consent has been received, the second Responsible Body must be informed **within 2 working days** of receiving the consent, that a Concern has been received. All organisations involved with the Concern should then cooperate to agree:

- which of the organisations will act as the lead in coordinating and investigating the Concern;
- who will directly communicate with the person who raised the Concern and keep them updated;
- a joint response to the Concern, issued by the lead organisation;
- the sharing of information relevant to the Concern, subject to consent which should be obtained at the outset;
- appropriate representation of the organisations at any relevant meetings.

Concerns raised with the Health Board by a patient or his or her representative about services provided by a Primary Care practitioner (Regulations 18 to 21)

7.56 When the Health Board receives a Concern relating to NHS services provided by a Primary Care practitioner in their area they need to decide in the first instance whether it is more appropriate for it to investigate a Concern, or whether the Primary Care provider should do so. Before making this decision, the Health Board will first of all **within 2 working days** contact the person who raised the Concern to:

- ask whether the Concern has already been raised with and had a response from the Primary Care provider and
- seek consent for details of the Concern to be sent to the Primary Care provider.

7.57 If the Concern has already been dealt with by the Primary Care provider and a response issued in accordance with Regulation 24, then the Health Board will not investigate it again. However, the Health Board can offer to facilitate any further resolution between the provider and the person raising the Concern as long as both parties agree. The person will be advised of this and reminded of their right to take the matter to the Public Services Ombudsman for Wales.

7.58 If the Concern has not been looked at by the Primary Care provider, the Health Board may consider that this is a Concern that it would be appropriate, in principle, for the Primary Care Provider to investigate. The Health Board will obtain the consent of the person who raised the Concern, to allow details of the Concern to be sent to the Primary Care provider who is the subject of the Concern. The Health Board will undertake a monitoring role and ask the provider to send a copy of their response to the Health Board's Concerns Team.

7.59 If the person who notified the Concern does not consent to details being passed to the Primary Care provider, the Health Board cannot investigate the Concern.

7.60 The only exception to this is if there is an issue so serious that it

would merit an investigation anyway, without the direct involvement of the Primary Care practitioner, or the consent of the individual patient.

7.61 The Health Board has **5 working days** to make the decision about who will investigate the Concern and to inform the patient or his or her representative and the Primary Care provider who is the subject of the Concern, and to provide reasons for the decision.

7.62 If the Health Board decides to investigate a Concern about a Primary Care provider then it will let the person who raised the Concern and the Primary Care provider know, and then carry out an investigation. Primary Care providers are under an obligation to cooperate with investigations undertaken by the Health Board. However, the Health Board may not make any determination about the liability in tort of a Primary Care provider. If such matters are alleged by the patient or arise during the investigation, then the Primary Care provider will be advised to involve their medical defence organisation. The patient will need to be advised that the Health Board cannot become involved in those aspects of any concern about a Primary Care provider.

Health Board asked by a Primary Care provider to undertake an investigation (Regulation 20)

7.63 The process to be followed by the Health Board when it receives such a request is very similar to the one described above for Concerns raised with the Health Board by patients about Primary Care providers.

7.64 Where the Primary Care provider asks the Health Board to investigate a Concern about services provided by them, the Health Board, **within 2 working days** needs to:

- check with the Primary Care provider that the person who has raised the Concern consents to the Health Board considering the Concern; and
- establish whether the Concern has been considered by the Primary Care provider and whether a response has already been issued by the Primary Care provider under Regulation 24.

7.65 If the person who notified the Concern is unwilling to consent to the Health Board considering the Concern, or if a Primary Care provider has already issued a response under Regulation 24, then the Health Board cannot investigate the Concern and must let the Primary Care provider know. If the person who notified the Concern is content for the Health Board to consider the Concern and a response has not been issued under Regulation 24, the Health Board has **5 working days** to make the decision about who will investigate the Concern.

Investigation of Concerns in accordance with the Regulations

7.66 When a Concern is received by the Health Board, the date of receipt must be noted - this date is used to calculate the number of days it will take to respond. In cases where Redress may be considered, it will also be the date from which the limitation period is suspended. In cases involving Concerns notified to the Health Board about Primary Care providers, the date of receipt is still the date on which the concern was first received.

7.67 A chart defining the timescales for handling Concerns can be found at Appendix J.

Acknowledgement of Concerns

7.68 All Concerns must be acknowledged within **2 working days** of first receipt. For Concerns involving Primary Care providers to be investigated by the Health Board, once the Health Board has decided that it will investigate, then they will send a formal acknowledgement letter outlining the Concern to be investigated, as required by the guidance.

7.69 The acknowledgement of the Concern must be in writing and if received electronically can be acknowledged electronically. Verbal Concerns that are not managed "on-the-spot" must also be acknowledged in writing.

7.70 At this stage, the Health Board will provide the person who raised the Concern with a **named contact** for use throughout the handling of the Concern and details of how to contact that person. At the outset, the person raising the Concern must be offered the opportunity to discuss:

- any specific needs they may have which should be taken into account as the investigation proceeds;
- the way in which the investigation will be handled;
- how long it is likely to take and when a response can be expected, and
- the availability of advocacy and support.

7.71 As a matter of good practice, the discussion should also seek to establish:

- what the person who raised the concern is expecting as an outcome, and
- that the person understands their clinical records will be looked at as part of the investigation.

7.72 The discussion can take place by telephone or at a meeting. This offer of a discussion needs to be included in the acknowledgement based on the Health Board's template letter.

7.73 If there is to be a meeting with the person raising the Concern at this stage, it is useful to remember that it is more likely to be successful if the person knows what to expect from the meeting and is able to offer some suggestions towards how the matter can be resolved for them. The person raising the Concern should always be encouraged to bring a relative or friend, or an advocate to any meetings.

7.74 On rare occasions, a meeting alone may be sufficient to resolve a Concern. If the meeting is successful and the actions to resolve the Concern are agreed by all parties the Concern can be considered as resolved and no further investigation may be required. The meeting must be followed-up by a full written response based on the discussions and include confirmation that the Concern is now resolved. If any follow-up actions were agreed then the person who raised the Concern must be told when they can expect to receive information about the outcome of these actions.

7.75 In most cases, a meeting will serve the purpose of establishing some

basic information and agreeing a way forward. The investigation will then proceed.

7.76 If the person does not want to discuss their Concern, the Health Board will determine how they will manage the Concern and then inform the person in writing of the proposed actions to manage their Concern.

7.77 Any person who is the subject of a Concern must be given a copy of the Concern unless:

- they have already been sent a copy by the person raising the Concern, or
- informing the person of the Concern, would, in the reasonable opinion of the Health Board, prejudice its consideration of the matters raised by the Concern.

Accessing Medical Records and Consent

7.78 In the majority of cases, the investigation of a concern requires access to medical records, and so the issue of consent will need to be considered.

7.79 The Data Protection Act 1998 requires that data controllers must comply with the Data Protection principles when processing personal data.

7.80 For the purposes of the Act, health records will constitute sensitive personal data. If there is any doubt as to whether the processing of sensitive personal data without the consent of the data subject is unlawful, appropriate legal advice should be sought.

7.81 Where the patient him/herself raises the concern, then in doing so, they can be deemed to have given implied consent to an investigation. This will also apply if a concern is raised by a representative who has shown proof that they are legally entitled to act for the patient/data subject (e.g. the representative has a Power of Attorney). However, in order for individuals to be clear in the knowledge that their medical records may need to be accessed, this should be explained in the acknowledgement letter so that they have the opportunity to indicate if they do not want their health records accessed.

7.82 Where a third party has raised a concern on behalf of someone else, then the patient or their representative will have to be asked to give written consent to the access to medical records and the conduct of an investigation.

7.83 Further information about when to seek consent to investigate Concerns is set out in Appendix K.

7.84 In terms of Concerns raised which relate to patient safety incidents reported by members of staff, the Data Protection Act 1998 allows for certain sensitive personal data (i.e. medical records) to be processed without the consent of the data subject (i.e. patient) to allow for legitimate activities such as the internal investigation of a patient safety incident to take place. In these situations there is no need to seek the consent of the individual to the use of their medical records in an investigation.

7.85 However, where an incident occurs and there has been moderate or severe harm or death, the Health Board must advise the patient to whom the concern relates, or his or her representative, of the concern and

involve them in the investigation of the concern. This should be managed in accordance with advice set out in *Being Open.* The exception to this is if informing the patient or their representative would not be in the best interests of the patient because, for example, involving them could cause deterioration in their physical and/or mental health. Hence, where there has been moderate or severe harm or death, the investigation would commence straightaway and as part of this discussion, consent should then be sought to access medical records.

7.86 In any investigation and in line with data protection legislation and the Caldicott Principles, only information relevant to the investigation of the concern should be accessed and then only by those people who have a demonstrable need to have access.

7.87 In addition, being open from the outset and providing a person with access to their own medical records can often help them understand what has happened and avoid any suspicions developing. No fees will be charged where a person inspects written records, but a fee may be charged if they want copies. The *Putting Things Right* Regulations state that copies of records relevant to any concern should be provided to the person raising the concern without charge.

7.88 A person has the right to have access to personal information held about them in written records and on computer e.g. medical and nursing notes, X-ray reports or blood results. Where a person requests to view medical records, the person must be accompanied and appropriate assistance made available to explain any questions around procedures and terminology.

7.89 However, access can be refused if:

- following discussion with a health professional the provision of access would seriously harm the physical or mental well-being of the person or any other individual involved with the Concern, e.g. member of staff such as a health professional; or
- the request for access has been made by someone who is not the data subject (such as the parent of a child) where the information was provided in the expectation that it would not be disclosed to the applicant. This includes the results of any examination or investigation which the patient has requested should not be disclosed.

7.90 If access is denied, the individual can complain to the Information Commissioner or, if still not satisfied, individuals may seek remedy through the courts.

Investigations

7.91 All Concerns must be managed and investigated in the most appropriate, efficient, and effective way. Where the Concern notified includes an allegation that harm has or may have been caused it must consider:

- the likelihood of any qualifying liability arising;
- the duty to consider Redress; and
- where it is clear from the outset that, regardless of the fact that there is or there may be a qualifying liability, that damages if a

qualifying liability were to be established would exceed £25,000 the Redress arrangements should not be triggered and the person who notified the Concern should be advised to seek legal advice and also be given the contact details for their local CHC. If they choose to pursue a claim for compensation they can do so in the usual way, outside the provisions of the Regulations.

Establishing the investigation and initial assessment of a Concern

7.92 Investigations need to be undertaken by staff who have completed the relevant training, are competent, objective, have recognised authority and are credible and respected. To maintain competence, staff should undertake approximately 3 RCAs/year or have received refresher training.

A register of trained staff across all Directorates will be maintained by the Concerns Team.

Declaring conflict of Interests

7.93 If a member of staff is involved at any level with a concern that involves a family member, they must declare a conflict of interests. Any investigating officer or person signing off a Concern, must not have any family relationship with either the person who raised the concern, or the person who is the subject of the Concern. This ensures that the integrity of the process is assured without compromising the rights of any individual involved.

7.94 The process for establishing an investigation following a patient safety incident and that for a Concern received from a patient or representative is the same, and is covered in the previous section - 7B – Concerns Raised by staff as Patient Safety Incidents.

Communication with the person or representative who raised the Concern

7.95 Staff must ensure that the person who notified the Concern is kept updated in a timely manner about the investigation. Consideration should also be given to inviting them to attend meetings with staff and at what stage in the investigation those should most usefully be arranged. It can do more harm for clinical staff to meet a patient too early; neither should things be left so long that the person raising the Concern feels they have been forgotten about. Timing should be carefully considered to allow everyone to prepare and for any meeting to be as useful as possible.

Support for staff involved in Concerns

7.96 Whilst some form of mistake often contributes to the occurrence or outcome that is the subject of a Concern, it will usually have occurred as a result of one or a number of underlying causes that lie in organisational systems. In such situations, blame cannot, and will not, be attributed to individual members of staff. The Health Board is committed to reducing risk through investigating and analysing the events that are the subject of Concerns, to identify the fundamental and underlying causes and to taking actions to address those issues. Identifying and addressing system problems is, therefore, the key to reducing future risk.

7.97 In this respect the Health Board will, when appropriate, utilise the 'Incident Decision Tree' tool, developed by the National Patient Safety Agency, to ensure appropriate and consistent decisions are made.

7.98 Reporting a Concern in the form of a patient safety incident does not

constitute an admission of liability. The information is used to enable the Health Board to gather all the facts for investigation, analysis, consideration of Redress, learning and future risk reduction.

7.99 Being the subject of a Concern or even reporting a Concern as a member of staff can be very stressful. When an issue is raised, whether by a patient or through a report from a member of staff, the details should be shared with the staff member involved wherever appropriate. This should be done supportively and staff may want to have a member of their professional association or Trade Union representative present in any meetings. Consideration should also be given under HR policies as to whether a staff member may need more proactive support such as counselling. For any member of staff involved in a Concern, their line manager should be involved in any decisions that are taken.

7.100 Staff may need to prepare reports or evidence during the investigation of the concern – support for this can be provided by the Concerns Team. Above all, it is important that staff are kept informed about the progress of the investigation of any Concern that they raised or which directly involved them, and the final outcome.

Witness accounts

7.101 Where staff have been involved in or witnessed an incident, they may be required to write and sign a witness account in support of an incident investigation. This should be written as soon as possible after the event and be factual in nature.

7.102 A template for a witness form is provided at Appendix L. The report can be completed either electronically or manually.

Coroner's Statements for Inquests

7.103 If death occurs in any of the following circumstances, it may be reported to the Coroner:

- after an accident or injury
- following an industrial disease
- during a surgical operation
- before recovery from an anaesthetic
- if the cause of death is unknown
- if the death was violent or unnatural
- if the death was sudden and unexplained
- if the deceased was not seen by the doctor issuing the medical certificate after he or she died, or during the 14 days before the death.

7.104 An inquest is a legal inquiry into the medical cause and circumstances of a death. It is held in public, sometimes with a jury, by a Coroner.

7.105 Health Board staff are - on occasion - required to provide statements for the Coroner; some may be required to attend as witnesses. The Concerns Team will provide advice and support for staff in these circumstances. Staff should adhere to the guide for staff on how statements for the Coroner should be prepared, which is provided at

Appendix M.

Obtaining independent clinical or other advice

7.106 There may be occasions when it is necessary to secure an independent opinion on a matter relating to a concern, with a view to resolving it. This may include:

- Obtaining a second opinion to aid a patient's understanding of their own care, or to see whether there are any other issues which need to be explored in terms of the provision of care and treatment, as part of the investigation.
- In instances when an allegation of harm has been made by the patient, and where the Health Board is unable to determine to whether there is a qualifying liability in tort.
- Where the Redress arrangements are triggered, any instruction of medical experts must, be carried out jointly by the person who notified the concern and the Welsh NHS body.

7.107 A database has been set up containing the names and details of potential independent expert advisers who may be commissioned by NHS organisations in Wales to provide advice in the circumstances set out above. The database contains experts from across the health professions, disciplines and specialities/sub-specialties.

7.108 Legal & Risk Services can be contacted for further advice on how to engage an independent expert adviser.

Alternative Dispute Resolution

7.109 The Health Board may need to consider whether a concern can be resolved by using alternative dispute resolution (ADR), such as mediation, facilitation or conciliation. This approach is often useful when the person who raised the concern is upset or there is unease between the Health Board and the person raising the concern.

7.110 The independence afforded with ADR can help to bring about a resolution of the concern and prevent it escalating further. ADR may help:

- where staff or practitioners are having difficulty in dealing with the concern;
- when the person who raised the concern feels anxious that the approach of the Concerns team/lead person is not impartial;
- when there are misunderstandings with relatives, during the treatment of a patient. ADR can lead to a 'shared view' of the situation including their differences.

7.111 To progress ADR, both parties need to provide signed agreement to their involvement in the process and patients need to give consent to their personal records being viewed by an independent party. All meetings, telephone calls, other exchanges and information provided must be carefully documented.

7.112 The Community Health Councils may be able to assist in this process. All CHC advocates are also trained in mediation skills, but the same CHC advocate cannot take on both roles in the same case.

Dealing with people who make unreasonable demands

7.113 People raising Concerns have the right to be heard, understood and respected and every effort should be made to assure individuals that their concern will be investigated thoroughly. However, there may be times when the distress of a situation leads to the person raising a concern, acting out of character and becoming determined, forceful, angry, make unreasonable demands of staff or even resort to violence.

7.114 People who are unhappy about the process or outcome of the investigation of their concern, despite being advised on other avenues available for them, may also show aggression towards staff or continue to persistently pursue their concern by phoning, writing or in person. Although staff understand that a person's anger and aggression may be as a result of the distress that has been caused to them or to their loved ones, behaviour that escalates into actual or potential aggression towards staff is not acceptable.

7.115 Further information on how to deal with people who make unreasonable demands can be accessed at Appendix N.

Where a concern needs additional consideration

7.116 When a concern first comes to light, or at any stage during an investigation, the Health Board must consider whether further actions are required, for example, referral of any matter to other processes such as HR conduct or capability policies or to other bodies such as:

- Welsh Government (for serious incidents)
- Professional Bodies, e.g. General Medical Council,
- Nursing and Midwifery Council
- Healthcare Inspectorate Wales
- Health & Safety Executive (RIDDOR)
- Medicines Healthcare and Regulatory Agency (MHRA)
- Information Commissioner's Office
- Police
- Coroner
- Local Safeguarding Children Board
- Local Adult Protection Committee

7.117 These referrals can happen at the same time as an investigation is being carried out.

Health Board's duty to consider whether there may be a qualifying liability in tort

7.118 The Health Board has an additional duty, where there has been an allegation of harm, to consider the likelihood of any qualifying liability in tort arising, and to apply Redress. This is dealt with under Section 8.

Timescales for responding to a Concern

7.119 The Health Board will aim to issue a final response under Regulation 24 or Regulation 26 within 30 working days of first receipt of a concern from the person or their representative.

7.120 If it is not possible to issue a final response within 30 working days of first receipt of the concern, the person raising the concern must be

informed of the reason for delay. The Regulations allow for these cases and a response must then be sent as soon as possible and **within 6 months** of the date the concern was received.

7.121 If, in very exceptional circumstances, the response cannot be issued within 6 months, then the person raising the concern must be informed of the reason for delay and given an expected date for response.

7.122 Regulation 24 responses are where it is determined that there is no qualifying liability in tort to which the Redress arrangements could apply. If, however, it is considered that there is or there may be a qualifying liability in tort worth less than £25,000, an interim response in accordance with Regulation 26 may be issued.

Final response under Regulation 24

7.123 The Health Board's final response report must include the following:

- an apology;
- a summary of what the concern was about;
- an explanation of how the concern was investigated;
- copies of any expert opinion obtained as part of the investigation;
- copies of any relevant medical records, where appropriate;
- an explanation of any actions taken;
- an offer to discuss the response to the concern with the Clinicians involved in the care of the patient;
- details of the person's right to raise their concern with the Public Services Ombudsman for Wales;
- in respect of a concern that alleges harm has, or may have, been caused - an explanation of the reasons why there is no qualifying liability;
- an explanation of why the Redress arrangements will not be triggered in response to Concerns alleging harm has been caused where the financial value of the claim would, if proven, exceed the financial threshold set out in Regulation 29.

7.124 The response must be signed off by the Director of Nursing or the designated deputy, prior to obtaining the signature of the Chief Executive.

7.125 In terms of responding to Concerns which are reported by staff members relating to patient safety incidents, then in cases where the patient is not involved, these will be reported to the Directorate Integrated Governance / Patient Safety meetings. In reported incidents where there has been moderate or severe harm or death, the patient or representative will have been informed and involved in the investigation and so they may need to be sent a response either under Regulation 24 or 26 as appropriate.

Interim response under Regulation 26

7.126 Where the Health Board considers there is or may be a qualifying liability which would attract financial compensation of £25,000 or less, an **interim report** under Regulation 26 may be issued **within 30 working days** of first receipt of a concern from the person or their representative. If this is not possible, the person making the complaint should be

informed of the reasons why there has been a delay and given guidance on when a response can be expected.

Interim Report

7.127 When an interim report is issued it must include the following:

- a summary of the nature and substance of the issues contained in the concern;
- a description of the investigation undertaken so far;
- a description of why in the opinion of the Health Board there is or may be a qualifying liability;
- a copy of any relevant medical records, if appropriate;
- an explanation of how to access legal advice without charge;
- an explanation of advocacy and support services which may be of assistance;
- an explanation of the process for considering liability and Redress;
- confirmation that the full investigation report will be made available to the person seeking Redress;
- details of the right of the person to take their concern to the Public Services Ombudsman of Wales;
- an offer of an opportunity to discuss the contents of the interim report with the responsible officer or person acting on their behalf

7.128 The interim report should be signed off by the Director of Nursing or the designated deputy, before being given to the Chief Executive for signing.

Additional information - guidance on dealing with Concerns that are not notified through the normal routes described in the main guidance.

Action to take when a request for access to health records is received by the Health Board

7.129 On occasions, the first notification of a concern might be through a request to access health records by a solicitor acting on behalf of a patient or their representative. In this instance, the Health Board may not be clear as to the reason why the records have been requested, and whether a concern is in fact being notified under the Regulations. The *Putting Things Right* guidance contains a template letter which can be used by the Concerns Team, which provides information about the new arrangements that can be passed on to the individual by their solicitor.

Action to take when a concern is notified indicating a conditional fee agreement or insurance premium

7.130 In this instance, as soon as the Responsible Body receives notification of a concern from a solicitor and where it appears that the patient has entered into a conditional fee agreement or insurance premium, they must liaise with Legal & Risk Services immediately, who will support them in dealing with this type of concern. The concern can be handled and investigated in line with the principles of the Regulations.

8. Redress

8.1 Regulations 25 to 33 cover the arrangements that apply when Redress is to be considered. If at anytime during the management and investigation of a concern it is considered that a qualifying liability that would attract financial compensation of £25,000 or less exists or may exist, the Health Board must determine whether or not an offer of Redress should be made.

8.2 Redress relates to situations where the patient may have been harmed and that harm was caused by the NHS in Wales. Redress can comprise of:

- a written apology;
- a report on the action which has or will be taken to prevent similar Concerns arising;
- the giving of an explanation;
- the offer of financial compensation and/or remedial treatment, on the proviso that the person will not seek to pursue the same through further civil proceedings;

8.3 Remedial treatment is that which is offered to the patient with a view to trying to improve their condition and to restore them, a far as possible, to the position that they would have been in, had they not been subjected to the treatment complained of, or negligent care.

Qualifying Liability in Tort

8.4 Redress can only be considered if there is a proven qualifying liability in tort. Investigations will therefore be seeking to prove that the Welsh NHS body has **both failed in its duty of care** to a patient **and** that the breach of duty of care has been **causative of the harm that the person has suffered**. It is only when both these tests are satisfied that a payment of compensation should be considered.

8.5 This must be made very clear to patients and their representatives, as often people believe that there only needs to have been poor care for the test of negligence to be satisfied, and for compensation to be owed. However, it is the case that the person also needs to have suffered harm as a consequence (known as 'causation of damage'). Determining causation can be very difficult, particularly if the patient was very ill anyway, or might have expected some pain and complications during their recovery as a result of treatment. This is the stage at which it will be necessary almost certainly to commission expert advice. This will be done by the Concerns Team in conjunction with Legal & Risk Services.

When Redress does not apply

8.6 Redress cannot be offered where there is no qualifying liability in tort. Nor can it be offered if the concern is or has been subject to civil proceedings (i.e. where court proceedings have been issued). If the person or their representative raising the concern wishes to pursue their claim through the courts and has issued civil proceedings, any consideration of Redress under these Regulations must cease and the person informed.

8.7 Redress under these Regulations does not extend to Primary Care

providers or independent providers.

8.8 The Redress arrangements should not be engaged where it is considered at the investigation stage that the amount of financial compensation that would be awarded would exceed the limit set out in Regulation 29, currently £25,000.

Suspension of the limitation period

8.9 If a case may be subject to the Redress provisions, then Regulation 30 allows for the suspension of the limitation period, which is the time normally allowed for a person to bring a legal Claim – usually three years from the date of the treatment or incident complained about, or three years from the date that the person became aware of the matter which is the subject of their claim.

8.10 During the time that Redress is being considered the limitation period is suspended, that is, the "clock is stopped". This applies from the date on which the concern was first received by the Health Board. The suspension of the limitation period will also continue once the Health Board has made an offer of Redress or refused to make an offer. The reason for this is to ensure that no person is disadvantaged, or prevented from bringing legal action, should they be unhappy with the outcome of the Redress investigation.

8.11 The person and their legal representative have up to 9 months to accept an offer of financial compensation from the date of the offer, after this the limitation clock will start to run again. If the offer is accepted the person or their representative has to sign a formal agreement and legal waiver, that they will not pursue the concern through civil proceedings. The 9 month time period for suspension of limitation also applies if they choose to reject the offer.

8.12 It is important that the person or their representative understand that where a financial offer of Redress is made, that they only have 9 months to consider the offer. After that time, the Redress arrangements will no longer apply.

8.13 There may be cases where a Concern is notified just before the limitation period will expire, where it has not been possible for an investigation to be concluded. In any such cases, the Health Board will consider to agreeing to an extension of the limitation period, in order to allow for completion of the investigation and provision of response, whilst avoiding the need for a the patient / potential Claimant to issue court proceedings.

8.14 In circumstances where it is admitted that there may be a qualifying liability, and it subsequently transpires that financial compensation in respect of this will exceed £25,000, the Health Board will write to the patient or their representative indicating that it will not make an offer of Redress under the regulations. The patient will benefit from the 9 month extension of limitation, from the date of this letter.

Legal advice

8.15 Where the Redress arrangements are engaged, legal advice **without charge** to the person who notified the concern will be available, should the person or his representative want it, in relation to:

- the joint instruction of clinical experts including clarification of issues

arising from their reports;

- any offer of Redress;
- any refusal to make an offer; or
- any settlement agreement that is proposed.

8.16 Legal advice may only be sought from a recognised firm of solicitors with known expertise in clinical negligence who are accredited by the Law Society or from the Action against Medical Accidents Clinical Negligence Panel. The list is accessible via Legal & Risk Services. The cost of such legal and clinical advice must be funded by the Health Board and not the person who raised the concern.

8.17 Further detail on the cost of legal fees is provided in the *Putting Things Right* Guidance

Redress investigation

8.18 In order to determine whether an offer of Redress can be made under the Regulations, it is necessary to undertake a certain amount of additional investigation, which may include the need to address the following matters:

Whether there is a qualifying liability

8.19 A determination will be needed on whether there has been a breach of duty of care and whether that breach has caused or materially contributed to the symptoms or condition the patient currently complains of. The checklist attached at Appendix O will assist in all investigations but in particular with determining the issues around breach of duty of care.

8.20 This may require additional external expert evidence, and an up to date assessment of condition and prognosis. This can be obtained from the patient's treating clinician with agreement of both parties, or from an independent expert, or from up to date general practitioner records.

Compensation Recovery Certificate (CRC)

8.21 A CRC showing any state benefits paid or payable to the patient must be obtained at the outset. Any loss of earnings which may form part of compensation payable may be reduced if the person has been in receipt of certain benefits.

Quantification of any financial loss

8.22 Any damages that may be payable within the £25,000 limit will be made up of general damages (i.e. payable for pain, suffering and loss of amenity) and special damages (i.e. monetary loss which can be calculated with a degree of accuracy such as loss of earnings, costs of care and assistance, etc.). Details of expenditure in respect of additional treatment, care, prescriptions, clothing must be obtained with invoices and receipts where available.

8.23 Where loss of earnings is claimed, then wage slips, letters from employer, P60, etc. must be obtained. If the patient is unable to provide details, they must be asked for appropriate addresses to enable the investigator to obtain the necessary details. Proof of loss of earnings is mandatory.

8.24 If a future loss of earnings is anticipated by the patient the evidence above is required and information regarding future job prospects should

be addressed in the medical evidence or the expert advice commissioned. The evidence of actual financial loss should be set out clearly in the offer of financial Redress, separate from the offer of compensation for the injury/harm.

8.25 Should the patient accept the offer of free legal advice, all the evidence referred to above should be provided with the report.

8.26 The Concerns Team are able to contact Legal & Risk Services for advice to ensure they have covered all matters at this stage.

Instruction of independent expert advisers

8.27 There may be a number of issues on which expert advice may be required, including those relating to breach of duty, causation, condition and prognosis and/or quantum to establish whether there is a qualifying liability in respect of which an offer of Redress should be made. Under the Redress arrangements, any expert required to provide advice under the Regulations should be instructed **jointly** by the person raising the concern and the Health Board – Legal & Risk Services will advise the Concerns Team in this regard.

8.28 If the person has accepted the offer of free legal advice then their legal adviser should also be allowed input to the instruction of the expert(s).

Redress – Financial

8.29 Where liability in tort is accepted, the Health Board can make an offer of financial compensation that does not exceed £25,000.

8.30 Where it is acknowledged that any financial compensation will exceed £25,000 then the concern **must not** be considered under the Redress arrangements and financial compensation may not be offered under Part 6 of the Regulations.

8.31 However, it is recognised that it is difficult at the outset of an investigation to be certain about the financial value of a claim and it is inevitable that some cases that were entered into the Redress arrangements because it was considered that financial compensation, should liability be proven, would be worth less than £25,000 transpire, on investigation, to be worth more. In these cases Regulation 29(3) provides that Welsh NHS bodies may give consideration to making an offer of settlement outside of the provisions of the Regulations, for example, an out of court settlement. The Health Board might at this stage, and in the spirit of the Regulations, consider offering to pay the patient's legal costs associated with obtaining advice on any such out of court settlement. However, there is no obligation for them to do so.

<u>Tariff</u>

8.32 The assessment of general damages for pain, suffering and loss of amenity is calculated on a common law basis. An all-Wales tariff has been developed to provide guidance for the quantification of lower value clinical negligence claims that are subject to the Redress arrangements. This is provided within the *Putting Things Right* Guidance document.

8.33 In some cases it may be appropriate to commission an independent expert to determine quantum (or the value of a claim). The Health Board should usually consult Legal & Risk Services for support when determining

damages.

Redress – Communicating the decision

8.34 The offer of Redress or decision not to make an offer, in accordance with Regulation 33, must be communicated to the person raising the concern, or their representative, **within 12 months** of the first receipt of the concern.

8.35 In exceptional circumstances, if the Health Board is unable to make a decision within the 12-month period then the reason for delay and an expected date for the decision should be explained in writing to the person who notified the concern.

8.36 The person raising the concern or their representative must also be advised of all the relevant timescales detailed at Section 6 above.

8.37 If an offer of Redress is made this offer will be by way of a formal agreement. By accepting the offer of Redress the person or their representative must sign a waiver to any right to take the same concern, for which they have accepted Redress, to court.

8.38 There may be cases where a proposed Redress settlement will require approval by a court, for example, where a liability relates to a child or person lacking capacity under the Mental Health Act 2005.

8.39 Where a Redress settlement requires approval by a court, the Health Board must pay all reasonable legal costs to obtain the approval of the court.

Redress - Investigation Report

8.40 Where a person is seeking Redress, the findings of the investigation must be recorded in an investigation report. This must be provided to the person who raised the concern and is seeking Redress within 12 months of first receipt of the concern. In practice the communication of the decision and investigation report will be issued at the same time.

8.41 The investigation report must contain:

- copies of any independent expert advice used to determine whether or not there is a liability;
- a statement by the Health Board confirming whether or not there is a liability; and
- the rationale for their decision.

8.42 However, it is not necessary for the Health Board to provide a copy of the investigation report:

- before an offer of Redress is made;
- before a decision not to make an offer of Redress is communicated;
- if the investigation of Redress is terminated for any reason; or if
- the report contains information which is likely to cause the person or other applicant for Redress significant harm or distress.

A flowchart detailing the Redress process within the Health Board is provided in appendix v.

Investigation reports which exceed the 12 month time limit

8.43 Where an investigation report cannot be provided within the set 12 month timescale, then the person raising the concern must be informed of the reason for the delay and given an expected date for response.

8.44 A flowchart which summarises the process of handling Concerns that are highlighted as 'complaints', and that of Redress, is provided at Appendix P.

9. Financial Compensation Process

9.1 Within the *Putting Things Right* guidance, this section supersedes the Welsh Health Circular (97)17 - most of the advice related to and has been incorporated into the Claims Policy and Procedure. For the purpose of the Concerns Policy and Procedures document, it **relates only** to Concerns involving a qualifying liability in tort, resolved by the settlement of damages to a maximum of £25,000 under Redress.

9.2 Welsh Government will seek Assurance from the Welsh Risk Pool Services (WRP) through the WRP Standards Assessment process, that all necessary processes and procedures, structures, and governance arrangements are in place to ensure:

- Promotion of good and economic practice in the management of Concerns against the NHS, and
- Assurances that learning from events with the objective of improving standards in patient safety are foremost.

Qualified Legal Advice

9.3 Authority for granting access to qualified legal advice is delegated by the Chief Executive Officer to the Director of Nursing.

9.4 The final decision on whether to negotiate a settlement or to continue defending a compensation claim is also taken by the Director of Nursing on behalf of the Board, in discussion with solicitors at Legal & Risk Services.

Database

9.5 The Health Board will maintain its databases to include all relevant information on all compensation claims, maintaining staff and patient confidentiality at all times.

9.6 The Concerns Team and Finance Department will collaborate to ensure that systems are accurate and consistent.

Delegated Limits

9.7 Settlements are approved by the Health Board in line with the agreed delegated financial limits. These are detailed in the Claims Procedures.

Novel, contentious or repercussive payments

9.8 Despite the general approach to delegation, all compensation claims involving "novel, contentious, or repercussive" expenditure should still be referred to the Welsh Government for advice and approval. The most likely instances are those:

- Involving some unusual new feature, which if not correctly handled, might set an unfortunate precedent for other NHS litigation;
- Which appear to represent test cases for a potential class action, or cases which although not formally part of a class action appear to be very similar in kind to concurrent compensation claims against other Responsible Bodies.

Financial Reporting

9.9 All payments in settlement of compensation claims will be entered into the Health Board's register of losses and special payments.

9.10 Where the Health Board settles a compensation claim where the total expenditure does not exceed £25,000, as for Redress, known as *Appendix U* checklist should be completed (found at Appendix Q in this document - Notification of Compensation Claims below £25,000).

9.11 In cases where the total expenditure exceeds £25,000, the process is detailed in the Claims Procedure.

9.12 Regular financial reports will be provided to the Claims Scrutiny Panel, for governance and scrutiny purposes.

10. Cross-Border Arrangements for Handling and Investigating Concerns

10.1 In general, Concerns and complaints about care and treatment provided on behalf of the Health Board by organisations outside Wales should be dealt with in accordance with the relevant complaints procedure which applies to that organisation.

10.2 However, if during an investigation of a complaint under a relevant complaints procedure by an organisation outside Wales, it becomes apparent that there may be a qualifying liability in tort to which the Redress arrangements may apply, then the provisions in part 7 of the Regulations may be engaged.

11. Learning from Concerns

11.1 The outcomes of all investigations into Concerns must be used to maximise opportunities for learning and quality improvement. This is a key element in the Health Board's commitment to reducing adverse events and avoidable harm to patients, service users, carers and staff, and is consistent with the aims set out in 1000 Lives Plus programme and the Health Board's key priorities. well as local learning, the Health Board is expected to contribute to the wider opportunities for shared learning.

11.2 Concerns should be seen as opportunities to improve our care and services:

Concerns

Leading to

Improvements in

Care

11.3 The Health Board uses the Datix Risk Management system to record Concerns, and to identify trends. The arrangements for monitoring these are detailed in Section 12, and are intended to ensure:

- the review of the outcome of any Concerns,
- identification of areas for learning from Concerns,
- avoidance of recurrence of harm, and
- that action is taken to improve systems and services wherever necessary.

Action Plans

11.4 Not all Concerns will require an action plan, for example where the cause of an incident is addressed directly as part of the initial investigation. Where needed, Action Plans can be effective tools in supporting improvements, however, to be effective they need to be SMART (specific, measurable, achievable, realistic and specify timescales for completion), formally approved and effectively implemented and monitored. To ensure consistency across the organisation, they should be developed using the template in Appendix S.

11.5 The support of the Clinical Audit & Effectiveness Team should be engaged to ensure that recommendation's arising from Concern action plans are audited and change(s) in practice are realised. As such where an action plan identifies clinical audit or effectiveness issues, a copy of the action plan should be sent to the Audit Lead and Clinical Audit and Effectiveness Manager.

11.6 Each Directorate must review the development and the implementation of Concerns action plans. This process needs to ensure ownership of the action plans and progression of actions by key individuals within the relevant Directorate.

11.7 Within the action plans there are often recommendations relating to education and training. It is essential that Education/Training forums for all disciplines are involved in any training recommendations as any issues that may affect the organisation as a whole require presenting to the appropriate staff Educational Forum e.g. Post/Under Graduate programme, Nursing and Midwifery and Allied Health Professional forums.

11.8 The Action Plans will be monitored via each Directorate's Patient Safety/Integrated Governance group. The process as a whole is scrutinised by the Concerns (Claims) Panel. This process is summarised in the flowchart at Appendix R.

11.9 Lessons learned from the thorough investigation of Concerns are a

powerful tool for inclusion in training and development of staff. Every opportunity will be utilised to share these lessons widely through anonymised individual examples or trends, which will include:

- Induction
- Postgraduate and undergraduate clinical education
- Links with the local University and the Deanery
- Directorate meetings at every level to ensure inclusion of all staff
- Primary Care contractors
    - Practice Manager's meetings
    - Vocational Training Scheme
- Newsletters

11.10 The Health Board will also share lessons learnt externally to reduce the risks of recurrence of similar Concerns in other areas. Mechanisms for this will include:

- Reporting to the Welsh Government's Improving Patient Safety Team for sharing lessons.
- Reports to the All Wales Concerns Manager's Network
- Patient Safety Incident reporting to the NPSA

Patient Safety Alerts

NPSA Alerts

11.11 Through analysis of reports of patient safety incidents, and safety information from other sources, the National Reporting and Learning Service (NRLS) develops advice for the NHS that can help to ensure the safety of patients. When issues arise, advice is issued via the Central Alerting System directly to NHS organisations in Wales. Alerts cover a wide range of topics, from vaccines to patient identification. Types of alerts include Rapid Response Reports, Patient Safety Alerts, and Safer Practice Notices. A flow chart for the distribution, implementation and monitoring is included in appendix u.

Other types of Alerts

11.12 Patient safety alerts from other sources are also issued, including those from the Welsh Government via Chief Medical / Chief Nursing Officer letters, as well as those from the Improving Patient Safety Team.

11.13 Management of patient safety Alerts is covered in the Patient Safety Alerts Procedures.

12. Monitoring, Reporting and Assurance arrangements

Monitoring

12.1 The Health Board has systems in place to monitor its processes for dealing with Concerns and maintains records to support this activity.

12.2 All Concerns are reported into a central register, where they will open until all corrective action has been fully implemented.

Statistical returns to Welsh Government

12.3 Welsh Government pilot is in the process of reviewing its data collection form. Once finalised, the Concerns Team will provide the Health Board's data to the Welsh Government's Statistical Directorate.

12.4 In the interim the Health Board records:

- Each concern notified to it;
- The outcome of the Concerns and whether they were well founded and;
- The timescales within which responses were sent and whether the timescales for response had been extended.

12.5 The Health Board also reports information on Concerns raised about:

- Services provided by the Health Board;
- Services provided by Primary Care practitioners in the Health Board area where the concern has been dealt with; and
- Services provided by Primary Care practitioners in the Health Board area where the concern has been dealt with by the practice in accordance with the Regulations.

12.6 In practice there will be a need to collect considerably more data than this minimum, to ensure that the information from Concerns is being interrogated and used effectively to learn lessons and improve patient safety and experience.

Internal Systems and Processes for monitoring

Directorate Reports

12.7 Concerns reports will be provided and discussed at each Locality or Directorate Patient Safety / Governance Groups. Reports will include statistical detail of numbers and trends, and details of serious incidents, as well as being a means of sharing lessons with, and learning lessons from other Directorates. The aim will be to ensure that appropriate action is being taken at Directorate level to identify and minimise risks and to improve care to patients. The group must update the Directorate and organisational Risk Register appropriately, and escalate any issues where improvements are needed but there is insufficient progress within defined timescales.

Concerns Scrutiny Panels

12.8 The purpose of these Panels is to provide a forum of expertise for scrutiny, to ensure that Concerns cases are managed in line with the Regulations, and in a manner which minimises clinical, financial and organisational risks. The Panels take a strategic overview of the Concerns process and trends, and also assess the degree of effective management, and quality of responses in a sample of cases. The scope of the Panel applies to the whole organisation.

Clinical Governance Committee

12.9 The Clinical Governance Committee receives a quarterly report on Concerns, which includes trends and details of the most serious Concerns, as well as details of any residual risk, and action being taken to make

improvements.

The Clinical Governance Committee will provide:

- timely advice to the Board to assist it in discharging its functions and meeting its responsibilities with regard to the quality and safety of healthcare;
- assurance to the Board in relation to the Health Boards arrangements for safeguarding and improving the quality and safety of patient centred healthcare in accordance with its stated objectives and the requirements and standards determined for the NHS in Wales.

Board meetings

12.10 The Board receives regular progress reports on individual serious incidents, reports on trends relating to all Concerns, and exception reports where residual risks remain high, and require escalation or are reported for information.

12.11 The reporting and assurance framework is summarised in the table at Appendix T.

Reporting Patient Experience

12.12 It should always be remembered that the Patient's Experience is paramount when managing Concerns. This needs to be conveyed as an integral part of Concerns reporting within meetings at all levels of the organisation. Staring meetings with a Patient Story supports this approach - this has become an established practice within the Health Board.

12.13 The use of Patient Stories is now actively promoted as part of the 1000 Lives Plus Programme, as an effective and powerful way of making sure that the patient's voice is heard, and that improvement to services is centred on the needs of the patient. It is a requirement of the programme that stories are used to ensure that the patient, carers, and staff's voices are heard at the highest level. The Health Board is engaged in this workstream, which is managed by the Citizen Engagement Manager within the Planning & Performance team. This team are preparing and recording Patient Stories from across the Health Board, and are developing a 'library' of stories, catalogued according to themes. They can be contacted for support and advice with reporting Patient Stories.

Independent Assessment against Standards

12.14In line with the framework set out in *Standard 23, Dealing with Concerns and Managing Incidents* (*Standards for Health Services in Wales*), the Welsh Risk Pool will undertake an annual assessment against the *Concerns and Claims Management Standard*. The results of this external and independent assessment, will be reported to the Board via the Concerns Scrutiny Panels and Clinical Governance Committee. The Health Board will use the results to further improve its approach.

Annual Report

12.15 The Health Board will prepare an annual report for each year, in compliance with Regulation 51. The report will contain, as a minimum:

- The number of Concerns received (including Concerns reported under Part 7 of the Regulations related to cross border services);

- The number of Concerns deemed well founded; and
- Number of Concerns referred to the Public Services Ombudsman for Wales.

12.16 In accordance with regulation 51(1)(d) the Annual Report will also summarise:

- The nature and substance of Concerns received;
- Any matters of general importance arising out of these Concerns or the way that they were handled including areas of concern within particular departments, staff groups, treatments or services provided, that is reporting on trends; and
- Actions taken to improve services as a result of a concern/s being notified

12.17 Where a Welsh NHS Trust, Primary Care provider or Independent provider has entered into an agreement or arrangement with the Health Board for the provision of services, they must send a copy of their annual report on the handling and investigating of Concerns to the Health Board with which they entered into such agreement or arrangement.

12.18 The Health Board must include all data collected, and must make their reports available to publicly available

12.19 An annual report will be produced using the template provided in the *Putting Things Right* guidance, to include:

- An overview of arrangements in place for dealing with Concerns
  - Any planned developments
  - Reference to working with other responsible bodies
  - Effectiveness of the arrangements, and how this has impacted on patients and staff
  - An indication of services used, for example expert advice, legal advice, alternative dispute resolution, advocacy services.
- Concerns Statistics
- Themes, trends, and key issues
- Lessons learnt
- Conclusion and priorities for improvement

12.20 The report will be placed on the Health Board's internet site, and published as part of the organisation's Annual Quality Statement.

13. Bibliography

Guide to report writing following Root Cause Analysis of patient safety incidents (National Patient Safety Agency) www.npsa.nhs.uk/nrls

National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

National Framework for Reporting and Learning from Serious Incidents Requiring Investigation (National Patient Safety Agency) March 2010

Putting Things Right – Guidance on dealing with Concerns about the NHS from 1 April 2012, Welsh Government.

Raising and Acting on Concerns about patient safety (General

14. Glossary

Term	Explanation
Access to Health Records Act 1990	Access to the health records of a deceased person is governed by the Access to Health Records Act 1990
Alternative dispute resolution	Means mediation, conciliation or facilitation
Being Open	Being Open involves acknowledging, apologising and explaining when things go wrong. The National Patient Safety Agency policy on 'Being Open' was re-launched in the Autumn of 2009
British Dental Association	The British Dental Association (BDA) is the professional association and trade union for dentists in the United Kingdom. Membership, is voluntary. The majority of members are in independent community based practices
Caldicott Principles	The Caldicott principles support safe and appropriate sharing of personal identifiable information
Child	A person who has not attained the age of eighteen years.
Claim	A claim is the basis for demanding or getting something, e.g. a patient who has been harmed makes a claim for compensation
Compensation	A financial payment or remedial treatment or a combination of both financial and remedial treatment
Complaint	Any expression of dissatisfaction
Concern	Any complaint, claim, or reported patient safety incident to be handled under the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011
Confidentiality	Ensuring that information is accessible only to those authorised to have access
Consent	As part of an investigation of a concern, permission (consent) is required from the patient to access their clinical record. Consent can be implied, such as in a case of a mother with a small child or explicit e.g. carer acting on behalf of a patient
Disciplinary Proceedings	Means any procedure for disciplining employees adopted by a NHS organisation for disciplining employees
General Medical Council	The purpose of the General Medical Council (GMC) is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine
Governance	A system of accountability to citizens, service users, stakeholders and the wider community within which healthcare organisations work, take decisions and lead their people to achieve their objectives
Health Inspectorate Wales	Healthcare Inspectorate Wales (HIW) is a unit of the Welsh Government

Independent Complaints Facilitation	An independent person (a Facilitator) will listen to the person's Concerns, talk to the people involved with the concern and to try to help resolve the concern
Independent Provider	Provider of health care under arrangements made with a Welsh NHS organisation which is not an NHS body or Primary Care provider, e.g. Private Hospital or Care Home
Individual Patient Funding request	A request made to a Local Health Board or Welsh Health Specialised Services to fund health care for an individual patient that falls outside the range of services and treatments that the Health Board has agreed to provide, e.g. high cost drugs, rare conditions, new surgical procedures
Limitation	In accordance with the Limitation Act 1980 a concern may not be notified three or more years from the date of the incident complained about or three or more years from the date that the patient became aware of the matter which is the subject of the concern
Local resolution	Means to resolve the concern locally in the first instance
Mental Capacity Act 2005	The Mental Capacity Act is a law that empowers and protects people who may lack capacity to make some decisions for them
National Patient Safety Agency	The National Patient Safety Agency leads and contributes to improved, safe patient care by informing, supporting and influencing the health sector
Non-Executive Director / Non-Officer Member	A member of the Board of a Local Health Board who is not an employee of that organisation. They are often referred to as Independent Board Members
Notification	Reporting or telling someone about a concern
Office Member	Means a member of a Local Health Board who is an employee of that organisation
Patient	A person who has received or will receive services from a responsible body
Primary Care Provider	A person or organisation (body) that has entered into a contract with a Local Health Board to provide Primary Care services e.g. General Practitioner, Dentist, Community Pharmacist or ophthalmic medical practitioners
Patient Safety Incident	Any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare
Public Services Ombudsman for Wales	If a person raising a concern remains dissatisfied they can request an independent review by the Public Services Ombudsman for Wales (PSOW). However, the PSOW expects the responsible body to respond to the person raising a concern before agreeing to review
Qualifying liability	There is proven personal injury or loss arising out of, or in connection with the care or treatment of a patient due to the service provided by the responsible body

Medical records	A medical record can consist of any information related to an individual, e.g. clinical letters, reports, test results, X-rays, observation charts, nursing notes, doctors notes, Multi-Disciplinary Team meeting records, microfiche, photos, etc.
Redress	Redress relates to situations where the patient may have been harmed and that harm was caused by the NHS in Wales. Redress can comprise of: • a written apology; • a report on the action which has or will be taken to prevent similar Concerns arising; • the giving of an explanation, and • the offer of financial compensation and/or remedial treatment, on the proviso that the person will not seek to pursue the same through further civil proceedings
Resolution	Resolution is the satisfactory outcome of a concern.
Responsible Body	Means a Welsh NHS body, a Primary Care provider or an independent provider
Responsible Officer	In the case of a Welsh NHS organisation, is a person who is an office member or an executive director of that body and who has overall responsibility for the effective day to day operations for dealing with Concerns
Root Cause Analysis	Root Cause Analysis (RCA) is a systematic investigation technique that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context on which the incident happened. (*Seven Steps to Patient Safety, NPSA 2004*)
Tariff	A tariff in respect of compensation is a fixed amount of money paid according to the level of harm a patient has suffered. This can assist staff involved in the process of appropriately and consistently determining the level of financial compensation to be awarded to patients where this is an appropriate remedy
The Data Protection Act 1998(DPA)	The DPA is the law on the processing of data on identifiable living people
Tort	A tort is a "wrong" that involves a breach of a civil duty owed to someone else, which is dealt with through civil proceedings

Cwm Taf Health Board

"On the Spot" Concerns Form

This form can be used at ward/departmental level to assist NHS staff with the recording of a concern dealt with on the spot

Details of person who raised concern:

Title - Mr/Mrs/Miss/Ms/ State other:	
Name in full and date of birth:	
Address and postcode:	
E-mail address:	
Daytime contact number: Mobile number:	
Hospital Number	

If above is not the patient, please provide the patients details:

Title - Mr/Mrs/Miss/Ms/ State other:	
Name in full and date of birth:	
Address and postcode:	
E-mail address:	
Daytime contact number: Mobile number:	
Hospital Number	

Details of the concern:

1. Date concern brought to your attention:	
2. Date concern occurred: (if different to above)	

3. If person raising the concern is not the patient, what is their relationship to the patient:
4. Name of Ward/Dept/Hospital/individual/Service/Section the concern relates to:
5. Other persons involved in the concern:
6. Outline of Concerns – what went wrong, description of the affect this has had, how they have suffered:
7. What patient/third party thinks should be done to put things right:
8. Action taken:
9. Has the person who raised the concern been advised of the action taken? YES / NO
10. Is person satisfied that their concern has now been dealt with? YES / NO (If 'No' please give leaflet on Raising a Concern – available on intranet site)

Name:	
Signature:	
Date:	

Verbal Concerns to be handled under the Regulations

This form should be completed by NHS staff when someone wishes to raise their Concerns verbally and when the concern will go on to be handled under the Regulations. A copy of the completed form should be given to the person raising the concern.

SECTION A: Details of person raising the concern

Title: State other:	Mr/Mrs/Miss/Ms/Other
Name in full and date of birth:	
Address and postcode:	
E-mail address:	
Daytime contact number: Mobile number:	
Hospital Number	

Please indicate the method you prefer to be contacted by:

[ ] Written: Post [ ]
Email [ ]

If you have any special requirements, for example English is not your first language or you have a sensory impairment, please tell us:

SECTION B: Details of the person who the concern is about if different to section A

Patient's name in full and date of birth:	
Patient's Address and postcode:	
What is your relationship to patient? i.e. friend/relative/next of kin/advocate/carer etc	
Hospital Number	

SECTION C: Details about the concern
(please answer the following questions and continue on a separate sheet(s) if necessary).

1. Name of the hospital/GP Practice/department/section/service you have Concerns with.
2. What do you think they did wrong, or failed to do?
3. Describe how you personally and or the patient have suffered or have been affected.
4. What do you think should be done to put things right?

5.	Date concern occurred or when did you first become aware of the concern?
6.	If it is more than 12 months since you became aware of the concern, please give the reason why you have not raised this concern before now.
7.	Please attach any documents to support your concern.

SECTION D: If the person raising the concern is the patient please read the statement and sign below – if you are not the patient, ignore section D and please ask the patient to complete section E.

I hereby agree that my health records and any personal information can be used in the investigation of my concern. I understand that access to my records and personal information will be limited to what is relevant to the investigation of the concern and will only be disclosed to people who need to know it in order to investigate my concern.

Signature of patient:	
Date:	

SECTION E: If person raising the concern is not the patient:

I hereby authorise

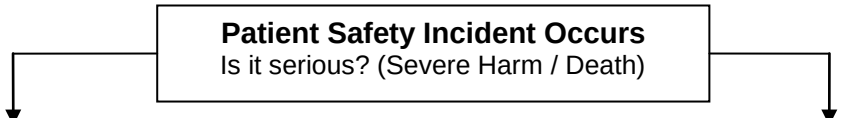
Name of person raising the concern:	
Address (if different from above):	

to act on my behalf and to receive any and all information that may be relevant to the concern.

I hereby agree that my health my health records and any personal information can be used in the investigation of my concern. I understand that access to my records and personal information will be limited to what is relevant to the investigation of the concern and will only be disclosed to people who need to know it in order to investigate my concern.

Signature of patient:	
Date:	

Appendix C – Process for managing Patient Safety Incidents



Appendix D – Grading of Concerns

Grading Framework for Dealing with All Concerns

The All Wales grading framework is based on a risk matrix developed by the National Patient Safety Agency, and has been used to assess and manage risks and incidents. This approach has been built on, to develop a framework for determining the level of investigation required in dealing with all types of Concerns in order to promote a consistent approach across NHS Wales. The impact or harm experienced by the patient is always the overriding factor for grading concerns. The harm grading is dynamic in nature, and must be considered throughout the investigation. Due consideration should also be given to the potential for litigation, regardless of the harm grading. However, there are many situations where the grading of harm is low, for example Grade 2, but there is indication that they will be pursuing a Claim.

Grade	NPSA Level of harm	Examples of Concerns	Potential for Qualifying Liability / Redress
1	**No harm** Impact Prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS funded care **OR** Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.	Concerns which normally involve issues that can be easily / speedily addressed, with no harm having arisen. For example: • outpatient appointment delayed, but no consequences in terms of health • difficulty in car parking • Concerns which have impacted on a positive patient experience	Highly unlikely
2	**Low harm** Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more	• Concerns regarding care and treatment which span a number of different aspects/specialities • Increase in length of stay by 1 - 3 days • Patient fall - requiring treatment	Unlikely

	persons receiving NHS-funded care.	• Requiring time off work - 3 days • Concern involves a single failure to meet internal standards but with minor implications for patient safety • Return for minor treatment, e.g. local anaesthetic	
3	**Moderate harm** Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.	• Clinical / process issues that have resulted in avoidable, semi permanent injury or impairment of health or damage that require intervention; • Additional interventions required or treatment / appointments needed to be cancelled; • Readmission or return to surgery, e.g. general anaesthetic; • Necessity for transfer to another centre for treatment / care • Increase in length of stay by 4 -15 days • RIDDOR Reportable Incident • Requiring time off work 4 -14 days • Concerns that outline more than one failure to meet internal standards • Moderate patient safety implications • Concerns that involve more than one organisation	Possible in some cases

4	**Severe harm** Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.	• Clinical process issues that have resulted in avoidable; semi-permanent harm or impairment of health or damage leading to incapacity or disability; • Additional interventions required or treatment needed to be cancelled; • Unexpected readmission or unplanned return to surgery; • Increase in length of stay by >15 days • Necessity for transfer to another centre for treatment / care • Requiring time off work >14 days • A concern, outlining non compliance with national standards with significant risk to patient safety • RIDDOR Reportable Incident	Likely in many cases
5	**Death** Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care, or Any patient safety incident that directly resulted in the death (or severe harm) of one or more persons receiving NHS-funded care.	• Concern leading to unexpected death, multiple harm or irreversible health effects • Concern outlining gross failure to meet national standards • Normally clinical/process issues that have resulted in avoidable, irrevocable injury or impairment of health, having a lifelong adverse effect on lifestyle, quality of life, physical and/or mental well-being. • Clinical or process issues that have resulted in avoidable loss of life • RIDDOR Reportable Incident	Very Likely

RADIATION INCIDENT INVESTIGATION REPORT FORM

Safe and Healthy Working

Datix Reference		
Directorate		
Date Incident Report Form Received by Investigator		
Investigation Report Date		
Investigators Details	**Name:**	
	Designation:	
	Contact details:	
Details of Incident	**Affected person:**	
	Where did it occur?	
	Date:	
	Time:	
	Reported by:	

INCIDENT INFORMATION – FACTS ONLY	
Background information (pre-incident)	
Description of incident (what happened)	
Description of immediate action taken	
Factors that may have had an influence on the incident	
If any, what lessons have been learnt as a result of the incident?	
Had the person(s) involved in the incident received relevant training for the task?	Yes ☐ Please state dates, details etc. Not applicable ☐
Have witness statements been requested / provided?	Yes ☐ No ☐ Not applicable ☐ Witness(s) declined to provide statement ☐
Photos attached?	Yes ☐ No ☐ Not applicable ☐
Has the Radiation Protection Adviser Been Informed?	Yes ☐ No ☐ Not applicable ☐
Has Health Inspectorate Wales been informed of the incident?	Yes ☐ No ☐ Not applicable ☐

Has Health & Safety Executive (HSE) been informed of the incident?	Yes ☐	No ☐	Not applicable ☐
Have Patient Safety been Informed?	Yes ☐	No ☐	Not applicable ☐
Have details of the radiological exposure been forwarded to the RPA to enable dose calculations to be performed?	Yes ☐	No ☐	Not applicable ☐
Has a risk assessment form been completed or updated?	Yes ☐ Please send a copy with this form No ☐ Please explain why: Not applicable ☐		
Media interest (actual or potential)	**LOW** ☐	**MEDIUM** ☐	**HIGH** ☐
Have any other agencies been informed and involved in this incident?	Yes ☐ Please state: Not applicable ☐		
Possibility of a complaint or litigation as a consequence of the occurrence?	**LOW** ☐	**MEDIUM** ☐	**HIGH** ☐

PLEASE USE THE FOLLOWING SECTION TO ADD ANY ADDITIONAL QUESTIONS OR RELEVANT INFORMATION YOU MAY WISH TO INCLUDE:

Are there any lessons to be learnt from this incident which would be of value to other Directorates within the Organisation, other health bodies or the NHS as a whole? **Yes** ☐ Please Explain Below **No** ☐

WHAT ACTION(S) NEED TO BE UNDERTAKEN TO EITHER PREVENT RECURRENCE OR REDUCE THE LEVEL OF RISK EXPOSURE?			
Action(s) Needed	**By Who**	**By When**	**Review Date**

WHAT MONITORING OR AUDIT MEASURES HAVE BEEN INTRODUCED TO ENSURE ANY IMPROVEMENTS THAT HAVE BEEN IMPLEMENTED ARE WORKING EFFECTIVELY?
(Please note - you will be asked to forward confirmation that all proposed improvements have been implemented completely and effectively and are reviewed on a regular basis)

INVESTIGATION REPORT AND ACTION PLAN REVIEWED AND AGREED			
Senior Nurse/ Manager		**Date**	
Directorate Manager or Equivalent (if applicable)		**Date**	

Appendix F – Welsh Government Serious Incident Reporting Form

RESTRICTED WHEN COMPLETED

NOTIFICATION OF SERIOUS INCIDENT
(FORM SI 1)

WG Reference		**WG Grading**	
Internal Ref or Datix No.		Date reported to Risk Management	
Organisation			
Reporters Name, Designation and contact details	Name: Job title: Contact details: E- mail:		
Date of making this report			
When did the incident occur?	Date:	Time (24 hours):	
Category of Incident (as per NRLS Incident Type Coding List)			
Is this a *never event*?			
Where did the incident occur, including site and speciality where relevant?		Local Authority Area	
Who did it affect and how many? **(*personal details must not be included*)**		Age of patient(s) if known ***(Do not provide DOB)***	

Brief description of what happened	
Brief description of immediate action taken	
Brief description of action taken if this SI involves another HB/Trust or WHSSC?	
Details of Media interest	
Has this SI been reported to the NRLS?	
What other external agencies have been informed about this incident e.g. HIW/WHSSC?	
Any other relevant information (include No Surprise ref no or Serious Incident ref no if applicable)	
Chief Executive / Executive Sign off **(This section must be completed)**	Signature: Print Name: Title: Date:
For WG use only:	

Appendix G – Welsh Government Serious Incident Update / Closure Form

Llywodraeth Cymru
Welsh Government

RESTRICTED WHEN COMPLETED

CLOSURE SUMMARY
(FORM SI 3)

WG Ref **NHS Ref**		NHS Grading	
Organisation		Date of incident	
Summary of incident (only complete if there is additional information to the original notification form)			
Please provide the following: Issues/problems identified Contributory factors Root causes			
Cause of death (if applicable)			
Confirmation of actions implemented and arrangements for completing outstanding actions		Timescale (s)	

Please indicate if the incident is associated with non-compliance of a patient safety alert, a never event or a schedule 5?			
Arrangements for dissemination of shared learning / action internally and whether they have been shared with any other NHS Organisation / agency externally			
Is there a recurring Root Cause / Theme / Concern			
Any additional information attached	Yes: [ ] No: [ ]		
Disclaimer	I confirm that this incident has been thoroughly investigated and the findings and recommendations have been agreed by the appropriate committee and have either been acted upon or plans are in place to implement the actions within an agreed timescale		
Chief Executive / Executive Sign off **(This section must be completed)**	Signature: Print Name: Title: Date:		
FOR WG USE ONLY:			
Incident Closed	**Yes: [ ]** **No: [ ]** **Signature:** **Date:**	**Further action required**	

Appendix H – Welsh Government 'No Surprises' Form

Llywodraeth Cymru
Welsh Government

RESTRICTED WHEN COMPLETED

NOTIFICATION OF NO SURPRISE/SENSITIVE ISSUE (FORM SI 2)

WG Reference	
Organisation	
Reporters Name, Designation and contact details	Name: Job title: Contact details: E- mail:
Date of making this report	
Brief description of issue	
Brief description of any action and media handling	
Any other relevant information (include SI ref no if applicable / age of patient(s) if known, rule 43)	
Chief Executive / Executive Sign off **(This section must be completed)**	Signature: Print Name: Title: Date:
For WG use only:	

Appendix I – Template for Root Cause Analysis Investigation Report

Root Cause Analysis Investigation Report

CONFIDENTIAL

Incident Investigation Title	
Executive Lead who commissioned the report	
Incident Date	*Date incident occurred*
Datix Incident Number(s)	*Include incident number and, if relevant, complaint/claim reference number*
Welsh Government Incident Reference (if applicable)	*Serious Incident Reference number if incident has been reported to Welsh Government*
Investigation Lead Officer & Author(s)	*Lead officer and other authors*
Job Title of Investigating Officer	
Investigation Report Date	
Report Status	*Version number* *Work in Progress, Draft or Final*
Executive sign-off (for completed investigation and closure)	*Name & Date* *Sign off/closure means that the investigation is complete and an action plan is in place.*

This report is CONFIDENTIAL and must not be released without express permission from the designated Executive Lead.

Contents

Terms of Reference of the investigation

- **To establish the facts across all relevant disciplines and specialties i.e. what happened (the *effect*), to whom, when, how and why (*root causes*)**
- **To establish whether issues occurred in care and/or service delivery**
- **To look for improvements rather than to apportion blame**
- **To establish how the risk of recurrence may be reduced or eliminated**
- **To formulate *recommendations* and an *action plan***
- **To provide a *report* as a record of the investigation process**
- **To provide a means of *sharing learning* from the incident**

EXECUTIVE SUMMARY	
Brief incident description	
This should be no more than a few sentences to provide an overview of what happened.	
Incident date	
Incident type	*Category from Datix code*
Directorate	
Grade and Level of harm (as a result of the incident)	*Grade 1-5; Level of harm i.e. Moderate, Severe, Death*
Level of investigation conducted (1 or 2)	
Source of identification	*Adverse Incident, Formal/Oral Complaint, Claim*
Care and service delivery problems	
Identified from the investigation	
Contributory factors	
Root Causes	
Lessons Learned	
Recommendations	
Any action already taken to reduce the risk of recurrence	
Arrangements for sharing learning (local, Health Board wide, national)	
e.g. staff meetings, newsletters, safety bulletins, emails, escalation through executive leads	

MAIN REPORT

Pre-investigation Risk Assessment

A Potential severity (1-5)	B Likelihood of recurrence at that severity (1-5)	C Risk Rating (C=A x B)

Terms of Reference of the investigation / Scope
To include: ▪ *time period covered, departments/teams involved* ▪ *key questions/issues to be addressed* ▪ *objectives/key deliverables* ▪ *was it a joint investigation with any other organisation?*
The investigation Team
Name all staff involved
Involvement and support of the patient and/or relatives
Example: The patient has been informed about the incident and given the name one contact. It has been explained that further details will become available throughout the investigation process and that a meeting to update them on initial findings has been arranged for XXX. Due to the complexity of the incident, it has been explained that they will need to be contacted with ongoing updates as information becomes available.
Involvement and support provided for staff involved
This could include an initial de-briefing, but must not be seen as a one off process. Counselling support also needs to be offered. Staff have been informed that an investigation is underway.
Investigation type, process and methods used
What has the investigation involved e.g. RCA, interviews with staff, incident decision tree etc.
Description of key events
This should be a description of the events surrounding the incident, using bullet points wherever possible and drawn from the tabular timeline/chronology below
Information and evidence gathered
i.e. interviews with staff, medical records reviewed, expert advice obtained etc.

Chronology (tabular timeline)	
Date & Time	**Event**

INVESTIGATION FINDINGS
Notable/Good Practice Identified
Points in the incident or investigation process where care and/or practice had an important positive impact and may provide valuable learning opportunities. *Example: Actions taken to inform the patient and relatives of the error in an open and honest way; the patient and carer having been given the opportunity to express their views on the incident.*
Care delivery or local problems (identified via tabular timeline, brainstorming, change analysis etc.)
These are either things that we haven't done but should have, or things that we did but shouldn't have been done. *Care delivery or local problems are problems that relate to direct provision of care. They arise in the process of care and are usually actions or omissions by members of staff. They have two essential features a) care deviated beyond safe limits of practice b) the deviation had at least a potential direct or indirect impact on the eventual*

adverse outcome for the patient, member of staff or "general public" *e.g. failure to monitor*
Service delivery or organisational problems (identified via tabular timeline, brainstorming, change analysis etc.)
Service delivery or organisational problems are failures identified during the analysis of the incident, which are associated with the way a service is delivered and the decisions, procedures and systems that are part of the whole process of service delivery. e.g. No maintenance contract for equipment.
Contributory Factors (e.g. classification framework, fishbone or '5 Why's')
A summary of the significant problems need to be listed, and each one analysed to identify the factors that contributed to the problem. *Where many contributory factors are identified, the classification framework (and fishbone) should be included in the Appendices to show the full list of factors identified.* *e.g:* • *Staffing levels were low at the time due to unfilled vacancies.* • *There were no beds available in the hospital due to full occupancy* • *Flu epidemic caused staff shortages and increased admissions*
Root causes
These are the most fundamental underlying factors which contributed to the incident that can be addressed. Root causes should be meaningful, (not sound bites such as communication failure) and there should be a clear link, by analysis, between root CAUSE and EFFECT on the patient. *Root causes will be a summary of the most important contributory factors identified in the process above.*
Lessons Learned
Lessons identified (which directly contributed to the incident)
Key safety and practice issues identified which directly contributed to the incident from which we can learn to prevent the concern from recurring.
Incidental learning (other problems identified during the investigation which did not impact upon the concern)
Key safety and practice issues identified which may not have contributed to this incident but from which others can learn. *e.g. During the investigation it became evident that the clinical information documented on the patient clinical record was below an acceptable standard and hindered the investigation process i.e. results not filed and observations not recorded.*
Recommendations
Recommendations (numbered and referenced) should be directly linked to root causes and lessons learned, They should be clear but not detailed (detail belongs in the action plan). It is generally agreed that key recommendations should be kept to a minimum wherever possible.
Arrangements for Shared Learning
Describe how learning has been or will be shared with staff and other organisations (e.g. through bulletins, professional networks, NPSA, etc.). Must ensure that there is organisational wide learning. Where appropriate the report will be shared with Welsh Government and other networks to support wider pan NHS Wales learning.
Distribution list

NB – All completed appendices should be included with this report

Post-investigation Risk Assessment

A Potential severity (1-5)	B Likelihood of recurrence at that severity (1-5)	C Risk Rating (C=A x B)

Appendix J – Timescales for Handling Concerns

NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

TYPE OF RESPONSE AND REGULATION WHICH APPLIES	Type of Case	Within 2 working days*	Within 30 working days of first receipt Majority of cases	Within 6 months of first receipt Exeptional (Reasons must be given)	Within12 months of fist receipt Majority of cases	Longer that 12 months Exeptional (Reasons must be given)
Acknowledgement letter (Regulation 22)	All cases	✓				
Final response (Regulation 24)	Cases that do not involve issues of liability		✓	✓		
Interim response (Regulation 26)	Cases that do or may involve issues of liability		✓	✓		
Investigation Report and Communication of Decision (Regulations 31 and 33)	Cases that do or may involve issues of liability				✓	✓

***Important note** – The two working day acknowledgement period falls within the overall 30 working days for response

Appendix K – Guidance on Consent to Investigation of Concerns

This note sets out when explicit consent needs to be obtained from the patient or, if deceased, the next of kin, in order to carry out an investigation of a concern.

1. Concern raised by a patient or their personal representative

If, as in the majority of cases, the patient him/herself raises the concern, then in doing so, they can be deemed to have given implied consent to an investigation. This will also apply if the person has a representative who is entitled to act for them legally (e.g. Power of Attorney). However, in order for individuals to be clear in the knowledge that their medical records may need to be accessed, this should be explained. This scenario is set out at acknowledgement letter "1" under the heading *Medical Records* contained in the letter. In the event that the patient/personal representative contacts the Health Board after raising the concern to say that they are not happy for consent to be inferred and they do not want their records to be accessed, then Health Board must take a view on whether the issue in question is of sufficient seriousness to merit an investigation without access to the medical records. It is not necessarily the case that there will be no investigation of the concern. Organisations should evaluate the issue to determine whether it would be in the interests of the health service to continue to look into the matter. This decision must be recorded before proceeding with or closing the matter.

2. Concern raised by a carer/family member/elected member/other individual (e.g. person visiting someone else)/casual observer

Where a concern is raised on behalf of a patient, then written consent to investigate the matter should be obtained from the patient, unless the person raising the concern is already legally entitled to represent the patient (e.g. through a Power of Attorney – see section 1 above). Again, if it is not possible to obtain written consent for whatever reason, the Health Board must take a view on whether the issue in question is of sufficient seriousness to merit an investigation without access to the medical records. It is not necessarily the case that there will be no investigation of the concern. The Health Board should evaluate the issue to determine whether it would be in the interests of the health service to continue to look into the matter. This decision must be recorded before proceeding with or closing the matter.

3. Concern raised about a deceased person by their next of kin/personal representative

In this instance, then the same situation applies as set out at section 1 above, whereby implied consent is assumed. The investigating officer should be satisfied that the person is entitled to act on behalf of the deceased. The same consideration is required in terms of the continuation of the investigation as in section 1 above, if the next of kin/personal representative indicates that they are not happy for records to be accessed.

4. Concern raised about a deceased person by someone other than their next of kin/personal representative

In this instance, the same situation applies as in section 2 above, where the written consent of the next of kin or personal representative should be obtained.

The same consideration is required in terms of the continuation of the investigation as in section 2, if it is not possible to obtain this written consent.

5. Concern raised in behalf of a child or person who lacks mental Capacity

It is acceptable for people to raise Concerns on behalf of a child (e.g. by a parent/guardian) or someone who lacks mental capacity (e.g. an advocate/carer). In these instances, consent to access medical records is not required, but if the patient is a child, the Health Board will need to decide whether it is reasonable for another person to represent the child, or if they are able to take forward the concern themselves, with support if necessary. The key issue is the involvement of the child in the handling of the matter. Because someone else has raised a concern on behalf of a child, this does not remove the right of the child to take the concern forward themselves, with support. The Health Board should therefore satisfy itself as to whether the child wishes to raise a concern themselves, with assistance or if they are happy for the person who raised the concern to represent them. If the child is not willing to allow the concern to be investigated then a decision will need to be taken about proceeding and specialist advice sought if appropriate. Particular regard needs to be given to safeguarding issues, and it may be necessary to proceed with an investigation, even if a child appears unhappy to do so. The Health Board is under no obligation to provide a response to the person who raised the concern in the first place. For both children and people who lack mental capacity, the Health Board must assure itself that the representative is a suitable person (i.e. that they are entitled to represent the patient). If difficulties arise and it is not possible to establish who is entitled to bring forward a concern on behalf of a patient, the same consideration as set out in sections 1 and 2 in relation to the continuation of the investigation is required, and this must be recorded.

6. Concern raised by a staff member

Concerns about something having gone wrong during treatment can be raised by staff members. An initial investigation into the circumstances should proceed immediately in the interests of patient safety, in order to determine the extent of harm or otherwise that may have been caused. The patient's consent is not required to undertake this initial investigation. However, if the initial investigation reveals that moderate or severe harm or death has resulted from the situation, then the patient or their representative must be contacted. They should be advised that initial investigations have given rise to Concerns, and that further, more detailed investigations are required. In these situations, the written consent of the individual in question is required. If this consent is withheld, once again, the Health Board must take a view on whether the issue in question is of sufficient seriousness to merit an investigation without access to the medical records. It is not necessarily the case that there will be no investigation of the concern. The Health Board should evaluate the issue to determine whether it would be in the interests of the health service to continue to look into the matter. This decision must be recorded before proceeding with or closing the matter.

Appendix L – Template Form for Witnesses

CONFIDENTIAL WITNESS FORM

Incident Reference No.	W
Surname	
Forename	
Title	Dr ☐ Mr ☐ Mrs ☐ Ms ☐ Miss ☐
Job Title	
Home Address	
Contact Telephone No.	

INCIDENT DETAILS			
I WAS A WITNESS TO AN INCIDENT THAT OCCURRED:			
Site Hospital, clinic, other etc.			
Exact location Section, room etc.			
On - date		**Time**	
To (if known)			
FACTUAL DESCRIPTION OF THE INCIDENT			

I confirm that the contents of this my statement are true to the best of my knowledge, information and belief			
Signature		**Date**	

Preparing for an Inquest

Guidelines for Staff

Contents

1. Introduction

Most people do not relish the prospect of being a witness in either a criminal or a civil case. Frequently, at the heart of the person's reluctance to attend Court is a fear of what the process of giving evidence will involve. The fear is based primarily upon a lack of knowledge of what goes on in a Courtroom and the role of a witness, which is aggravated by misleading portrayals of cases on television. The aim of this document is to explain the role of the Coroner, the purpose of inquests and provide guidance to staff involved in an inquest.

2. Role of the Coroner

The Coroner is an independent judicial officer, a doctor or lawyer, with statutory responsibility for investigating deaths under various circumstances, where the death must be reported to him. The Coroner's role is to establish who died, where they died, when they died and how they came by their death, i.e. by what means and in what circumstances, including the medical cause of death. The coroner also has jurisdiction to inquire into any treasure which is found in his district and who is the finder of the treasure.

3. Reportable Deaths

The Coroner investigates deaths reported to him/her. There is no statutory duty upon a doctor to report any death to the Coroner. However, there is thought to be a common law duty on every citizen to report a death which occurs under circumstances requiring an inquest to be held. Regardless of the precise duty, it is considered good practice for doctors to be aware of reportable deaths and to report them promptly and correctly. A list of reportable deaths is included at **Annex 1**.

4. Post Mortem

Notification will be sent to the responsible clinicians where the Coroner requests a post mortem examination be carried out. The clinicians will be advised of the date and time of the examination. If it is thought that the death occurred solely or partly due to the negligence of a medical practitioner, the medical practitioner cannot carry out or assist at the post mortem but will be entitled to be represented there.

5. Requests for Statements

If an inquest is to be held witness statements will be required. In this situation the Coroner's Office will contact the Concerns Department, to request statements be obtained from all relevant staff involved in the patient's care and treatment. The Concerns Investigation Officer will request statements from the relevant staff via the Director/Directorate Manager/Head of Nursing.

The Concerns Investigation Officer will contact the Health Board solicitor, if it is considered necessary. This will be the case where certain care issues are identified, there is potential for public embarrassment arising from the patient's NHS treatment or it is thought the family is likely to pursue a claim against the Health Board. If the Health Board's solicitor has been contacted they will ask to see the witnesses to go through their evidence. The solicitor will focus on any areas of concern and help witnesses as necessary.

The Concerns Investigation Officer and Health Board solicitor, as appropriate, will provide staff and managers with advice and support for inquests, as needed.

The Concerns Investigation Officer will forward all statements to the Coroner within 28 days of receipt of the request.

For information on the format and content required for witness statements please see **Annex 2**.

6. The Inquest

An inquest is an enquiry into the medical cause and circumstances of a death. It is a fact finding enquiry, not a trial and as such it is not the Coroner's job to blame anyone. It is a hearing for the benefit of the living, not retribution for the dead. However, an inquest may have a bearing upon legal action pursued in another court.

An inquest is held in public and may have a jury. The Coroner will organise the enquiry to best serve the public interest and the interests of the relatives.

Relatives can attend an inquest and ask questions of witnesses. These questions can only relate to the medical cause and circumstances of death.

6.1. Attendance

An invitation to attend a coroner's inquest is an order and as such the individual must attend. The Coroner has legal authority to issue a summons, if necessary. Staff who have not been requested to attend may still do so if required to provide support.

6.2. Before the Inquest

It is usual for a request for written statements to be submitted before an inquest. Statements should be completed as soon as possible, and within 28 days, and contain a full and factual account of the individual's involvement in the patient's care. Full details of statement requirements are contained in **Annex 2**. The statement should only be prepared with access to the relevant medical records. If it is considered necessary the Concerns Investigation Officer or Health Board solicitor can provide assistance in drafting statements and reports.

Upon receipt of the statements and any other supporting information the Coroner will decide which witnesses are required to attend court. Whether or not witness evidence can be read out in court or needs to be given orally is at the discretion of the Coroner. The Coroner's Office will send summonses to the Concerns Department for distribution to the relevant staff as appropriate.

Staff may wish to seek advice and help from their respective professional organisation or union and may wish to visit the Coroner's court prior to the inquest, this can be arranged via their line manager.

It is advisable to read the statement that you have submitted prior to attending the hearing and to take a copy with you. It is also advisable to familiarise yourself with the health care records prior to the inquest, especially for the Consultant in charge or for any senior member of staff that might be presenting another individuals account. The original records will be available for reference in the court if required.

The Concerns Team will provide each person called as a witness with a copy of all the evidence / statements submitted to the Coroner.

6.3. The Hearing

Witnesses will be informed of the date, time and location of the inquest. Witnesses should remember they are representing the Health Board and as such should arrive at least half an hour prior to the start of the hearing and be smartly dressed. This helps convey a professional image and demonstrate respect for the deceased and their relatives. A Do's and Don'ts guide for witnesses is included in **Annex 6**.

There is no dress code although smart/smart-casual and the coroner should be addressed as Sir or Ma'am. Witnesses may wish to bring a friend or colleague for support at the inquest and this is entirely acceptable. The Concerns Officer and/or Health Board solicitor will also be present, if necessary.

The layout of the Court: the Coroner will sit behind a bench at the front, with the barristers and solicitors on the first row in front of him. If a barrister is representing a party then their solicitor will sit behind them.

The Coroner decides in what order witnesses will be called. However, this is normally in chronological order in respect of the deceased's care.

Witnesses give evidence under oath, meaning you must swear on a holy testament to tell the truth or if you do not have a faith, you may give an affirmation. Several holy books of different faiths will be available.

Reading over your statement and the deceased's records will allow the witness to respond with greater ease and gives a good impression. If a witness needs to refer to the medical records they should simply ask the Coroner for the opportunity to do so before answering. Witnesses should only answer the question asked and not attempt to answer questions outside their area of expertise.

Relatives are invited to ask questions, after the Coroner has finished questioning the witness and some families choose to be represented at the Inquest by a solicitor and some by a barrister. A barrister is generally more experienced in appearing in Court to ask questions than a solicitor. The barristers have to obey the Code of Conduct. If a Health Board representative is in attendance they may ask questions after the family, or their representative, has finished.

A witness is not expected to answer any question which could incriminate them and should decline to do so. If professional conduct or competence is called into question an adjournment can be requested so legal representation can be arranged.

Once the witness has finished giving evidence they will be asked to step down. Upon request to the Coroner, the witness may leave the court.

6.4. Evidence from the Pathologist

Depending on its relevance to the issues, the Concerns Investigation Officers may obtain a copy of the post mortem report before the start of the inquest, although release of post mortem reports is entirely at the discretion of the Coroner. The pathologist may be an employee of the Health Board working in a diagnostic capacity but is independent of the Health Board (and paid accordingly) when performing Coroner's post mortems.

Where the medical cause of death is clear the pathologist is normally called at the beginning of the inquest. Where there are questions regarding care or causation it is usual for the pathologist to be called at the end of the inquest. In this situation it is advised that senior clinicians remain, until the pathologist has finished giving evidence, as consultation may be necessary to formulate a precise cause of death. In some instances the Pathologist may not be called and the post mortem report or the final conclusion of the report may be read out in court.

6.5. Jury Inquests

The majority of inquests are held with the Coroner sitting alone. However, under Section 8 of the Coroners Act 1988, a number of instances exist where a jury must be called. **Annex 3** gives a list of these situations. The Coroner also has discretionary power to summon a jury, in cases other than those listed.

The role of the jury is to listen to the evidence, ask appropriate questions and reach a factual verdict based on the evidence presented.

The jury is selected from the electoral register, in the same way as it is summoned to the Crown Court. The jury will consist of no less than seven and no more than eleven members.

6.6. Possible Verdicts

When all the evidence has been presented and, prior to the verdict being given, the Coroner will normally provide an oral summary. A verdict is given on the balance of probabilities, except for a number of exceptions. A number of possible verdicts, such as natural causes, suicide, accident/misadventure and unlawful killing, are suggested in the Coroners Rules 1984. An open verdict will be given where the evidence is inconclusive. Evidence must prove beyond a reasonable doubt for a verdict of suicide to be given. Narrative verdicts have become more common in recent times and give a simple factual statement of the circumstances in which the patient died.

Clinical negligence cannot be indicated in any way by the given verdict. The Coroners Rules allow recommendations to be made to organisations where action is believed necessary to prevent potential similar deaths – Rule 43.

6.7. Press and Publicity

As inquests are held in public the press will often be present throughout. Staff attending an inquest should not speak to the media. Any enquiries should be directed to the Concerns Department, and will be managed collaboratively with the Head of Communications.

7. After the Inquest

The Coroner's verdict and any recommendations or comments will be disseminated to the relevant Directorate for consideration. Discussion will take place regarding lessons to be learnt and actions to be taken in order to minimise the risk of similar incidents occurring in the future. A subsequent follow up may be carried out by the Patient Safety Department and a report presented to the appropriate Committee.

8. Step by Step Guide

A step by step guide to inquests is attached at **Annex 4**.

9. Coroner for Bridgend and the Glamorgan Valleys

Louise Hunt
HM Coroner Bridgend and the Glamorgan Valleys
Coroners Court,
Council Buildings
1st Floor, Rock Grounds
Aberdare
CF44 7AE
Telephone 01685 885202

10. References

- Coroners Act 1988
- Mental Health Act 1983
- Health and Safety at Work etc. Act 1974

ANNEX 1

Reportable Deaths

A death should be referred to the Coroner in the following situations:

- It cannot readily be certified as being due to natural causes
- The deceased was not seen by a doctor within the 14 days prior to death.
- There is any element of suspicious circumstances or history of violence
- The death may be linked to an accident (whenever it occurred)
- There is any question of self-neglect or neglect by others
- The death has occurred or the illness arisen during or shortly after detention in police or prison custody (including voluntary attendance at a police station)
- The deceased was detained under the Mental Health Act
- The death is linked with an abortion
- The death might have been contributed to by the actions of the deceased himself (such as a history of drug or solvent abuse, self-injury or overdose)
- The death could be due to industrial disease or related in any way to the deceased's employment.
- The death occurred during an operation or before full recovery from the effects of an anaesthetic or was in any way related to the anaesthetic (in any event a death within 24 hours should normally be referred)
- The death may be due to a lack of medical care.
- There are any other unusual or disturbing features to the case.
- The death occurs within 24 hours of admission to hospital. (unless the admission was purely for terminal care)

It is recommended to report any death where there is an allegation of medical mismanagement.

ANNEX 2

Coroner Statement Requirements

The following is a guide on how statements for the Coroner should be prepared, presented and the information they should contain.

Format

- The statement should be typed on Health Board headed paper.

- State clearly in the header the name of the patient the statement is referring to. Details of names, dates of birth/death, hospital number and dates of specific incidents must be included.

- The statement should clearly identify your name, current position and that at the time of the incident, any relevant qualifications that you hold and years obtained, number of years of experience in the relevant area and where you are normally based, e.g. clinical area and directorate where you were based at the time.

- The statement should include, to the best of your knowledge, the number of staff on duty and the number of other patients on the ward.

- In the footer the statement should be numbered, signed and dated.

Content

- Write the statement in chronological order providing an account of your involvement with the patient.

- The statement should be factual and not contain personal opinion about matters outside your field of expertise. The statement must not contain hostile, offensive or unnecessarily defensive comments.

- The statement should be written in the first person singular, e.g. “I saw ……”

- Write the statement using the past tense, e.g. “I went” or “I recorded in the notes.”

- Call the patient by their name rather than “the patient”.

- Be consistent through the entire statement in using the past tense, the patient’s name and the way that you write the date, i.e don’t put 5/10/2012 and then refer to 5 October 2012.

- Where you refer to other individuals, clarify who they are by using their name and job title.

- You must be as accurate as possible in relation to dates, times and dosages of drugs etc.

- Statements must not be written without access to the health care records

- Clearly state what you can and cannot recollect from memory and what has been taken from the records. It is acceptable to directly quote the records in circumstances where it might be helpful to do so. Reference to your normal practice may also be helpful if something is not noted in the records.

- Reference should be made to relevant policies, procedures and guidelines in use at the time, if appropriate, and copies attached to the statement. If you deviated from any policies/guidelines explain reasons for this.

- If you use abbreviations, ensure that full terminology is given at least once, with the abbreviation to be used in brackets. Technical terms can be used but you should try to explain them in lay terms where possible.

- Conclude your statement with a Statement of Truth "The facts stated in this Witness Statement are true" and the date, your designation and your signature.

- It would be helpful to ask a colleague to proof read your statement as submitting a statement with grammatical/punctuation errors may suggest to the coroner or the family that you have not taken the time and trouble to prepare properly.

Signed and dated statements are legal documents and may be disclosed to a patient, their representative or legal adviser.

Always retain a copy of your statement for future reference.

When drawing up a statement you have the right to seek advice from your legal defence body or union. Advice can also be sought from the Concerns Department and the Health Board's solicitor.

Copies of Statements **must not** be put in the patient's records.

ANNEX 3

Instances Requiring a Jury

As per the Coroners Act 1988 the following instances require the Coroner to hold an inquest before a jury:

- that the death occurred in prison or in such a place or in such circumstances as to require an inquest under any other Act.

- that the death occurred while the deceased was in police custody, or resulted from an injury caused by a police officer in the purported execution of his duty.

- that the death was caused by an accident, poisoning or disease notice of which is required to be given under any Act to a government department, to any inspector or other officer of a government department or to an inspector appointed under section 19 of the [1974 c. 37.] Health and Safety at Work etc. Act 1974.

- that the death occurred in circumstances the continuance or possible recurrence of which is prejudicial to the health or safety of the public or any section of the public.

ANNEX 4

Step by Step Guide

The following is a brief step by step guide to inquests and being a witness. This section should not be read in isolation and should be read in conjunction with the full guidance for inquests.

Statements

Patient Incidents

1. Coroner requests statements and information from the Concerns Investigation Officer.

2. Concerns Investigation Officer notify the Director/Directorate Manager and the Clinical Risk Facilitator of the request.

3. Director/Directorate Manager and Clinical Risk Facilitator forward all information and statements in their possession to the Concerns Investigation Officer.

4. Concerns Investigation Officer go through the information and
   a. if all the requested statements and information is present forward it to the Coroner (within 28 days of the request),
   b. if not all the statements or information is present, the Concerns Investigation Officer will contact the Director/Directorate Manager/Clinical Risk Facilitator to request that they gather the relevant information or that the member of staff is informed that they must write a statement,

5. Once the Concerns Investigation Officer receive the additional information it will be forwarded to the Coroner (within 28 days of the request).

Staff/Visitor Incidents

1. Coroner requests statements and information from the Concerns Department.

2. Concerns Investigation Officer notifies the Directorate Manager/Director and Risk Management Co-ordinator of the request.

3. Directorate Manager/Director/Risk Management Co-ordinator forwards all information and statements in their possession to the Concerns Investigation Officer.

4. Concerns Investigation Officer go through the information and
   a. if all the requested statements and information is present forward it to the Coroner (within 28 days of the request),

b. if not all the statements or information is present, the Concerns Investigation Officer will contact the Director/Directorate Manager/Clinical Risk Facilitator to request that they gather the relevant information or that the member of staff is informed that they must write a statement.

5. Once the Concerns Investigation Officer receive the additional information it will be forwarded to the Coroner (within 28 days of the request).

Health Board's Solicitors Involvement

If a potential legal claim is identified, through the investigation, the Concerns Department involve the Health Board's Solicitor.

1. As points 1 – 3 above.

2. Concerns Investigation Officer asks the Director/Directorate Manager to inform the relevant member(s) of staff that they will need to meet with the Health Board's Solicitor to go through their statement/evidence.

3. Solicitor meets with the member of staff and discusses the statement.

4. Member of staff passes their statement to the Director/Directorate Manager.

5. Director/Directorate Manager forwards the statement to the Concerns Investigation Officer.

6. Concerns Investigation Officer forwards the statements and all other information to the Coroner (within 28 days of the request)

Giving Evidence

The role of the witness: the key point is that he or she is there to help the Court by telling the Coroner the facts and information that is within his or her realms of knowledge. Although the witness may not have been directly involved with all of the deceased's care, the Coroner will expect the witness to have a good overview of their care and be able to answer general questions on any aspect of it.

Remember

- You are not on Trial.
- You should be yourself when giving evidence.
- The Coroner will not think ill of you if you do not know the answer to a question or cannot remember something.

- The Coroner will be sympathetic to the fact that you have had to come to Court and he will be extremely grateful that you have taken the trouble to do so.
- You will be able to refer to your witness statement, when giving evidence, to refresh your memory – it is not a “memory test”.
- You will be allowed a break if they require one.
- Oppressive or unfair questions from the opposing barrister or solicitor will be disallowed.

The Coroner will expect you to be familiar with the patient’s care and medical records and will want you to speak meaningfully about the treatment given.

1. Read over statement written for the Coroner and the patient’s records, if appropriate

2. Arrive promptly and smartly dressed

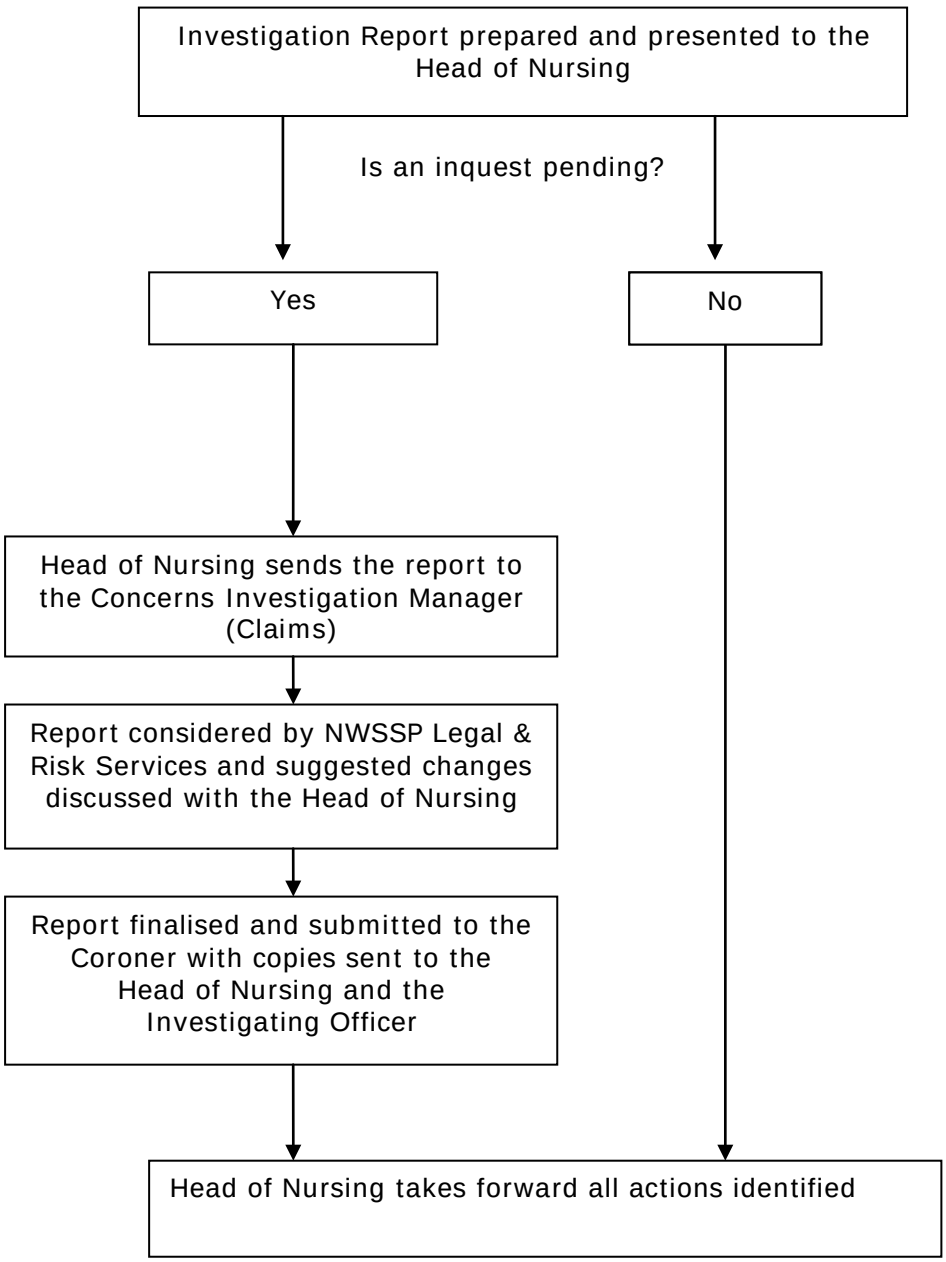
3. Answer only the question asked and none that are outside your area of expertise

4. If you need to look at the patient’s notes request permission to do this from the Coroner, prior to answering the question

5. After you have been told to step down you may by request to the Coroner leave the Court.

ANNEX 5

Flow Chart for Investigation Reports



Do's and Don'ts for witnesses

DO:

- Speak up.
- Speak slowly.
- Answer the question asked.
- Keep the answer as succinct as possible.
- Ask the question to be repeated if it was not audible.
- Reply "I don't know" if you do not know the answer.
- Reply "I can't remember" you cannot remember a particular point.
- Be courteous.
- Take your time.
- Think about the question and the answer before giving it.
- Stick to what you know from your own knowledge.
- Ask to refer to the witness statement if you need to refresh your memory.
- Tell the Coroner you do not understand the question if that is the case.
- Direct all answers to either the Coroner or the family of the patient if they are in Court, and not the barrister or solicitor.
- Familiarise yourself with the contents of your witness statement at least the night before and, if necessary, again during the morning before the Inquest starts.
- Inform the barrister or solicitor, before the start of your evidence, if any of the contents of the statement are incorrect.
- **Tell the truth.**

DON'T:

- Guess or speculate on the answer to a question.
- Argue with the barrister or solicitor.
- Ask questions of the barrister or solicitor or rhetorical questions.
- Get angry or upset.
- Keep going if you need a break.
- Be rushed into giving an answer without thinking.
- Be forced to answer questions at a pace with which you are uncomfortable; answer questions at your own pace.
- Allow yourself to be browbeaten into saying "yes" when you have said "no" to the same or similar question several times already.
- Give the barrister or solicitor the answer he wants simply to get him off your back.
- Speak to other witnesses about your evidence.
- Speak to anyone about the case if there is a break and you are still in the middle of giving your evidence.
- Swear or use coarse language unless you are repeating something you overheard which is relevant to the case.
- Turn up at Court only 5 minutes before the case is due to start; arrive either at the time the solicitor has directed or, in any other case, at least half an hour before the case is due to start.
- Waffle.

- Worry or concern yourself with the *argument* the barrister or solicitor is seeking to make; stick to the facts.
- Try and anticipate the questions the barrister or solicitor is going to ask you in a few minutes' time; take each question one at a time.
- Refuse to answer a question (unless you are told by the Coroner that you may do so).
- Turn up and tell the Coroner you have not had the chance to read your witness statement recently or you are not sure if the contents of it are true (this will cause unnecessary delay).
- Tell the Coroner the contents of your statement are true even though you know one or two points are not but you feel that you must stick to the statement because you have signed it on a previous date (if the statement contains an inaccuracy that must be corrected at the outset).
- Worry or concern yourself about how you will come across; if you be yourself you will be fine.

Appendix N – Dealing with people who make unreasonable demands

This section aims to provide a summary of how to manage a concern where the person raising the concern starts to behave unreasonably, becomes abusive, threatening or violent towards NHS staff. This summary must be read in conjunction with the Health Board's Violence and Aggression Policy and in line with the training provided.

People raising Concerns have the right to be heard, understood and respected. However, there may be times when the distress of a situation leads to the person raising a concern acting out of character and becoming determined, forceful, angry, make unreasonable demands of staff or (rarely) even resort to violence. People who are unhappy about the outcome of the investigation of their concern, despite being advised on other avenues available for them, may also show aggression towards staff or continue to persistently pursue their concern by phoning, writing or in person. Although NHS staff understand that a person's anger and aggression may be as a result of the distress that has been caused to them or to their loved ones, behaviour that escalates into actual or potential aggression towards NHS staff is not acceptable. Examples of unacceptable aggressive or abusive behaviour include:

- Verbal threats e.g. personal abusive comments, rudeness or derogatory remarks. - - Unsubstantiated allegations or offensive statements can also be termed as abusive behaviour;
- Physically violent behaviour;
- Threatening remarks e.g. both written and oral which result in staff being afraid or left feeling abused;
- Unreasonable demands e.g. the demand for responses within unrealistic timescales, repeatedly phoning, writing or insisting on speaking to particular members of staff.

Dealing with unacceptable actions or behaviour

When people behave in an unacceptable manner towards staff, appropriate action should be taken in line with your organisational policy and procedures.

Where a person raising a concern becomes aggressive or abusive you should consider the following:

- If there are threats or use of physical violence then the incident should be reported to the police;
- If correspondence (letter, electronic or fax) is abusive and contains threats to staff or the organisation this must be reported to Senior Mangers/ police;
- If written unsubstantiated allegations are received then the person should be told that the language used is unnecessary and unhelpful. It should be made clear to them that if the behaviour and use of language continues all forms of communication will stop;

- If person is aggressive, abusive or offensive whilst on the telephone then they should be told that their behaviour is unacceptable and if it continues the call will be ended.

Managing persistent behaviour

If a person repeatedly telephones, visits or raises a concern which has already been investigated and a response sent then you should consider:

- Putting an arrangement in place whereby calls can only be received from them at set times on set days;
- One member of staff to be allocated as a contact point for written or verbal communication;
- Restricting contact to written correspondence only;
- Only making appointments to meet with the person if there is no other way of communicating with them – **Never meet them alone**;
- Communicating a decision that no further correspondence or telephone calls will be accepted unless a new issue is raised;

At each stage, it should be made clear to the person what actions are being taken and why.

Reporting Violent or Aggressive Behaviour

Incidents where violence and/or aggression occur must be reported and recorded using the Datix system. Recording incidents where a person raising a concern has become violent or aggressive will identify trends and 'hot-spots' where incidents of aggressive behaviour occur. The Health Board can then learn lessons to protect staff and prevent similar incidents of aggression.

Supporting Staff

If you find yourself in a threatening or violent situation, remember the 3 R's:

- **R**etreat

- **R**aise the alarm

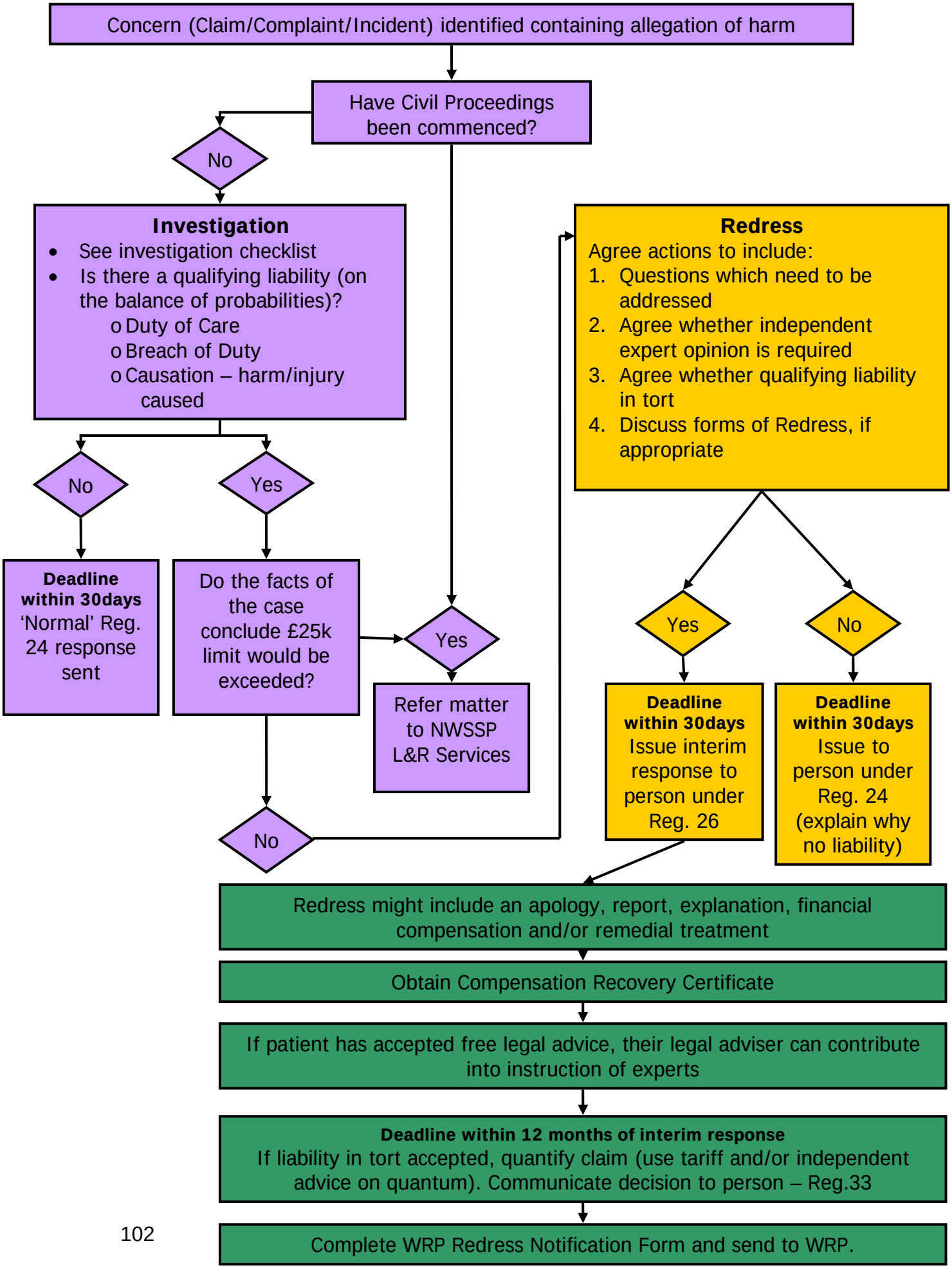
- **R**e-assess

You should never put yourself in a risky situation, if this should happen your first duty is to protect yourself by getting out, staying out, and obtaining support.

Appendix O – Redress Investigation checklist

1. Review the PAS System. Identify any radiology relevant to the treatment which is the subject of the concern.
2. Check the patient's medical records and copy only those records which are relevant to the concern including clinical notes, correspondence, operation note(s), consent form(s), anaesthetic records, pre-operation check-list(s), postoperative notes, discharge summary, test results, temperature and blood pressure chart(s), medication charts (if any) and nursing care plans/Kardex.
3. Check whether there are any incident forms and/or policies/protocols in existence of relevance to the concern.
4. Identify the Healthcare professionals involved in providing the care and/or treatment to the patient which is the subject of the concern and the clinical lead in charge of the patient's care at the time. This may be a medical Consultant or another professional lead, such as the relevant Head of Nursing.
5. Provide the relevant healthcare professional lead, with details of the concern raised and request that they provide you with a detailed factual account of their involvement with the patient, and their comments upon the concern(s) raised. Ask professional lead in charge of the patient's care at the relevant time if they are able to comment upon whether they consider any aspect of the patient's care and/or treatment to have fallen below a reasonable standard of care (Bolam test) and if so, whether they feel able to comment upon any affect that any failings have had upon the patient's treatment and/or outcome (causation). You may need to approach a Consultant in an alternative specialty for comments upon causation. N.B. Any comments will be disclosable should legal proceedings be brought against the Health Board in relation to the subject matter of the concern.
6. Consider whether there would be merit in requesting a face to face meeting with any of the healthcare professionals involved if the comments you have received do not serve to address the patient's concern(s) or assist your investigations.
7. Consider whether there would be merit in obtaining a report upon breach of duty and/or causation and condition and prognosis (patient's long term outcome) from an independent clinical expert and the field of expert it will be necessary to instruct. N.B. Any expert evidence will be obtained on a joint basis between the healthcare provider and the person who raised the concern.
8. Provide a copy of any independent clinical reports to the relevant professional lead and request that they provide you with any comments they have upon the content of the report(s).
9. Review clinician comments and/or independent clinician reports and consider whether there is a qualifying liability, on the balance of probabilities.
10. If you have any queries at any stage of the investigation process, contact NWSS Partnership Legal and Risk Service.

Appendix P – management of Concerns (Complaints) – Process Flow Chart



Appendix Q – 'Appendix U' under *Putting Things Right*.

Notification of Compensatory Payments below £25,000

Name and address of Health Board/Trust	Cwm Taf Health Board Ynysmeurig House Navigation Park Abercynon CF45 4SN		
Health Board Reference			
LASPAR Reference			
If relates to a SI – WG SI Reference No:			
Name and contact number of person dealing with the concern			
Name of Patient			
Index date of incident			
Type of incident	**Clinical**		
	Personal Injury		
Brief description of incident			
Settlement under Redress	**Yes/No** **If yes please complete as follows:**		
	Date concern received		
	Date of interim report acknowledging qualifying liability		
	Date of final report		
Breach of duty identified			
Description of injury/injuries sustained			
Damages/Compensation paid £	**General Damages**		
	Special Damages	**Amount**	
		Type	
	CRU		
Details of rehabilitation agreed			
Claimants Costs/Independent Legal Advice	**Source of Costs Claim**		
	Total Sum paid £		
	Conditional Fee Agreement		**Yes/No**
	Insurance Premium Paid		
Defence Costs/Expert's Fees paid	**Amount**		
	Type		

Lessons Learned including monitoring auditing measures	
Lessons of value to other Responsible Bodies or NHS	
I confirm that to the best of my knowledge the above information is true and accurate. Signed…….. Date…… Authorised signatory	

For completion by WRPS

WRPS Reference	
Date inputted on Database	
Actioned by	

Please return the completed form within 56 days of conclusion to:

Head of WRP Services, Alder House, Alder Court, St Asaph Business Park, Denbighshire, LL17 0JL and send a copy to redress@wales.nhs.uk

Appendix R – Action Plan Flowchart – using and monitoring Action Plans to ensure sustained improvement

Appendix S – Action Plan Template for ensuring improvement action following Concerns

ACTION PLAN – CORRECTIVE ACTION FOR IMPROVEMENT

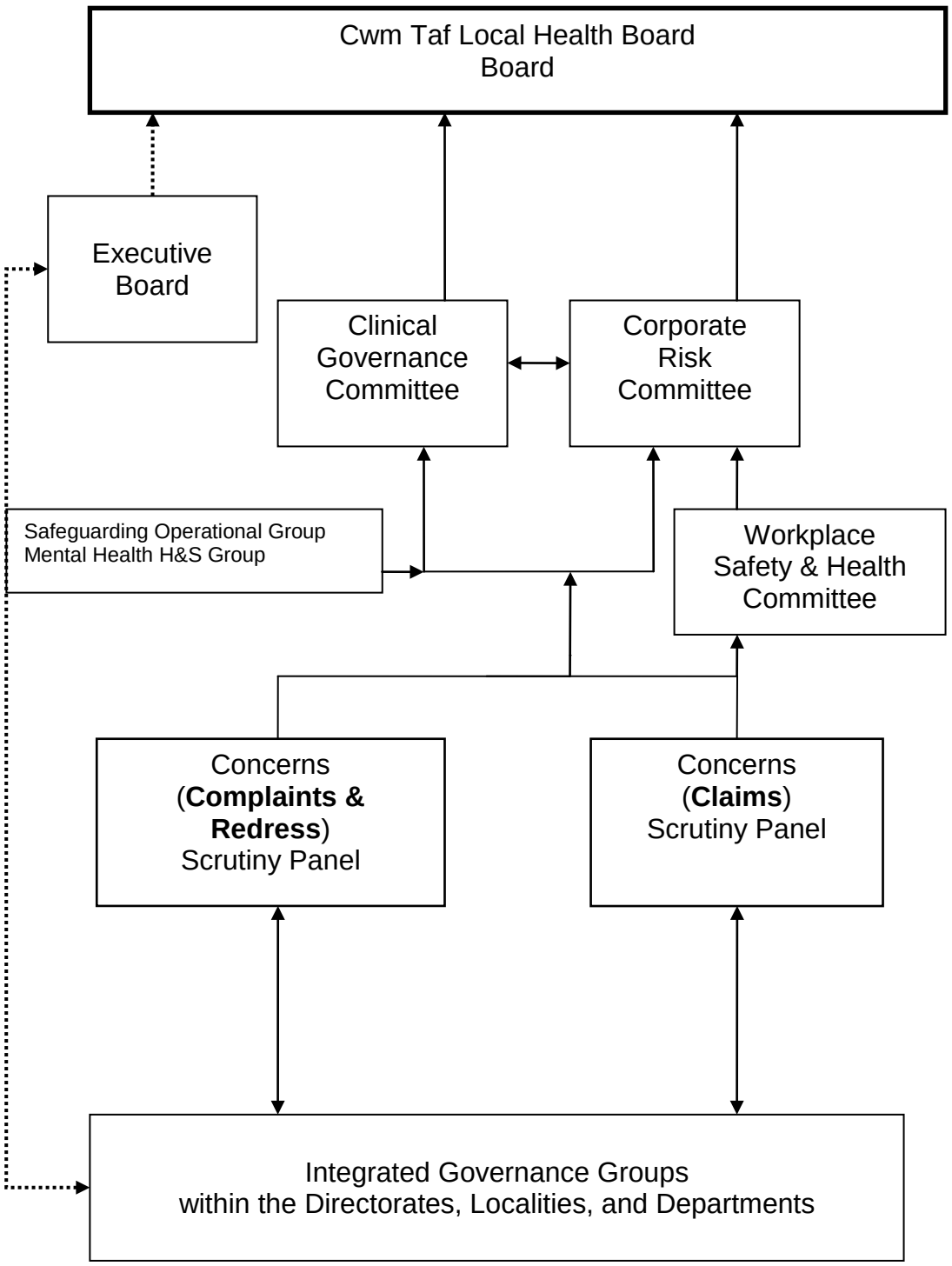
Datix reference number (claim/incident/complaint)	
Date of Incident/Complaint/Claim	
Date action plan commenced	
Lead Officer for Action Plan (name & title)	
Directorate	
Synopsis	

Recommendation	**Action & progress**	**Risk Rating**	**Monitoring and Evaluation arrangements** (state HB group where progress is reported)	**Responsible Person**	**Deadline for Completion** (use traffic light system to indicate status), **insert date of completion**

Status of action (update background of last column)**:**

GREEN	Complete
AMBER	In progress, within deadline
RED	Missed deadline for completion - escalate

Appendix T – Reporting and Assurance Framework



Assurance

- High Risks – trends
- High Risk Concerns (High-value Claims, Serious Incidents, Ombudsman)

Scrutiny – overview

- Trends
- Exceptions & Highlights
- Learning & improvement

Specialist

- Trends
- Compliance with legislation & specific HB processes

Scrutiny

Organisational- wide

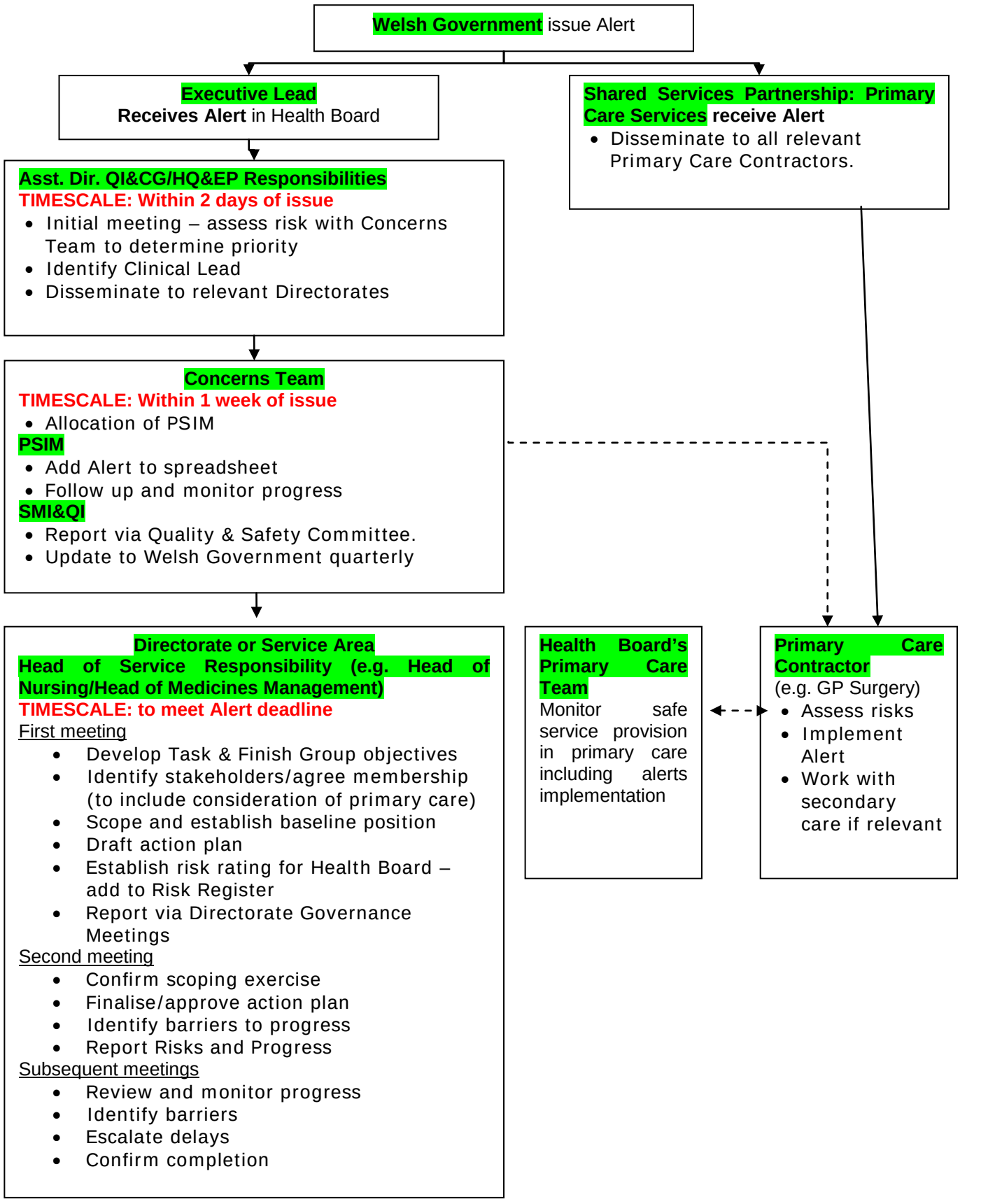
- Trends
- High Risks
- Quality Assurance
- Ensure Learning is identified & shared
- Monitoring Action Plans

Monitoring & ensuring action

- Numbers
- Local Trends
- Risks – identified & managed
- Local Trends
- Learning & Improvement

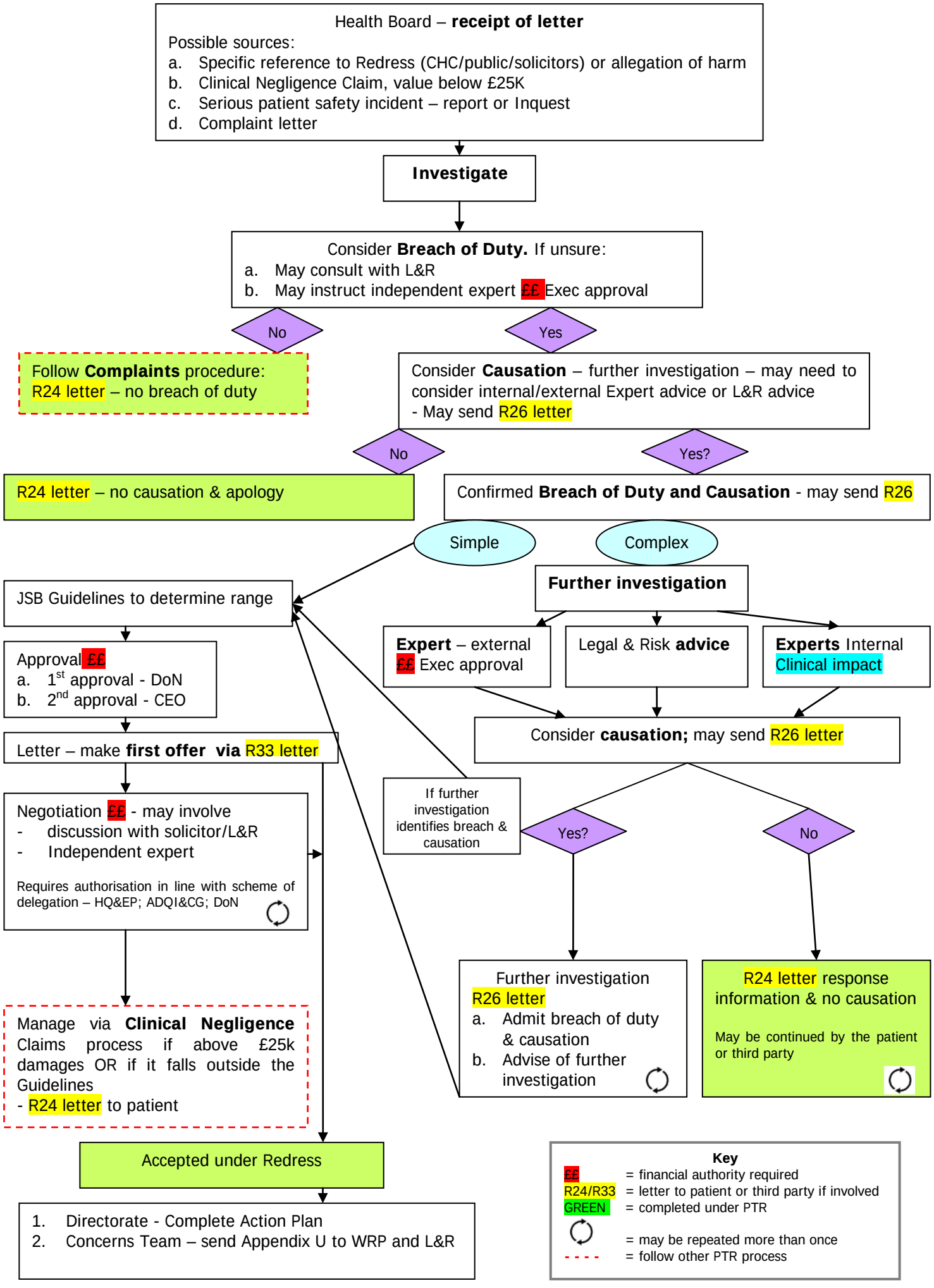
Appendix U – Patient Safety Alerts (Safer Practice Notices, Rapid Response Reports)

Distribution, Implementation and Monitoring flowchart



Key
Asst Dir QI&CG = Assistant Director for Quality Improvement and Clinical Governance
HQ&EP = Head of Quality and Effective Practice
SMI&QI = Senior Manager for Investigations and Quality Improvement
PSIM = Patient Safety Improvement Manager

Appendix V- Redress – Internal Process flowchart



EQUALITY IMPACT ASSESSMENT

Form 1: Preparation

Part A must be completed at the beginning of a Policy/function/strategy development or review, and for every such occurrence. (Refer to the Step-by-Step Guide for additional information).

Step 1 – Preparation		
1.	**Title of Policy** - what are you equality impact assessing?	Managing Concerns
2.	**Policy Aims and Brief Description** - what are its aims? Give a brief description of the Policy (The What, Why and How?)	The policy is aimed at all staff within Cwm Taf Health Board, to support the management of all Concerns.
3.	**Who Owns/Defines the Policy?** - who is responsible for the Policy/work?	Cwm Taf Health Board Concerns Team are responsible for the local policy.
4.	**Who is Involved in undertaking this EqIA? -** who are the key contributors and what are their roles in the process?	Concerns Team
5.	**Other Policies** - Describe where this Policy/work fits in a wider context. Is it related to any other policies/activities that could be included in this EqIA?	Incident Reporting Policy Being Open Policy Communication Strategy Claims Policy & Procedure Risk Management Policy
6.	**Stakeholders** - Who is involved with or affected by, this Policy?	All Staff, the Concerns Team, patients, relatives and carers.
7.	**What might help/hinder the success of the policy?** These could be internal or external factors.	Wide communication and understanding of the key messages will ensure the successful implementation of this policy. Strong executive lead and support to demonstrate the importance of the policy. Lack of ownership by the Health Board, Executives and senior clinicians will hinder the implementation.

Form Two – Information Gathering

Is the policy relevant to the public duties relating to each equality strand. Tick as appropriate.							
	Race	Disability	Gender	Sexual Orientation	Age	Religion Belief	Welsh Language
Is the policy relevant to "eliminating discrimination and eliminating harassment?"	✓	✓	✓	✓	✓	✓	✓
Is the policy relevant to "promoting equality of opportunity?"	✓	✓	✓	✓	✓	✓	✓
Is the policy relevant to "promoting good relationships and positive attitudes?"	✓	✓	✓	✓	✓	✓	✓
Is the policy relevant to "encouragement of participation in public life?"	✓	✓	✓	✓	✓	✓	✓
In relation to disability, is the policy relevant to "take account of difference, even if it involves treating some individuals more favourably?		✓					

The Human Rights Act contains 15 rights, all of which NHS organisation have a duty to act compatibly with and to respect, protect and fulfil. The 7 rights that are particularly relevant to healthcare are listed below. For a fuller explanation of these rights and other rights in the Human Rights Act please refer to Appendix A: The Legislative Framework. Consider the relevance of your Policy to these Human Rights and list any available information to suggest the Policy may interfere with, or restrict the enjoyment of these rights.
The right to life
The right not be tortured or treated in an inhuman or degrading way
The right to liberty
The right to a fair trial
The right to respect for private and family life, home and correspondence
The right to freedom of thought, conscience and religion
The right not be discriminated against in relation to any of the rights contained in the Human Rights Act

Equality Strand	Evidence Gathered
Race	
Disability	**"You Can make a Difference"**
Gender	
Sexual Orientation	
Age	**"On the Right Track"**
Religion or Belief	
Welsh Language	**Welsh language Scheme and NHS Welsh Language Unit**

Form 3: Assessment of Relevance and Priority

Equality Strand	Evidence: Existing evidence to suggest some groups affected. Gathered from Step 2. (See Scoring Chart A)	Potential Impact: Nature, profile, scale, cost, numbers affected, significance. Insert one overall score (See Scoring Chart B)	Decision: Multiply 'evidence' score by 'potential impact' score. (See Scoring Chart C)
Race	0	0	0
Disability	3	+3	9 (P)
Gender	0	0	0
Sexual Orientation	0	0	0
Age	3	+3	9 (P)
Religion or Belief	0	0	0
Welsh Language	3	+3	9 (P)
Human Rights	3	+3	9 (P)

Scoring Chart A: Evidence Available

3	Existing data/research
2	Anecdotal/awareness data only
1	No evidence or suggestion

Scoring Chart B: Potential Impact

-3	High negative
-2	Medium negative
-1	Low negative
0	No impact
+1	Low positive
+2	Medium positive
+3	High positive

Scoring Chart C: Impact Decision

-6 to -9	High Impact (H)
-3 to -5	Medium Impact (M)
-1 to -2	Low Impact (L)
0	No Impact (N)
1 to 9	Positive Impact (P)

FORM 4: (Part A) Outcome Report

Policy Title:	Managing Concerns
Organisation:	Cwm Taf Local Health Board
Name: **Title:** **Department:**	Mr Ceri Chaplin Senior Manager for Investigations & Quality Improvement Patient Care & Safety Unit
Summary of Assessment:	Cwm Taf Health Board is committed to continuously improving patient safety and the quality of healthcare provided. The commitment to deal openly and fairly with patients, their family and/or carers, and ensuring that they lead to improvements in care, is an integral part of the process.
Decision to Proceed to Part B Equality Impact Assessment:	**No** Please record reason(s) for decision Policy has a positive impact on equality.

Action Plan You are advised to use the template below to detail any actions that are planned following the completion of Part A or Part B of the EqIA Toolkit. You should include any remedial changes that have been made to reduce or eliminate the effects of potential or actual adverse impact, as well as any arrangements to collect data or undertake further research.					
	Action(s) proposed or taken	**Reasons for action(s)**	**Who will benefit?**	**Who is responsible for this action(s)?**	**Timescale**
What **changes** have been made as a result of the EqIA?					
Where a Policy may have differential impact on certain groups, state what arrangements are in place or are proposed to **mitigate** these impacts?	1. Inclusion of information for staff, patients, and the public on the intranet site and website. 2. Annual report. 3. Training	Provide communication to patients, staff and the public	Patients, relatives, carers and staff	1. Concerns Team; all staff 2. Concerns Team 3. Concerns Team and all managers	
Justification: For when a policy may have adverse impact on certain groups, but there is good reason not to mitigate.	N/A	N/A	N/A	N/A	N/A
Describe any **mitigating actions** taken?					

Provide details of any actions planned or taken to **promote equality**.					
Date:					
Monitoring Arrangements:	Concerns Scrutiny Panel				
Review Date:					
Signature of all Parties:					

Appendix U - Training Impact Assessment

If training requirements are identified a policy training impact assessment is to be completed and forwarded to the Workforce and Organisational Development Directorate

1. Will training be required as a result of the policy?

✓ Yes	Proceed to question 2
No	If no, please state how this policy will be communicated within the LHB

2. Please complete the following information relating to training

Course/ policy title	Incident Reporting/ Concerns
Course type	Patient Safety/Risk management
Reference to KSF/NMC Dimensions	Core Dimensions 1, 2, 3, 4, 5 & 6
Target Audience (refers to scope of policy)	All staff
Course / policy training objectives	To improve communication To learn and share lessons from incidents To promote cultural change To create an environment of trust and confidentiality To ensure the Implementation of the Being Open Policy *To comply with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011*
Course / policy training content	All staff should have an awareness of the organisation's responsibility to recognise Concerns and take them seriously. Some staff will require more in-depth knowledge on how to manage Concerns and how they should contribute to improvements in care. Training at different levels will be targeted according to staff roles and levels of responsibility.
Duration of course / programme	This will depend on the staff group
Name of trainer (or policy lead)	To be agreed
Approximate cost of providing training	No cost
Please embed lesson plan, link to e-learning, presentation or other relevant learning material	The lesson plans will depend on the staff group. Staff will also be made aware of the e-learning tool available via Moodle.