‘PUTTING THINGS RIGHT’
POLICY FOR THE EFFECTIVE MANAGEMENT AND RESOLUTION
OF CONCERNS

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Do not print this document. The latest version will be accessible via the intranet.
If the review date has passed please contact the Author for advice.

Disclaimer
Powys Teaching Health Board is the operational name of Powys Teaching Local Health Board
Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys
### Version Control

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ENGAGEMENT & CONSULTATION

Key Individuals/Groups Involved in Developing this Document

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Evidence Base

This Policy has taken into consideration all national guidance and legislation (see section 3 Policy Framework).

This Policy takes account of the Health and Care Standards in Wales 2015 and underpins Standard 6.3 Listening and Learning from Feedback.

The Policy has been shaped by the Improving Healthcare White Paper Series – No 14 “Listening and Learning to improve the experience of care” (June 2015)
## IMPACT ASSESSMENTS

### Equality Impact Assessment Summary

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This Policy has undergone an equality impact assessment screening process, using the toolkit designed by the NHS Centre Equality & Human Rights.

Details of the screening process for this Policy are available from the Equalities Manager.

### Risk Assessment Summary

Have you identified any risks arising from the implementation of this policy / procedure / written control document?

No risks have been identified from the implementation of this Policy.

Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document?

Sharing of personal identifiable information risks have been mitigated by following PTHB Information Governance policies and procedures and national guidance/legislation regarding confidentiality and data protection.

Have you identified any training and / or resource implications as a result of implementing this?

Training requirements for staff are described in section 12.
1 Executive Summary

This Policy sets out the arrangements, under Putting Things Right, by which Powys Teaching Health Board will manage, respond and resolve concerns in order to meet the requirements of the NHS Welsh Government legislation: Concerns, Complaints and Redress Arrangements (Wales) Regulations 2011. These Regulations came into force on 1 April 2011, except Part 7, which came into force in April 2012. Part 7 deals with the consideration of Redress where a Welsh NHS body has commissioned care from a NHS Provider in England – Cross Border Arrangements.

This policy ensures that Powys Teaching Health Board (PTHB) fulfils legislative requirements but also the specifications of Health and Care Standards, specifically Standard 6.3, and the Welsh Risk Pool: Standard 5 – concerns and claims management.

1.1 Strategic Aim

The Policy for Putting Things Right (PTR): The Management and Resolution Concerns provides clear assurance to the Board and external bodies about the commitment of PTHB to implement the legislation and embed practices that ensure that any concerns raised are taken seriously, thoroughly and proportionately investigated with the aim of resolution, together with a commitment to learning lessons and securing improvements.

The management of concerns ensures that any patient, client, carer or member of staff who raises a concern is given the opportunity to voice their concern, understand that it will be taken seriously, investigated appropriately and provided with an explanation with the aim of resolution.

Any errors will be openly acknowledged, an apology will be made with a consideration of redress where there is harm and breach and lessons learnt so that practice can change.

1.2 Concern

The term concern, in the context of PTR, should be taken to mean any complaint, claim or reported patient safety incident.
1.3 What concerns can be raised?

A concern may be raised about:

- Any service, decision and/or care and treatment provided by the Health Board (apart from those excluded under Regulation 14)
- A primary care provider about services they provide on behalf of the NHS
- An independent provider about services they provide under contract with PTHB

1.4 Concerns which are excluded for consideration under these arrangements (Regulation 14)

The following matters do not fall within the scope of this policy:

- A concern notified by a primary care provider which relates to the employment contract or arrangements under which it provides primary care services
- A concern notified by a member of staff relating to the contract of employment
- A concern which has been investigated by the Public Service Ombudsman for Wales
- A concern which arises out of an alleged failure of the organisation to respond to a Freedom of Information request
- Disciplinary action that the organisation intends to take as a result of the investigation of a concern
- An informal concern (made verbally) which is resolved within one working day
- A concern which has previously been investigated which the organisation does not consider reasonable to re-open.

2 Scope

The Policy applies to all staff, permanent and temporary, employed by or working within the PTHB, including independent providers who have a responsibility to report, manage and/or be involved in concerns raised or investigate concerns.
The Policy covers concerns involving:

- PTHB services
- Services provided by Health Board employed staff
- Services provided by independent contractors (GPs, dentists, optometrists, out of hours services and pharmacists)
- Services provided by the independent or voluntary sector which are funded by the Health Board
- Commissioned Services for Powys residents

Independent contractors are required to have a concerns procedure for their NHS patients in line with the Regulations.

3 Policy Framework

This is the overarching policy for the Putting Things Right: management of concerns, incidents and complaints and the management of Redress. The Policy sets out the principles for the handling, investigating and resolving formal concerns.

The Policy links to, and may need to be considered in conjunction with, the following documents:

- Welsh Government Putting Things Right – Guidance on Dealing with Concerns about the NHS from 1 April 2011: Version 3 November 2013
- NHS Concerns, Complaints and Redress Arrangements (Wales) Regulations 2010
- Welsh Risk Pool Concerns, Claims Management and Learning from Events Standard
- PTHB Procedure for the Management of Serious Incidents
- WHC (98) 80 (the Caldicott Report)
- The Data Protection Act (1998) DPA
- All Wales Protection of Vulnerable Adults (POVA) Procedures
- All Wales Child Protection Procedures
- Coroners Procedure
- Access to Health Records Act 1990
- Public Service Ombudsman for Wales Act (April 2005)
- Human Right Act 1998
- Freedom of Information Act 2000
• Race Relations Amendment Act 2000
• Welsh Language Act 1993
• Equality Act 2006
• PTHB/HR 006 All Wales Raising Concerns (Whistleblowing) at Work
• PTHB/H&S 005 Violence and Aggression Policy
• PTHB/HR 010 All Wales Disciplinary Policy & Procedures
• Mental Capacity Act
• Mental Health Act
• WCH (97) 17 Clinical Negligence and Personal Injury Litigation: Claims handling
• PTHB/CP 025 Management of Compensation Claims Policy
• PTHB Information Governance Policies and Procedures

4 Principles

In terms of the effective management and resolution of concerns, PTHB is committed to the principles of openness, accessibility, transparency, responsiveness and fairness.

In line with national equality and diversity legislation, the Board will take all reasonable steps to enable patients and/or their representatives to raise a concern in the most appropriate format.

It will also offer the support of advocacy services where necessary, working collaboratively with Powys Community Health Council.

Principles:

• That people have their concerns dealt with efficiently, openly, sympathetically and in a timely manner.
• The person raising the concern will be treated with respect and courtesy.
• The investigation will be proportionate to the severity of the concern raised (see Appendix B).
• If the concern is graded 4 or 5 the Process for Managing Serious Concerns will be considered (Appendix C).
• The person raising the concern will be guided as to independent support or Advocacy.
• A named Health Board contact will be allocated, usually the Investigating Officer, who will make early and regular personal contact with the person raising the concern.
- Action will be taken as a result of a concern being raised and assurance given that lessons will be learnt, where necessary.
- The concern will be managed in line with Welsh Government regulations.
- Consideration will be given to of an offer of Redress, in accordance with the Regulations, where investigation into the matters raised reveal that there is a qualifying liability in tort.

This Policy is based on the principles of “Being Open” (NPSA 2009).

4.1 Acknowledgement

All patient concerns/incidents will be formally acknowledged and reported and recorded as soon as they are identified. People raising a concern will be treated with compassion and respect by staff.

4.2 Single Point of Entry

The Health Board will provide a single point of entry for concerns, which is via the Quality and Safety Unit.

4.3 Truthfulness, Timeliness and Clarity of Communication

Information about the investigation will be given to the person raising the concern in a truthful and open manner, by an appropriately nominated person.

The principles of the regulations are that a patient will be informed when moderate or severe harm has been caused.

Where it is felt that it would not be in the best interests of the patient/representative to inform or involve them in the investigation:

- The rationale for that decision must be recorded, via Datix;
- As circumstances may change, the decision not to involve the patient/representative must be kept under review throughout the investigation.
4.4 Proportionate and Appropriate Investigation

Concerns will be investigated thoroughly but proportionately. The Grading of the concern (appendix b) and timescales for the investigation (appendix a) will help guide the Investigating Officer, as will making personal contact with the person raising the concern to identify and confirm the key issues.

Identifying the root cause of the concern will focus the investigation and help to improve the systems of care. The principle of conducting a thorough and proportionate investigation into a concern and reassuring patients, their families and carers that lessons have been learned should help to minimize the incident recurring.

4.5 Apology

Verbal apologies or a written apology will clearly state that the Health Board is sorry for the suffering or distress resulting from the concern. This is important as evidence suggests that people raising a concern want their concern validated.

It is important to note that saying sorry is not an admission of liability.

4.6 Confidentiality

In line with the Data Protection Act, the details of a patient’s concern should, at all times, be considered confidential.

4.7 Staff Involvement

Information about the investigation must be given to the staff involved in a truthful and open manner although, if imparting this information may jeopardise the investigation, then it is advised not to inform the member of staff. As with section 4.3, the rationale must be recorded on Datix.

Any information shared is based solely on the facts known at the time. Staff must explain that new information may emerge as the
investigation is undertaken and that the person raising the concern will be kept up to date with the progress of an investigation.

4.8 Professional Support

The relevant Senior Management Team and the Concerns Team will provide support for those involved with investigating a concern.

Referral for staff support should also be considered. Healthcare professionals may seek support from their relevant professional bodies such as the GMC, RCN, HCPC and the MDU etc.

4.9 Multidisciplinary Responsibility

Most healthcare provision is through multidisciplinary teams. This should be reflected in the way that patients, their families and carers are communicated with when things go wrong. This will ensure that the Putting Things Right process is consistent with the philosophy that incidents usually result from system failures and rarely from the actions of an individual.

4.10 Continuity of Care

Patients are entitled to expect that they will continue to receive all usual treatment and continue to be treated with dignity, respect and compassion, without fear of reprisals for raising a concern.

If a patient expresses a preference for their healthcare needs to be taken over by another team, where possible the appropriate arrangements should be made for them to receive treatment elsewhere.

5 Roles and Responsibilities

5.1 Chief Executive Officer (CEO)

The Chief Executive Officer has overall accountability for dealing with concerns. This has been delegated to the Director of Nursing, as the
Executive Lead and Responsible Officer, with day-to-day operational responsibility being assigned to the Assistant Director - Quality and Safety (named as the Senior Investigations Manager)

5.2 Responsible Officer (RO)

As stated above, the Director of Nursing is the Responsible Officer for leadership and overseeing the management of concerns arrangements.

The Responsible Officer ensures arrangements are in place to:

- Manage concerns in line with the Regulations
- Consider whether a qualifying liability exists
- Ensure that concerns (incidents, complaints and claims) are dealt with under a single arrangement in compliance with Welsh Government regulations
- Ensuring an annual report is prepared which summarises the organisations activities under the Regulations NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2010. (Regulation 10.2)
- Ensuring that arrangements for dealing with concerns are published in a variety of media, formats and languages and that a copy of the arrangement must be given free of charge, to any person who requests it, in the format requested.

5.3 Senior Investigations Manager

The Senior Investigations Manager is the Assistant Director - Quality and Safety and is responsible for the handling and consideration of concerns under the Regulations. Their role requires them to undertake other functions in relation to dealing with concerns and to cooperate with other persons or organisations, e.g. primary care providers, to facilitate the handling and investigation of concerns.

This role is supported by an additional trained staff member – the Patient Experience and Concerns Manager.

The Senior Investigations Manager provides leadership and advice to clinicians and managers on patient safety and on the handling and management of concerns. This includes implementing a system across
the Health Board to ensure remedial actions are taken to avoid a recurrence of concerns and the sharing of lessons learnt across the organisation.

The SIM will monitor compliance to the Regulations, escalating issues to the RO.

The SIM will monitor draft responses to ensure policy compliance.

### 5.4 Locality General Managers

The Locality General Managers are responsible for establishing robust structures to ensure that concerns are appropriately managed, investigated and resolved, in line with the regulations, within their sphere of responsibility.

This includes compliance to investigation timescales, validation of draft responses for submission to the Concerns Team, reporting and monitoring arrangements within their Locality, establishing a culture of learning and implementation of action plans.

### 5.5 Investigating Officers (IOs)

Investigating Officers are responsible for completing a comprehensive, open and honest investigation addressing all the concerns raised, as agreed with the person raising a concern, abiding by the timescale outlined within the PTR Guidance.

Grade 1, 2 and 3 concerns should be managed, to completion, within 30 working days.

The Investigating Officer will complete a formal report and draft a response letter, using the PTHB templates, which will be submitted to the Locality General Manager for ratification. The IO will consider if there is any breach in duty and resultant harm that may need to be considered by the Redress Panel. The Investigating Officer will discuss actual or potential breach of duty and harm with the Concerns Team. They will also ensure that an action plan is completed to address any improvements required, which is recorded via Datix.
If there is a delay in completing an investigation or complying with the 30 working day turnaround time for complaints, the Investigating Officer must seek permission from the Locality General Manager to have an extension to the timescale. The person who raised the concern must be notified and a holding letter sent, in collaboration with the Concerns Team.

5.6 Patient Experience and Concerns Manager

Is responsible for:

- Logging of the concern via Datix and determining initial grading.
- The production of an acknowledgement letter which is sent within 2 working days of receipt of the concern.
- Timely sharing of the concern with the respective Locality General Manager, for investigation and providing guidance regarding return time.
- Supporting the Investigating Officer with the production of holding letters, in compliance with PTR Regulations.
- Quality assuring the final draft response ahead of RO and CEO sign off.
- Identifying potential or actual breach of duty, harm and qualifying liability in collaboration with the Investigating Officer.
- Escalating policy and regulation compliance issues to the SIM.
- Producing monthly statistics on compliance to PTR Regulations, performance, themes and learning.
- Providing a bi-monthly report to the Quality and Safety Committee.
- Providing an Annual Report for the Board.

5.7 Responsibility of All Staff

- To abide by the principles outlined in this Policy.
- To ensure an open, responsive and transparent approach when concerns are raised.
- To cooperate fully and openly in the investigation of concerns.
- To comply with PTHB Values and Behaviours Framework.
- To actively learn from concerns.
6. Reporting Mechanism / Monitoring the Process

Concerns will be reported to the Quality and Safety Committee and will form part of regular alternate month reports. Details of the subject and nature of the concern together with the outcome of the investigation will be recorded. Compliance with the stated time periods for response will be monitored and reported, together with emerging themes.

The Board will be informed of concerns which may adversely affect organisational reputation, by the Chair of the Quality and Safety Committee or the Responsible Officer.

The RO will provide an annual report to the Board, which has been signed off by the Quality and Safety Committee. This report will include:

- The number of concerns notified to the Health Board;
- The number of concerns notified to the Public Service Ombudsman for Wales.
- The number of concerns referred to Redress (in accordance with WRP Standard 5).

The report will also focus on providing assurance to the Board that lessons identified during the investigation of a concern are learnt and that appropriate remedial action is implemented, monitored and evaluated for effectiveness.

6.1 Localities

Each Locality will have a Quality and Safety Forum, which includes in its Terms of Reference the need to review, monitor and audit the management and resolution of concerns. This work will be led by the Head of Nursing and Head of Therapies, on behalf of the Locality General Manager.
Policy and Regulation compliance will be reviewed at the Senior Leadership Team Meetings, led by the Director of Primary & Community Care.

6.2 Quality and Safety Committee

The Quality and Safety Committee has corporate responsibility to ensure that organisational risks identified through the investigation of concerns are managed appropriately and that remedial actions are taken. It will also satisfy itself that lessons learnt are disseminated across PTHB.

Annual performance reports will be provided to the Welsh Government in line with the reporting arrangements described in the PTR Guidance.

7 Notification of Concerns

A concern may be notified by:

- A person who receives or has received services from the organisation.
- Any person who is affected or likely to be affected by the action, omission or decision of the organisation.
- An independent member.
- A member of staff (this should not be confused with whistle-blowing which is subject of separate Policy.

A concern may be notified by a person acting on behalf of another person in the following circumstances:

- If the person affected has died.
- If the person affected is a child.
- If the person affected lacks capacity to raise a concern themselves.
- If the person affected has requested another person to act on their behalf (in this instance consent will be required).

Powys Teaching Health Board must be notified of a concern not later than 12 months after the date on which the matter occurred, or not later than 12 months from when the concern became known. These timescales are not
absolute and may be subject to consideration involving the SIM &/or the RO if there are reasonable reasons for non-compliance to the timescales, for example bereavement.

7.2 Managing Cross Border Concerns

Where a concern involves an organisation cross-border, which is providing care on behalf of Powys Teaching Health Board, the provider organisation will be required to comply with the Welsh Regulations (2011), which will be outlined in the contractual arrangements.

7.3 Concerns involving other organisations, primary care providers and independent contractors

7.3.1 Concerns which involve other agencies

When a concern either involves more than one responsible body or appears to relate solely to another responsible body, the following action should be taken:

- Inform the person raising the concern that another NHS organisation is involved in their concern, and
- Seek consent from the person raising the concern to contact and notify the NHS organisation that they are involved in the concern.

The second responsible body must be notified within 2 working days of receipt of the consent. Arrangements should be made to ensure that when a concern involves more than one responsible body, the handling of the investigation is co-ordinated and a joint response is given. All organisations have a duty to co-operate fully and this may include identifying a lead and sharing information.

7.3.2 Concerns Involving Primary Care Providers and Independent Providers

If PTHB receives a concern from a person in relation to services from primary care providers and independent providers, the following action should be taken:

- PTHB will establish with the person raising the concern, whether the
provider has already considered the concern and whether a response has been issued;

- If a response has been provided, PTHB do not investigate and informs them of their right to take their concern to the Public Service Ombudsman for Wales (PSOW);

- If a response has not been provided, the consent of the person raising the concern must be gained in order for the details of the concern to be sent on to the provider;

- If consent is not granted, this must be recorded on Datix. PTHB can investigate the concern, but they must make it clear to the person who raised the concern that there will be limitations to the findings because of the non-involvement of the primary care providers;

- If consent is granted, the SIM will determine whether it is appropriate for the Primary Care or Independent provider to investigate the concern;

- If it is decided that the Primary Care or Independent provider can investigate the concern, then they manage the concern in line with the handling and investigation of concerns as outlined in this policy; and

- If it is determined that PTHB will investigate the concern, the person who raised the concern and the Primary Care or Independent provider must be informed of this decision.

8 Grading of Concerns

The All Wales Grading Framework is based on a matrix developed by the National Patient Safety Agency and is used to assess and manage incidents. The grading of a concern should be viewed on receipt of the concern and following the investigation.

This matrix will be adopted to determine the level of investigation required in dealing with all types of concerns in order to promote a consistent approach across PTHB and Wales and to ensure a proportionate investigation (Appendix B)
9 Management of Serious Concerns

PTHB have developed a separate procedure to guide staff in the management of serious concerns i.e. those graded at 4 or 5 (Appendix C)

10 Concerns about Children and Adults at Risk

When a person raises a concern on behalf of a child or an adult at risk, PTHB must be satisfied that:

- There are reasonable grounds for concern being notified by a representative and not by the individual themselves (Reg. 12 (3) (a)).
- When the child or adult at risk raises a concern themselves the organisation must ensure that they are given reasonable assistance in order to pursue the concern.
- Where a concern indicates that a child or adult at risk may have been abused, the All Wales Child Protection or Adult at Risk Procedures must be used. The decision to instigate child or adult protection procedures must be logged on Datix with the rationale clearly identified.
- Where Child Protection or Adult at Risk issues are identified during the investigation of a concern, then a discussion should take place at the earliest opportunity with the Senior Investigation Manager and the Head of Safeguarding.

The concern must be considered for any possible Safeguarding issues and action taken as outlined in organisational Safeguarding policies and procedures.

Following an investigation where a breach of duty has or may have occurred which caused harm, then the case must be referred to the Concerns Team for consideration of Redress in the event of a qualifying liability.

11 Redress

Under the legislation, the Health Board is required to consider when investigating a concern, whether there is a qualifying liability in tort i.e. whether there has been a breach of duty of care and whether that breach of duty is causative of any harm or loss to that person. Where this is
indicated, there is a qualifying liability in tort and a consideration of an offer of redress is necessary.

Redress can take the form of:

- An apology.
- Remediial action.
- Investigation and explanation.
- Financial compensation up too £25, 000.00.

A Redress Panel has been established to enable the Health Board to manage its responsibilities under the Regulations. The Panel is chaired by an Independent Member, Where an Investigating Officer determines a breach of duty has occurred or considers this may be likely, the case will be presented to the Redress Panel for consideration, coordinated by the Patient Experience/Concerns Manager.

12 Training

Putting Things Right training is essential. The level of training required by individual staff is in line with the Key Skills Framework.

Staff at all levels of the PTHB can access the online learning at Learning@NHSWales via their ‘Trust Applications’ - http://www.mle.wales.nhs.uk

The training is divided into sections for all staff, at all levels:

- All staff should complete Sections 1, 2 and 5.
- Sections 3 and 4 are applicable to Managers, Specialist Leads, Locality Leads and Board Members.

Staff need to be informed about, and receive, appropriate training in respect of the operation of the arrangements for the reporting, handling and investigation of concerns. Staff should consider training in related areas such as:

- Customer care
- Safeguarding
- Records management
• Root Cause Analysis training
• Legal training / awareness

Training for Investigating Officers is provided as part of the Workforce and Organisational Development training prospectus.

Staff who are investigating a concern are expected to use the toolkit developed by the Quality and Safety Unit to guide their investigation and to ensure a consistent approach to investigating, reporting, managing and resolving concerns.

13 Learning from concerns

Powys Teaching Health Board is committed to listening to service users and learning lessons when experiences have not met the expected standards, embracing guidance set out in the Improving Healthcare White Paper Series no:14 “Listening and learning to improve the experience of care” (Spencer et al, 2015).

Themes from concerns and lessons learnt will be discussed at the Patient Experience Steering Group. Additionally lessons and actions taken will feature in the Concerns Annual Report.

14 Storage and Management of Concerns Files

• The concerns file must include the Investigating Officers report and any other relevant information concerning the investigation.
• The concerns file is discloseable.
• The (paper and electronic) concerns file must be kept for a period of 10 years. Records relating to maternity concerns should be retained for 25 years and in the case of children until they attain the age of 25 (with the minimum 10 year provision).
• The Concern File, including the Investigating Officer’s file, should be combined into one full file. This file is the responsibility of the Locality General Manager. On request from the Quality and Safety Unit a paper copy of the full file is to be provided.
• It is the responsibility of the Locality Management Team to ensure that this file is complete, accurate and holds no contentious remarks.
• If a concern becomes a claim then the file will be combined into the Litigation File.
15 Investigations undertaken by the Public Service Ombudsman

If it is not possible to resolve a concern through local resolution, the person raising the concern can refer the matter to the Public Service Ombudsman for Wales. Contact details for the Ombudsman must be provided in the acknowledgement or response letter to the person raising the concern.

16. Review and change control

This Policy will be monitored by the Quality and Safety Committee and will be subject to review every three years or sooner in light of new guidance, legislation or organisational change.
### NHS (Concerns, complaints and Redress Arrangements) (Wales) Regulations 2011

#### Timescales for Handling Concerns

<table>
<thead>
<tr>
<th>Type of Response and Regulation which applies</th>
<th>Type of Case</th>
<th>Within *2 working days</th>
<th>Within 30 working days of receipt.</th>
<th>Within 6 months of receipt.</th>
<th>Within 12 months of receipt.</th>
<th>Longer than 12 months.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledgement letter. (Regulation 22)</td>
<td>All cases</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Final response, (Regulation 24)</td>
<td>Cases that do not involve issues of liability</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interim response (Regulation 26)</td>
<td>Cases that do or may involve issues of liability</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigation Report and Communication of Decision. (Regulations 31 and 33)</td>
<td>Cases that do or may involve issues of liability</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*IMPORTANT NOTE: The 2 working day acknowledgement period fall within the overall 30 working days for response.*
### Grading of Concerns

<table>
<thead>
<tr>
<th>Grade</th>
<th>Examples of Concern</th>
<th>Potential for Qualifying Liability / Redress</th>
</tr>
</thead>
</table>
| **1** No Harm | - Concerns which normally involve issues that can be easily/speedily addressed, with no harm having arisen (e.g. outpatient appointment delayed but no consequences in terms of health, difficulty in car parking etc.) but have impacted on a positive patient experience.  
- Labelling error in Pathology detected pre analytically. | Highly Unlikely. |
| **2** Low Harm | - Concerns regarding care and treatment which span a number of different aspects/specialties.  
- Increase in length of stay by 1-3 days.  
- Patient fall - requiring minor treatment.  
- 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. requiring local anaesthetic, further treatment/monitoring by GP.  
- Samples taken from the wrong patient – not acted upon but require repeat venepuncture.  
- Pathology labelling error detected post analytically before further intervention | Unlikely. |
<table>
<thead>
<tr>
<th>Grade</th>
<th>Examples of Concern</th>
<th>Potential for Qualifying Liability / Redress</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3</strong></td>
<td>Moderate Harm</td>
<td>Possible in some cases.</td>
</tr>
<tr>
<td></td>
<td>• Clinical process/issues that have resulted in avoidable, semi-permanent injury or impairment of health or damage that requires intervention.</td>
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<td></td>
<td>• Additional interventions required or treatment/appointments needed to be cancelled.</td>
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<tr>
<td></td>
<td>• Re-admission or return to surgery, e.g. requiring general anaesthetic.</td>
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<tr>
<td></td>
<td>• Necessity for transfer to another centre for treatment/care (e.g. fork incident in a GP Practice, admission to hospital).</td>
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<tr>
<td></td>
<td>• Increase in length of stay by 4-15 days.</td>
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</tr>
<tr>
<td></td>
<td>• RIDDOR reportable incident (moderate harm).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Requiring time off work – 4-14 days.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Concerns that outline more than one failure to meet internal standards.</td>
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<tr>
<td></td>
<td>• Moderate patient safety implication.</td>
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<tr>
<td></td>
<td>• Concerns that involve more than one organisation (e.g. cross border incidents that may involve English Providers or other Health Boards, incidents involving interface with Local Authority or Ambulance Trusts).</td>
<td></td>
</tr>
<tr>
<td><strong>4</strong></td>
<td>Severe Harm</td>
<td>Likely in many cases.</td>
</tr>
<tr>
<td></td>
<td>• Clinical process issues that have resulted in avoidable, semi-permanent harm or impairment of health or damage leading to incapacity or disability.</td>
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<tr>
<td></td>
<td>• Additional interventions required or treatment needed to be cancelled.</td>
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</tr>
<tr>
<td></td>
<td>• Unexpected re-admission or unplanned return to surgery.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Increase in length of stay by more than 15 days.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Necessity for transfer to another centre for treatment/care.</td>
<td></td>
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<tr>
<td></td>
<td>• Requiring time off work – more than 14 days.</td>
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<tr>
<td></td>
<td>• A concern outlining non compliance with national standards, with significant risk to patient safety.</td>
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<tr>
<td></td>
<td>• RIDDOR reportable incident (significant harm).</td>
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<tr>
<td></td>
<td>• Pathology: Specimen loss, labelling error detected post analytically following further intervention.</td>
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<td></td>
<td>• ‘Wrong Blood’ transfusion</td>
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</tr>
</tbody>
</table>
### Grade 5

**Catastrophic Harm**

<table>
<thead>
<tr>
<th>Examples of Concern</th>
<th>Potential for Qualifying Liability / Redress</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Concern leading to unexpected death, multiple harm or irreversible health effects.</td>
<td>Very likely.</td>
</tr>
<tr>
<td>• Concern outlining gross failure to meet national standards.</td>
<td></td>
</tr>
<tr>
<td>• Clinical/process issues that have resulted in avoidable, irrecoverable injury or impairment of health, having a lifelong adverse effect on lifestyle, quality of life, physical and mental wellbeing.</td>
<td></td>
</tr>
<tr>
<td>• Clinical process or issues that have resulted in avoidable loss of life.</td>
<td></td>
</tr>
<tr>
<td>• RIDDOR reportable incident (catastrophic harm).</td>
<td></td>
</tr>
<tr>
<td>• Significant/consistent reporting errors i.e. malignant as benign.</td>
<td></td>
</tr>
</tbody>
</table>
Flowchart for Reporting Investigation