Aneurin Bevan Health Board

Putting Things Right Policy
The Management of Concerns (Complaints, Claims and Patient Safety Incidents)

N.B. Staff should be discouraged from printing this document. This is to avoid the risk of out of date printed versions of the document. The Intranet should be referred to for the current version of the document.
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1 Executive Summary

Welsh Government legislation the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011), (the Regulations) sets out the requirement that all Local Health Boards must make arrangements in accordance with the Regulations for the handling and investigation of concerns.

These regulations came into force on 1 April 2011, except Part 7 which deals with the consideration of Redress where a Welsh NHS body has commissioned care from a NHS Provider in England – Cross Border Arrangements – Part 7 will come into force on April 2012. This policy helps to ensure that ABHB fulfils the requirements of standard 23 of the Standard for Healthcare services, the management of patient concerns. The Policy also provides assurance to the Welsh Risk pool under standard 5 , concerns and claims management.

Strategic Aim
The Policy for Putting Things Right provides clear assurance to the Board and external bodies about the commitment of Aneurin Bevan to implement the legislation in line with the being open principles endorsed by the National Patient Safety Agency. 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 to resolve their concern. This will be achieved through errors being acknowledged, an apology being made where appropriate and lessons being learnt so that practice can change.

Concern
The term concern should be taken to mean any complaint, claim or reported patient safety incident.

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 ABHB

Concems which are excluded for consideration under these arrangements (Regulation 14)
The following are matters which 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 their contract of employment;

• A concern which has been investigated by the Public Services 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 (in line with this policy);

• 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 ABHB, including independent providers, who have a responsibility to report, manage and or be involved in concerns raised or investigate serious concerns.

The Policy covers concerns about:

• The Aneurin Bevan Health Board 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;

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

3 Policy Framework

The policy will be 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 and investigation of concerns.

This policy will support the Policy and Procedure on the Management of Concerns raised by patients and their representatives, the Policy and Procedure for the Management of Serious Concerns and the Hazard and Incident Reporting Policy. It links and may need to be considered in conjunction with the following policy documents:

• Welsh Government Putting Things Right – Guidance on Dealing with Concerns about the NHS from 1 April 2011
• (NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2010
• Welsh Risk Pool Standard 5 concerns and claims
• National Patient Safety Policy on Being Open (2009)
• ABHB Policy and Procedure for the Management of a Concern Raised by a Patient or their Representative
• ABHB Policy and Procedure for the Management of Serious Incidents
• ABHB Policy and Procedure for the Management of Concerns Investigated by the Public Service Ombudsman Wales
• ABHB Hazard and Incident Reporting Policy
• WHC(98)80 (the Caldicott Report),
• The Data Protection Act (1998) DPA
• All Wales Protection of Vulnerable Adults (POVA) Procedures
• All Wales Child Protection Procedure
• Coroners Procedure
• Access to Health Records Act 1990
• Public Service Ombudsman for Wales Act (April 2005)
• The Code of Openness (1995),
• Human Rights Act 1998,
• Freedom of Information Act 2000,
• Race Relations Amendment Act 2000;
• Welsh Language Act 1993
• Equality Act 2006
• ABHB Whistle blowing Policy
• ABHB Violence and Aggression Policy
• ABHB Disciplinary Procedures
• Mental Capacity Act
• Mental Health Act
• WHC (97) 17 Clinical Negligence and Personal Injury Litigation: Claims handling.

4 Principles

The ABHB is committed to the following principles in order to ensure that the process for managing concerns is open, accessible and fair.

In line with national equality and diversity legislation the Board will take all reasonable steps to allow patients and their representatives to raise a concern in the most appropriate format. It will also offer the support of advocacy services as necessary.

• Ensure that people have their concerns dealt with efficiently and openly
• Treat the person raising the concern with respect and courtesy
• The investigation will be proportionate to the severity of the concern raised (see grading)
• If the concern is graded 4 or 5 the Management of Serious Concerns Policy should be adopted
• Provide advice on the availability of assistance to pursue a concern, and where they may obtain it;
• Provide a named contact throughout the handling of the concern and know how to contact the (complainant) person raising the concern
• Provide assurance that appropriate action has been taken as a result of them raising their concern and lessons learnt; and
• Ensure that the concern is managed and investigated in line with guidance issued by Welsh Ministers.
• Consideration is given to the making of an offer of redress in accordance with Part 6 of the Regulations where its investigation into the matters raised in a concern reveal that there is a qualifying liability in tort.

THIS POLICY IS BASED ON THE PRINCIPLES OF “BEING OPEN”

Acknowledgement
All patient concerns/incidents should be acknowledged and reported as soon as they are identified. Any concerns should be treated with compassion and understanding by all healthcare professionals.

Single Point of Entry
The Health Board will aim to provide a single point of entry for patient concerns.

Truthfulness, Timeliness and Clarity of Communication
Information about the investigation must be given to patients, their families and carers in a truthful and open manner by an appropriately nominated person.

The principles of the regulations are that the patient will be informed when there has been moderate or severe harm. However, 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; and

• As circumstances may change, the decision not to involve the patient/representative must be kept under review throughout the investigation

Proportionate and Appropriate Investigation
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 will help to prevent the incident recurring.

Apology
Verbal apologies or a written apology should clearly state as appropriate that the ABHB is sorry for the suffering and distress
resulting from the concern. It is important to note that saying sorry is not an admission of liability.

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

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.

Information given to patients and staff is based solely on the facts known at the time. Healthcare professionals should explain that new information may emerge as an investigation is undertaken and that patients, their families and carers will be kept up to date with the progress of an investigation.

Professional Support
The Divisional/Locality Senior Team and The Putting Things Right Team will provide support for those involved with investigating a concern. Referral to appropriate staff support services in collaboration with the staff member should be considered as needed. Healthcare professionals may also seek support from their relevant professional bodies such as the GMC, Royal College, the MDU etc.

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.

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. 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 received treatment elsewhere.
5 Roles and Responsibilities

Chief Executive
The Chief Executive Officer has overall responsibility for dealing with concerns. This responsibility has been delegated to the Medical Director with day-to-day responsibility delegated to the Assistant Director Putting Things Right.

Non Officer Lead
The delegated non officer for ABHB is the Board Chairman who is responsible for maintaining a strategic overview of the Policy (Regulation 2.6). This person is responsible, in particular for:

- Ensuring that the organisation complies with the arrangements it has in place for ensuring that the details of concerns received and investigated are considered so that lessons may be learned in order to seek to avoid such deficiencies recurring
- Ensuring that an annual report is prepared which summarises the organisation’s 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 arrangements must be given free of charge to any person who requests it, in the format requested.

Responsible Officer
The Medical Director is the Responsible Officer for overseeing the day to day management of these 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.
The responsibilities of the Medical Director are delegated to the Assistant Director for Putting Things Right, but remain under the direct control and supervision of the executive lead.

**Senior Investigations Manager (SIM)**

The Senior Investigation Manager/Assistant Director Putting Things Right is responsible for the handling and consideration of concerns under the regulations, and their role requires them to undertake other functions in relation to dealing with concerns and to co-operate with other persons or organisations, e.g. primary care providers, to facilitate the handling and investigation of concerns. This role is supported by additional suitably trained staff as part of the integrated arrangements. The SIM provides leadership and advice to the Board, 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 recurrence of concerns and the sharing of lessons learnt across the organisation and beyond.

**Divisional/Locality Directors**

Are responsible for establishing structures to ensure that concerns are appropriately investigated within their division. This includes establishing reporting and monitoring arrangements within the Division with a focus on lessons learnt.

**Responsibility of All Staff**

- Work to the principles outlined in this policy
- Learn from concerns
- Co-operate fully and openly in the investigation of concerns.

**6 Reporting Mechanism Monitoring the Process**

All serious concerns raised will be reported to the Quality and Patient Safety Committee and will form part of regular bi-monthly reports to the Board. Details of the subject and nature of the concern together with the outcome of the investigation must be recorded. Compliance with the stated time periods for response are monitored and reported. The Board are made aware of concerns which may adversely affect the reputation of Board by the chair of the Quality and Patient Safety Committee.
The ABHB will provide an annual report to the Board. This report will include the number of concerns notified to the responsible body, number of concerns referred to the Ombudsman for Wales and the number of matters referred to redress (in accordance with WRP standard 5).

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

**Divisions and Localities**

Each Division /Locality will establish a Quality and Patient Safety forum which includes in its terms of reference the need to review monitor and audit its management of patient concerns.

**Learning Committee**

The HB Learning 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 also ensures that lessons learnt are disseminated across the Health board.

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 form the organisation;
- Any person who is affected, or likely to be affected by the action, omission or decision of the organisation;
- A non-officer member; or
- A member of staff.

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

- If the person has died;
- If the person is a child;
• If the person lacks capacity to raise a concern themselves (see (insert LHB or NHS Trust) Policy on Vulnerable Adults and Mental Capacity Act Policy and Procedures); or
• If the person has requested another person to act on their behalf.

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 is to be adopted to determine the level of investigation required in dealing with all types of concerns in order to promote a consistent approach across ABHB and Wales and to have a proportionate investigation.

9 Management of Serious Concerns

ABHB has developed a policy and procedure to guide staff in the management of serious concerns graded a 4 & 5.

10 Concerns about Children and Vulnerable Adults

When a person raises a concern on behalf of a child or vulnerable adult, the organisation 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)); and
• When the child or vulnerable adult 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 vulnerable adult may have been Abused the Child Protection or Vulnerable Adult Procedures should be used in conjunction with this policy and management of concerns procedure.

• Where Child Protection or POVA issues are identified during the investigation of a concern, then a discussion should take place at the earliest opportunity with the Putting Things Right Team and the POVA or Child Protection lead. 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 needs to be referred to the ABHB redress panel for consideration 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 our duty of care and whether that breach of duty is causative or 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:
- An Apology
- Remedial Action
- Investigation and explanation
- Financial compensation up to £25,000

A Redress panel has been established to allow the Health Board to manage its responsibilities under the regulations. Where an investigation lead determines a breach of duty has occurred this case will need to be presented to the Redress panel for consideration.

12 Training

Organisational Development/Training
Putting Things Right training is mandatory; the level of training required by individual staff is in line with the KSF.

Staff at all levels of the ABHB can access the on line learning at Learning@NHS Wales via their ‘Trust applications’
http://www.mle.wales.nhs.uk

The training is divided into sections for all staff, at all levels of the ABHB; all staff should complete sections 1, 2 and 5. Sections 3 and 4 are applicable to Managers, Specialist Leads, Divisional/Directorate 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 – NPSA-RCA Training
- Being Open – NPSA - Being Open
- Legal training/awareness

Training for Investigating Leads is provided as part of the PTR training prospectus.

Staff who are investigating a concern are expected to use the toolkit developed by the PTR Team to guide their investigation and to ensure a consistent approach to investigation and reporting.

13 Storage and Management of Concerns Files

The concerns file should include the investigating lead’s file and any other relevant information concerning the investigation. The concerns file is disclosable.

The (paper and Datix) concerns file must be kept for a period of 10 years. Records relating to maternity/obstetrics 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 concerns file including the investigating lead file should be combined into one full file. This file is the responsibility of the (complaint co-ordinator) for the division. On request from the Legal Service Manager or the Putting Things Right Team/Concerns Review Manager a paper copy of the full file is to be provided upon request. It is the responsibility of the division to ensure that this file is complete, accurate and holds no contentious remarks.

If a concern becomes a claim then the file is combined into the litigation File.

14 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 of this must be provided in acknowledgement or response letter to the person raising the concern

15 Monitoring and Review

This Policy will be monitored by the (Quality and Patient Safety Committee) and will be subject to review every three years or in light of new guidance, legislation or organisational change.

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 policy owner.
### NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

#### Table to Show 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 First Receipt – Majority Of Cases</th>
<th>Within 6 Months Of First Receipt – Exceptional (Reasons Must Be Given)</th>
<th>Within 12 Months Of First Receipt – Majority Of Cases</th>
<th>Longer Than 12 Months – Exceptional (Reasons Must Be Given)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledgement letter (Regulation 22)</td>
<td>All cases</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Final response (Regulation 24)</td>
<td>Cases that do <strong>not</strong> involve issues of liability</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
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<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>
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<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>
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</tbody>
</table>
**IMPORTANT NOTE – The two working day acknowledgement period falls within the overall 30 working days for response**

### Grading of Concern

<table>
<thead>
<tr>
<th>Grade</th>
<th>Examples of concerns</th>
<th>Potential for qualifying liability / Redress</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 No Harm</td>
<td>a) 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</td>
<td>Highly unlikely</td>
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<tr>
<td>Grade</td>
<td>Examples of concerns</td>
<td>Potential for qualifying liability / Redress</td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------</td>
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<tr>
<td>2 Low</td>
<td>a) Concerns regarding care and treatment which span a number of different aspects/specialties</td>
<td>Unlikely</td>
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<tr>
<td>Harm</td>
<td>b) Increase in length of stay by 1 – 3 days</td>
<td></td>
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<tr>
<td></td>
<td>c) Patient fall – requiring minor treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d) Requiring time off work – 3 days</td>
<td></td>
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<td></td>
<td>e) Concern involves a single failure to meet internal standards but with minor implications for patient safety</td>
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<td></td>
<td>f) Return for minor treatment, e.g. requiring local anaesthetic further treatment/monitoring by GP</td>
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<td></td>
<td>g) Samples taken from the wrong patient – not acted upon but require repeat venepuncture.</td>
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<td></td>
<td>h) Pathology labelling error detected post analytically before further intervention</td>
<td></td>
</tr>
<tr>
<td>Grade</td>
<td>Examples of concerns</td>
<td>Potential for qualifying liability / Redress</td>
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<td>---------------------------------------------</td>
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<td>3 Moderate</td>
<td>a) Clinical / process issues that have resulted in avoidable, semi-permanent injury...</td>
<td>Possible in some cases</td>
</tr>
<tr>
<td>Harm</td>
<td>b) Additional interventions required or treatment / appointments needed to be cancelled</td>
<td></td>
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<tr>
<td></td>
<td>c) Readmission or return to surgery, e.g. requiring general anaesthetic</td>
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<td></td>
<td>d) Necessity for transfer to another centre for treatment / care (e.g. for an incident...</td>
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<tr>
<td></td>
<td>e) Increase in length of stay by 4 – 15 days</td>
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<td></td>
<td>f) RIDDOR reportable incident (moderate harm)</td>
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<td></td>
<td>g) Requiring time off work 4 – 14 days</td>
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<td></td>
<td>h) Concerns that outline more than one failure to meet internal standards</td>
<td></td>
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<tr>
<td></td>
<td>i) Moderate patient safety implication</td>
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<td></td>
<td>j) Concerns that involve more than one organisation (e.g. cross-border incidents that...</td>
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<tr>
<td>Grade</td>
<td>Examples of concerns</td>
<td>Potential for qualifying liability / Redress</td>
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| 4  
Severe哈默 | a) Clinical process issues that have resulted in avoidable, semi permanent harm or impairment of health or damage leading to incapacity or disability  
b) Additional interventions required or treatment needed to be cancelled  
c) Unexpected readmission or unplanned return to surgery  
d) Increase in length of stay by >15 days  
e) Necessity for transfer to another centre for treatment / care  
f) Requiring time off work >14 days  
g) A concern outlining non compliance with national standards with significant risk to patient safety  
h) RIDDOR reportable incident (significant harm)  
i) Pathology: Specimen loss; Labelling error detected post analytically following further intervention  
j) “Wrong blood” transfusion | Likely in many cases |
<table>
<thead>
<tr>
<th>Grade</th>
<th>Examples of concerns</th>
<th>Potential for qualifying liability / Redress</th>
</tr>
</thead>
</table>
| 5         | a) Concern leading to unexpected death, multiple harm or irreversible health effects  
             b) Concern outlining gross failure to meet national standards  
             c) Normally 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 well being.  
             d) Clinical or process issues that have resulted in avoidable loss of life  
             e) RIDDOR reportable incident (catastrophic harm)  
             f) Significant / consistent reporting errors i.e. malignant as benign.                                                                                       | Very likely                                 |

**Potential for qualifying liability / Redress**

- Very likely