



**GIG**  
CYMRU  
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WALES

Bwrdd Iechyd Prifysgol  
Cwm Taf Morgannwg  
University Health Board

## How to manage Serious Incidents in Cwm Taf Morgannwg University Health Board

# Serious Incident Management Toolkit

<b>Lead:</b>	Patient Care & Safety Unit
<b>Approved by (pending):</b>	Quality & Safety Committee
<b>Approved date:</b>	November 2020 V3





# Serious Incident Management Toolkit

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✓	Document Checklist
	Tabular timeline
	SI notification form submitted by CTM to WG
	Investigation report and summary of tools used e.g. RCA, statements
	Action plan
	SI closure form submitted by CTM to WG
	QA checklist completed by CTMUHB staff for that incident
	Evidence of how learning identified through the investigation embedded/led to change



## Why do we need the SI Toolkit?

### Purpose

The Serious Incident (SI) Toolkit has been developed to provide a clear and consistent approach to the identification, reporting, investigation and closure of incidents meeting the criteria, as set out by Welsh Government.

### Definition of a Serious Incident (SI)

A serious incident is defined as an incident that occurred during NHS funded healthcare (including the community) which resulted in one or more of the following:-

- Resulted in **unexpected or avoidable death or severe harm** of one or more patients, staff or members of the public;
- A Never Event – all never events are defined as a serious incident although not all never events necessarily result in severe harm or death.
- A scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services; including data loss, property damage incidents or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population.
- Allegations, or incidents, of physical abuse and sexual assault or abuse;
- Loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

**PTR Guidance link** <http://www.wales.nhs.uk/governance-emanual/putting-things-right>

Allegations, or incidents, of physical abuse and sexual assault or abuse can relate to staff, patients or a member of the public. Consideration should be given as to whether a Serious Incident or No Surprises is required.

A proportionate review / investigation should be undertaken. This toolkit is to be applied for serious incidents where there is no agreed investigation tool in place. Investigation Tools currently in place within the Health Board relate to:

- Pressure Damage
- Inpatient Falls
- Patients Absent Without Leave (AWOL)
- Infection Prevention & Control
- Ionising Radiation Medical Exposure Regulations, (IRMER)
- Unexpected Deaths in Mental Health

For further support or guidance please contact your ILG Leads or the Corporate Patient Safety Team via [CTHB\\_Patient\\_Safety\\_Incidents@wales.nhs.uk](mailto:CTHB_Patient_Safety_Incidents@wales.nhs.uk)



# We Treat Everyone With Respect


Immediate Actions			
Actions	Responsibility	Useful Information	Time frame
<p>Implement immediate make safe actions to ensure patient safety and reduction of risk. Consider the need to notify the Communication team. Identify if Safeguarding referral to be submitted. Contact MASH if required.</p>	ILG	<p><b>No Surprises</b> to WG if required  <b>E mail to central Inbox:</b>  <b>CTHB_Patient_Safety_Incidents@wales.nhs.uk</b></p> <p><b>CT MASH 01443 743730</b>  <b>Bridgend MASH 01656 634630</b></p>	Immediate
<p>Secure all relevant evidence to support further investigation e.g.</p> <ul style="list-style-type: none"> <li>• Staff Recollection of Events</li> <li>• Witness Recollection of Events</li> <li>• Records</li> <li>• Defective Equipment</li> <li>• Photographs/ CCTV</li> </ul>	ILG	<b>Recollection of Events</b>	Immediate
<p>Report Incident on DATIX/Verbal escalation to senior management/capture immediate actions.</p>	Staff	<b>Incident Form</b>	Immediate
<p>Support for Staff involved e.g. Staff debriefed.            Use <b>Just Culture</b> (where applicable) to ensure consistent and fair decisions regarding staff management and support.</p>	Senior Person in Charge	<p><b><u>The "Assist Me" Model</u></b>            Supporting Staff following an adverse event  <b><u>Just Culture Guide</u></b></p>	Immediate
<p>Where it is unclear if the SI threshold has been met, a <b>Review And Prioritisation Incident Discussion (RAPID)</b> is to be held within the unit. Professionals to attend to be identified who are <b>not directly involved</b> with the incident.            If the incident meets SI reporting criteria:</p> <ul style="list-style-type: none"> <li>• Report to WG</li> <li>• Agree level of investigation/internal/external</li> </ul> <p>Identify Investigating Officer (IO).</p>	ILG Quality & Safety Governance Leads	<p>If not an SI follow <a href="#">incident management procedure</a>.</p>	Within 2 working days

## Immediate Actions

Actions	Responsibility	Useful Information	Time frame
Patient Safety Manager (PSIM) to complete Datix SI proforma @ the meeting.			
<b>SI</b> notification to be completed at the RAPID meeting for Executive to sign. <i>*All SI notifications to be forwarded to the central inbox to be signed off by an Executive – no SI's to be forwarded to WG directly from ILG's</i>	ILG		Within 2 working days of knowledge of incident is an SI



## Working Together As One Team

<b>Serious Investigation process</b>			
<b>Actions</b>	<b>Responsibility</b>	<b>Guidance</b>	<b>Timeframe</b>
Timeline for incident - commence draft.	Lead IO	<b>Tabular Timeline Template</b>	Within 2 working days of confirmation of SI
Family liaison identified and contact made to inform patient & or family that incident has occurred, discuss investigation process, including any questions to be addressed and engagement. Ensure PTR guidance is addressed. <i>*Early, regular contact with family is advised.</i>	Family Liaison Officer	<b>Saying Sorry NHS Resolution Guidance</b>  PTR Guidance link <a href="http://www.wales.nhs.uk/governance-manual/putting-things-right">http://www.wales.nhs.uk/governance-manual/putting-things-right</a>	When appropriate: See Concerns Policy
<b>Serious Incident meeting</b> is undertaken Staff liaison identified Draft timeline discussed TOR and scope of investigation agreed. Finalise Serious Incident proforma Re-consider if any safeguarding concerns and complete referral Consider if SI Team involvement required.	Lead IO Department leads Corporate SI Team Key incident stakeholders Staff liaison officer	Terms of Reference for Serious Incident Meeting  <b>Safeguarding and Public Protection</b>   Serious Incident team criteria.docx	Within 3-5 working days of confirmation of SI
IO undertakes investigation including any immediate actions taken.	IO		To be completed within 30 working days
Action plan (SMART) development in draft within Datix.	Department with support from IO / PSIM	<b>Guidance</b>	To be completed within 30 working days
Scrutiny of the investigation report and action plan using patient safety internal assurance checklist.	PSIM	Assurance Checklist ( <b>Appendix 5</b> )	To be completed within 45 working days
Recommended Quality and Safety assurance meeting sits fortnightly to review investigation report	ILG Governance Quality & Safety Lead	<b>Terms of Reference</b>	Fortnightly

## Serious Investigation process

Actions	Responsibility	Guidance	Timeframe
presented by IO. The group should include Service manager, Unit Clinical Director, Head of Nursing, Directorate Manager, Governance Lead and PSIM.		Admin Support	
ILG Governance Lead approves the report and action plan and submits to ILG for Nurse/Medical director sign off.	ILG	Assurance Checklist <b>(Appendix 5)</b>	To be completed within 55 working days
<b>ILG lead complete</b> WG incident closure form and submit with action plan to patient safety inbox.	ILG Quality & Governance Lead	<b>CTHB_Patient_Safety_Incidents@wales.nhs.uk</b>	To be completed within CTMUHB organisational guidance of 60 working days
Central acknowledgement of receipt of closure. Forward to DU inbox	Corporate Patient Safety		
All doctors involved in an SI should reflect on incident with an appropriate person. <ul style="list-style-type: none"> <li>· For doctors in training, the reflection should take place with their educational supervisor.</li> <li>· For SAS doctors, the reflection should take place with a named educational supervisor if there is one, and the Clinical Director if not.</li> </ul> For consultants, the reflection should take place with the Clinical Director. The record of that reflection having been completed should be provided by the senior doctor and should form part of the evidence when the Learning from Events record is completed (see page 18 in SI toolkit). The content of the reflection should remain confidential.	ILG Group Director		To be completed within 6 months.



## Listening, Learning and Improving

- ✓ The Learning from Events Report (LFER) is used by Health Bodies in NHS Wales to report the issues that have been identified from a clinical claim or redress Investigation and how these have been addressed to reduce the risk of reoccurrence or reduce the impact of a future event. An alternative version of the document is recommended for use with personal injury or violence & aggression cases.
- ✓ Improvement to quality and safety in healthcare is aligned to learning which flows from case investigations, and the LFER provides a framework for regulators and inspection bodies to gather assurance that appropriate improvement has been implemented.
- ✓ The LFER needs to provide a sufficient explanation of the circumstances and background to the events which have led to the case, in order that colleagues who are scrutinising the report can identify the links to the findings and learning outcomes.
- ✓ Supporting information, such as action plans, expert reports and review findings may be appended to the LFER to evidence the learning activity. These should be referenced in the main document and the relevance of the attachments clearly outlined. The LFER must be signed by appropriate senior staff within the organisation.

### Learning From Events

Actions	Responsibility
Learning to be shared at local level – ILG Quality and safety forum	ILG Quality & Safety meeting
Wider organisational learning (Shared at Quality, Governance and learning, subcommittee, Safety bulletins, Person Safety events and Newsletter etc.)	ILG & Corporate Quality & Safety Team
External to Health Board, linking with external agencies, e.g. HEIW, Delivery Unit, CHC	Learning from Concerns Coordinator
Learning from Events Record Completed	ILG Q&S meeting

## Appendix 1

# Serious Incident Meeting – Within 3-5 Working Days Agenda

**Pt Safety Manager must use the SI/NE Checklist for assurance and place within Datix**

Item	Lead
<ul style="list-style-type: none"> <li>• Introductions</li> </ul>	
<ul style="list-style-type: none"> <li>• Apologies</li> </ul>	
<ul style="list-style-type: none"> <li>• Chronology of Events (establish an early timeline /sequence of events) presented by IO</li> </ul>	
<ul style="list-style-type: none"> <li>• Immediate Actions Required/Already Undertaken to make safe</li> <li>• Secure all the records</li> </ul>	
<ul style="list-style-type: none"> <li>• Terms of Reference of the investigation (including the scope of the investigation and specific issues for the investigation to address)</li> <li>• Timescale for information gathering</li> </ul>	
<ul style="list-style-type: none"> <li>• Confirmation of Family Liaison</li> <li>• Confirmation of Staff Liaison</li> </ul>	
<ul style="list-style-type: none"> <li>• Identification of any other stakeholders</li> <li>• Consider any matters relating to Safeguarding Adults/Children; Adult Practice Review</li> </ul>	
<ul style="list-style-type: none"> <li>• Any Media/Communication Implications identified</li> </ul>	
<ul style="list-style-type: none"> <li>• Confirm Follow Up Meeting required and dates agreed</li> <li>• Review Group – provisional date agreed</li> </ul>	
<ul style="list-style-type: none"> <li>• Any Other Business</li> </ul>	

## Appendix 2

# Investigation Report

**CONFIDENTIAL**

**Incident Investigation Title**

**Datix Incident Number(s)**

**Welsh Government Incident Reference (if applicable)**

<p><b>Unit Executive Sign-off</b> <b>Name:</b> <b>Title:</b> <b>Date of approval:</b></p>	
<p><b>Corporate Executive Sign-off</b> <b>Name:</b> <b>Title:</b> <b>Date of approval</b></p>	

# All CTM Serious Incident Reports must be completed using this agreed template



Contents	Page Number
<p><b>1. Incident Details</b></p> <ul style="list-style-type: none"> <li>○ ILG &amp; Specialty</li> <li>○ Incident date</li> <li>○ Incident type</li> <li>○ Level of harm</li> <li>○ Trigger for Investigation</li> <li>○ Incident Description</li> </ul>	
<p><b>2. Investigation Details</b></p> <ul style="list-style-type: none"> <li>○ Who commissioned the report</li> <li>○ Terms of Reference</li> <li>○ Scope of the investigation as agreed in Initial SI meeting</li> <li>○ Engagement and support provided to the patient, family or relevant persons</li> <li>○ Specific questions requested by the patient, family or relevant persons</li> <li>○ Involvement and support provided to staff</li> <li>○ Investigation process and methods used</li> <li>○ Information and evidence gathered</li> </ul>	
<p><b>3. Investigation Findings</b></p> <ul style="list-style-type: none"> <li>○ Description of Key Events</li> <li>○ Notable Practice</li> <li>○ Care &amp; Service Delivery problems</li> </ul>	
<p><b>4. Analysis</b></p> <ul style="list-style-type: none"> <li>○ Contributory Factors</li> <li>○ Fundamental Factors</li> </ul>	
<p><b>5. Conclusions</b></p> <ul style="list-style-type: none"> <li>○ Root Causes</li> <li>○ Response to specific questions not covered within the main body of the report</li> </ul>	

<b>6. Lessons Learned</b> <ul style="list-style-type: none"> <li>○ If applicable Lessons Identified</li> <li>○ If applicable Incidental Learning</li> </ul>	
<b>7. Recommendations</b> <b>Arrangement for sharing learning</b> (local, Health Board wide, national)	



<b>1. Incident Details</b>	
<b>Directorate &amp; Specialty</b>	
<b>Incident Date</b>	
<b>Incident Type</b>	
<b>Level of Harm</b>	
<b>Trigger for Investigation</b>	
<b>Incident Description</b>	

<b>2. Investigation Details</b>	
<b>Who commissioned the report</b>	<b>Use titles only</b>
<b>Investigation Team</b>	<b>Use titles only</b>

- 2.1 Terms of Reference as agreed in initial SI meeting**
- 2.2 Scope of the investigation**
- 2.3 Engagement and support provided to the patient, family or relevant persons**
- 2.4 Specific questions requested by the patient, family or relevant persons**
- 2.5 Involvement and support provided to staff**

**2.6 Investigation process and methods used**

**2.7 Information and evidence gathered**

### **3. Investigation Findings**

**3.1 Description of key events**

**3.2 Notable practice**

**3.3 Care and service delivery problems**

### **4. Investigation Analysis**

**4.1 Contributory Factors (linked to Care or service delivery problems)**

**4.2 Fundamental Factors**

### **5. Investigation Conclusions**

**5.1 Root Causes**

**5.2 Response to specific questions not covered within the main body of the report**

### **6. Lessons Learned**

**6.1 Lessons Identified (which directly contributed to the incident)**

**6.2 Incidental learning (other problems identified during the investigation which did not impact upon the concern)**

**6.3 Recommendations**

### **7. Arrangements for sharing learning**

## Appendix 3

# Investigation Report CRIB SHEET

<b>Unit Executive Sign-off</b> <b>Name:</b> <b>Title:</b> <b>Date of approval:</b>	<i>Name &amp; Date</i>  <i>Sign off/closure means that the investigation is complete and an action plan is in place.</i>
<b>Corporate Executive Sign-off</b> <b>Name:</b> <b>Title:</b> <b>Date of approval</b>	<i>Name &amp; Date</i>  <i>Sign off/closure means that the investigation is complete and an action plan is in place.</i>

<b>1. Incident Details</b>	
<b>Directorate &amp; Speciality</b>	
<b>Incident Date</b>	
<b>Incident Type</b>	<i>Example: in-patient fall, unexpected death, severe harm of one or more patients, delayed diagnosis.</i>
<b>Level of Harm</b>	<i>Link to All Wales Framework (SharePoint)</i>
<b>Trigger for Investigation</b>	<i>For example: Incident Reporting, Claim, Complaint, Inquest, Mortality Review</i>
<b>Brief Description of Incident</b>	<i>Provide a clear, concise description and its effect on (or outcome) for the patient, the staff, the service and any other stakeholder.</i>

<b>Investigation Details</b>	
<b>Who commissioned the report</b>	<i>Use titles only</i>
<b>Investigation Team</b>	<i>Use titles only</i> <ul style="list-style-type: none"> <li>- Job title (Lead investigator).</li> <li>- Job title</li> <li>- Job title</li> </ul> <i>These individuals were not involved in the incident directly and were selected to conduct an objective investigation and provide independent professional expertise, scrutiny and advice.</i>
<b>Terms of Reference</b>	<ul style="list-style-type: none"> <li>a) <i>Establish the Facts i.e. what happened to whom, when, where (the chronology), how and why (contributory factors and root causes)</i></li> <li>b) <i>Establish whether relevant standards, policies, procedures or guidelines were followed (the care and service delivery problems)</i></li> <li>c) <i>Identify whether gaps occurred in the care and treatment and whether these</i></li> </ul>

	<p>could have impacted on the incident (the care and service delivery problems)</p> <p>d) Look for improvements rather than apportion blame</p> <p>e) Make recommendation as to how the root causes may be reduced or eliminated</p> <p>f) Produce an action plan in response to the recommendations of the investigation team</p> <p>g) Provide a report as a record of the investigation process</p> <p>h) Provide a means of sharing learning from the incident</p>
<b>Scope of the investigation as agreed in initial SI meeting</b>	<p>The investigation covers the events from date and time leading up to when xxxxxx happened to date and time when xxxxxx happened. Provide rationale for this.</p> <p>To include specific issues in addition to the Terms of Reference</p>
<b>Engagement and support provided to the patient, family or relevant persons</b>	<p>This needs to include what communication has taken place with patients and or carers?</p> <p>This would include;</p> <ul style="list-style-type: none"> <li>- An apology,</li> <li>- Explanation of what has happened</li> <li>- Actions taken to address any problems incurred</li> <li>- On-going mechanisms of support e.g. allocated point of contact person</li> </ul>
<b>Specific questions raised by the patient/family or relevant persons</b>	<p>This includes all questions raised by the patients, family or relevant persons through interviews or in writing which may or may not be addressed in the main report. If there are no questions, please document.</p>
<b>Involvement and support provided for staff</b>	<p>This needs to include what communication had taken place with staff and has there been appropriate level of communication.</p> <p>This would include;</p> <ul style="list-style-type: none"> <li>- How staff were notified</li> <li>- Assist Me</li> <li>- Counselling where considered appropriate and de-briefing following the incident,</li> <li>- Staff updates relating to progress of the investigation</li> <li>- Communication of the outcome of the investigation</li> </ul>
<b>Investigation process and methods used</b>	<p>Summary of the tools used.</p> <p>Refer to investigation tools/information sources used;</p> <ul style="list-style-type: none"> <li>- Review of health records e.g.</li> <li>- fishbone analysis</li> <li>- Chronology/timeline</li> <li>- Just Culture Guide</li> <li>- Incident review meeting(s)</li> <li>- Barrier analysis</li> <li>- Interviews with individuals involved</li> <li>- recollection of events</li> </ul>

	<ul style="list-style-type: none"> <li>- Statements from staff</li> <li>- Five "whys"</li> <li>- External Independent expert opinion</li> <li>- Brainstorming</li> <li>- Post mortem report</li> <li>- Coroners involvement</li> <li>- Mortality review and site visits</li> </ul>
<b>Information and evidence gathered</b>	<p><i>This should include reference to evidence gathered.</i></p> <p><i>For example: recollection of events, documentation, policies, procedures, guidance, expert opinions, cause of death, mortality review</i></p>
<b>Investigation Findings</b>	
<b>Description of key events</b>	<p><i>This should include a summary of the key events identified. This can be presented as a tabular timeline.</i></p>
<b>Notable practice</b>	<p><i>Give a brief description of all practice, where it can be demonstrated that the care and treatment of the patient exceeded local and national practice standard. Use bullet points</i></p>
<b>Care or service delivery problems</b>	<p><i>The following are areas where the care and treatment fell below local and/or national practice standards, or where systems necessary to reduce risk and assure safety were missing; This information needs to be presented in a numerical narrative format.</i></p> <p><i>Care and service delivery problems are points in the timeline at which "something happened that shouldn't have happened OR something that should have happened didn't" These should be very specific, describe what happened and not why it happened</i></p> <p><i>Prioritise for analysis.</i></p> <p><i>Add in which tools were used to identify them.</i></p>
<b>Analysis</b>	
<b>Contributory factors (linked to Care or Service Delivery problems)</b>	<p><i>A summary of the significant problems need to be listed, and each one analysed to identify the factors that contributed to the problem.</i></p> <p><i>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.</i></p>
<b>Fundamental Factors</b>	<p><i>Key factors that have influenced the incident that are not directly linked to a care or service delivery problem. i.e. circumstances outside of our control, e.g. non-compliant patients</i></p>
<b>Conclusions</b>	
<b>Root Causes</b>	<p><i>Ensure the root cause addresses what you are investigating as set out in the terms of reference e.g. if you are investigating a fall, the root cause should relate to why the patient fell and numbered;</i></p>

	<p>1. XXXX 2. XXXX</p>
<p><b>Response to specific questions not covered within the main body of the report</b></p>	<p><i>These can include answers to specific questions asked by the patient/family and requested within the Terms of Reference. These could require referencing to previous sections of the report for detail; Question 1: XXXX Answer Question 2: XXXX Answer</i></p>
<p><b>Lessons Learned</b></p>	
<p><b>If Applicable Lessons Identified</b></p>	<p><i>(which directly contributed to the incident)</i></p>
<p><b>If Applicable incidental learning</b></p>	<p><i>Other problems identified during the investigation which did not impact upon the concern. These can be numbered or bullet pointed</i></p>
<p><b>Recommendations</b></p>	
<p><b>Arrangements for sharing learning (local, Health Board wide, National)</b></p>	
<p><i>Describe how learning has been or will be shared with staff and other organisations.</i></p>	

## Appendix 4

# Learning from Events Record

Learning from Events Report – Clinical Cases

- Clinical Negligence - compensation agreed/awarded where payment of financial compensation has or may exceed £25,000
- NHS Redress - compensation agreed/awarded
- Scheme for General Medical Practice Indemnity - compensation agreed/awarded
- Case exceeding £1m with Welsh Government approval required to agree damages
- Serious Incidents reported to Welsh Government

### Report on Learning following investigation to the Welsh Risk Pool

#### 4.00 Issues & Actions

Issue	Actions	Status
State what the issue is here. Examples of completed reports are available from the unit Governance lead	REF	Outline all of the actions taken  State whether completed
	Number Here	

Issue	Actions	Status
	REF	
	REF	

#### 5.00 Learning Assurance Plans

Ref	Topic	Plan Summary	Status
Add number here, e.g. 01	Add learning required, e.g. reflection and wider organisational learning	EG, share @ Governance meeting or a learning event organised	Add date of completion and evidence, e.g. minutes, presentation, attendance lists etc.

#### 7.00 Supporting Documentation

Ref	Title	Outline
Add number here, e.g. 01	E.G. national guidance or a revised policy	Summarise how this has been implemented

**GOVERNANCE DECLARATION**

I have considered fully the investigation findings, issues, actions plans and learning assurance, and confirm to the best of my knowledge, that the details recorded above are complete, accurate and reasonable response to the findings of the case.

Signed by

Date \_\_\_\_\_

Print Name - .....

Position - .....

## Appendix 5 Assurance Checklist

### Assurance review of processes for managing, investigating and learning from Serious Incidents (SIs) or Never Events (NE's)

Incident details	Timescales	
DATIX reference:	Date incident occurred/identified:	
WG reference:	Date submitted to WG/DU:	
Type of incident:	CTMUHB deadline (60 days):	
IRG position:	Assured / Not assured	Date:
Comments related to assurance:		
<b>If not assured – recommendation and actions for Health Board</b>		
IRG recommendation:		
<i>We recommend this serious incident is not closed</i> <input type="checkbox"/>	Signed and dated:	
Health Board actions:	Due date:	
-	-	
-	-	
-	-	
-	-	

Appendix A: Assurance Review Details

**Section 1: impact of incident on patient**

**1. Is it clear what happened? Is there a concise summary?**

YES	<i>Comments:</i>
NO	

**2. Were immediate actions taken to make the patient safe following the incident?**

YES	<i>Comments:</i>
NO	

**3. Was it clear what impact this incident had on the patient?**

YES	<i>Comments:</i>
NO	

**4. Did patient harm or could harm have resulted from this incident?**

YES	<i>Comments:</i>
NO	

## Section 2: impact of incident on staff and service

### 5. Were immediate actions taken to make the staff and situation safe following the incident?

YES	<i>Comments:</i>
NO	

### 6. Was it clear what immediate/contemporaneous impact (if applicable) this incident had on the service?

YES	<i>Comments:</i>
NO	

## Section 3: support and inclusion of individuals involved in the incident

### 7. Has appropriate communication and involvement taken place with the patient, and/or their family/carers?

*Including:*

- an apology, explanation of what has happened and clarification that this incident will be the subject of an investigation
- actions taken to address any problems incurred
- involvement in the investigation e.g. provision of recollection of events

YES	<i>Comments:</i>
NO	

### 8. Has adequate support been offered to the patient, and/or their family/carers?

YES	<i>Comments:</i>
-----	------------------

**9. Has appropriate communication has taken place with staff?**

*Including*

- how staff were notified
- communication of the outcome of the investigation

YES	<i>Comments:</i>
NO	

**10. For staff directly involved, have they been involved in the investigation and has adequate support been offered to them?**

*Including*

- counselling and de-briefing where considered appropriate
- involvement in the investigation, including opportunities to raise concerns for investigation

YES	<i>Comments:</i>
NO	

**Section 4: investigation**

**11. Did the investigation scope include all relevant issues?**

*Including*

- evidence of patient/family/staff involvement in agreeing the scope

YES	<i>Comments:</i>
NO	

**12. Is there evidence of broader information gathered to inform the background and context to the investigation?**

*Including*

- review of other information sources such as no/low harm incidents, other SIs, complaints, Reg 28 reports, risk registers, etc. to understand whether the incident or potential for the incident to occur has been identified
- review of similar incident(s) of this nature in the past
- patient safety solutions relevant to this incident and compliance status

YES	Comments
NO	

**13. Was an investigation team assembled which provided appropriate independence?**

1. No involvement with any aspect of the care under review
2. Representation outside of women's directorate
3. Representation from another health board

YES	Comments:
NO	

**14. Was an investigation team assembled which provided the necessary expertise?**

1. At least one member of the panel RCA trained
2. A skilled MDT investigation team capable of reviewing all aspects of care
3. A risk management representative

YES	Comments:
NO	

**15. Did the investigation being undertaken use recognised methodology and tools?**

YES	Comments:
NO	

<b>16. Were relevant care and service delivery problems identified?</b>	
YES	<i>Comments:</i>
NO	
<b>17. Were the identified problems explored or analysed to understand the underlying reasons why they occurred (i.e. contributory factors)?</b>	
YES	<i>Comments:</i>
NO	
<b>18. Do the root causes identified demonstrate an understanding of the underlying reasons why the incident occurred?</b>	
YES	<i>Comments:</i>
NO	
<b>19. Does the report identify what happened and why?</b>	
YES	<i>Comments:</i>
NO	

## Section 5: identifying and planning change

### 20. Is there a clear link between analysis and lessons learned?

YES	<i>Comments:</i>
NO	

### 21. Are recommendations linked to the analysis?

*Including*  
*-addressing the problems, contributory factors, and/or root causes identified*  
*-collaborate development with those who will implement and/or be affected by them*

YES	<i>Comments:</i>
NO	

### 22. Does the action plan address the problems identified and the recommendations made?

*Including*  
*-SMART (Specific, Measurable, Achievable, Relevant, Timely) and proportionate (strong/medium/weak) actions with clear deadlines and responsible individuals assigned*  
*-longer-term actions to monitor how learning from this investigation will be embedded and how change will be assessed*

YES	<i>Comments:</i>
NO	

### 23. Is it clear how will learning from this incident be shared:

- *across relevant areas/departments/sites*
- *with other organisations (where relevant)*

YES	<i>Comments:</i>
NO	

<b>24. Has any national learning been identified? If so, it is clear how this will be shared?</b>	
YES	Comments:
NO	

### Section 6: governance

<b>25. Is there evidence of robust quality assurance and independent scrutiny of this report?</b>	
<i>Including</i> -sufficient background and context to support the explanation of what happened and why - jargon free or with clinical terms explained -formatting, with correct spelling, completed sentences etc., with person identifiable information removed	
YES	Comments:
NO	
<b>26. Is there evidence that the health board has embedded learning from similar previous incidents (if any)?</b>	
YES	Comments:
NO	

<b>Date of QA Panel Meeting</b>	
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<b>Attendee name</b>	<b>Attendee title</b>



## Appendix 6 - Level of Harm Grading Framework

### 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 2 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 may be situations where the grading of harm is low i.e. a grade 2, but there is indication there they will be pursuing a claim.

**The examples listed are meant only to be a guide and not an exhaustive list.**

Grade	Harm	Examples of concerns	Consider potential for qualifying liability / Redress
1.	No harm	<ul style="list-style-type: none"> <li>a) Concerns which normally involve issues that can be easily / speedily addressed;</li> <li>b) Potential to cause harm but impact resulted in no harm having arisen;</li> <li>c) Outpatient appointment delayed, but no consequences in terms of health;</li> <li>d) Difficulty in car parking;</li> <li>e) Patient fall – no harm or time off work;</li> <li>f) Concerns which have impacted on a positive patient experience.</li> </ul>	Highly Unlikely
2.	Low	<ul style="list-style-type: none"> <li>a) Concerns regarding care and treatment which span a number of different aspects/specialities;</li> <li>b) Increase in length of stay by 1 - 3 days;</li> <li>c) Patient fall - requiring treatment;</li> <li>d) Requiring short period of time off work – up to 3 days;</li> <li>e) Concern involves a single failure to meet internal standards but with minor implications for patient safety;</li> <li>f) Return for minor treatment, e.g. local anaesthetic or extra investigations.</li> </ul>	Unlikely
3.	Moderate	<ul style="list-style-type: none"> <li>a) Clinical / process issues that have resulted in avoidable, semi-permanent injury or impairment of health or damage that require intervention;</li> <li>b) Additional interventions required or treatment / appointments needed to be cancelled;</li> <li>c) Readmission or return to surgery, e.g. general anaesthetic;</li> <li>d) Necessity for transfer to another centre for treatment / care;</li> <li>e) Increase in length of stay by 4 -15 days;</li> <li>f) RIDDOR Reportable Incident;</li> <li>g) Requiring time off work 4 -14 days;</li> <li>h) Concerns that outline more than one failure to meet internal standards;</li> <li>i) Moderate patient safety implications;</li> <li>j) Concerns that involve more than one organisation;</li> </ul>	Possible in some cases



Grade	Harm	Examples of concerns	Consider potential for qualifying liability / Redress
4.	Severe	a) Clinical process issues that have resulted in avoidable, 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 of work >14 days; g) A concern, outlining non-compliance with national standards with significant risk to patient safety; h) RIDDOR Reportable Incident;	Likely in many places
5.	Death	a) Concern leading to unexpected death 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;	Very Likely

National Patient Safety Agency (2008) A risk matrix for risk managers, NPSA, London



**Serious Incident Escalation Process**  
(Response required **within 60 working days\***)

**Approval of SI notification at Locality level**  
All completed SI notification should be sent to the Locality Director **for approval**; any SI's that relate to nursing to the Locality Nurse Director, those relating to medicine to the Locality Medical Director and maternity cases to the Director of Midwifery.

Locality Director who has approved the notification place a watermark of approval and email to their governance lead.

The Locality governance lead will forward their email of approval and attached SI document to:  
[CTHB.Patient.Safety.Incidents@wales.nhs.uk](mailto:CTHB.Patient.Safety.Incidents@wales.nhs.uk)

The corporate team will upload the email of approval and the approved document onto Datix; they will then send this to the Deputy Director to QA prior to presenting to Exec Director for approval and signature. Corporate team send signed notification to:  
[NationalSireports@wales.nhs.uk](mailto:NationalSireports@wales.nhs.uk)

ILG directs completion & closure of investigation and quality assurance of response.  
ILG send to:  
[CTHB.Patient.Safety.Incidents@wales.nhs.uk](mailto:CTHB.Patient.Safety.Incidents@wales.nhs.uk)

Central QA, Corporate sign off & Submission to DU by corporate team

Signed report returned to ILG to be shared with pt/ family



\*Breach of Duty admissions to be addressed via PTR





**GIG**  
CYMRU  
**NHS**  
WALES

Bwrdd Iechyd Prifysgol  
Cwm Taf Morgannwg  
University Health Board

**If you require any advice or assistance please contact the central CTM Serious Incident Team on**



**01443 744800**

<p><b>MAE EIN GWERHOEDD YN EIN HELPU NI I FOD AR EIN GORAU</b></p> <p><b>OUR VALUES HELP US BE AT OUR BEST</b></p>	<p><b>RYDYN NI'N GWRANDO YN DYSGU AC YN GWELLA</b></p>  <p><b>WE LISTEN, LEARN AND IMPROVE</b></p>	<p><b>RYDYN NI'N TRIN PAWB A PHARCH</b></p>  <p><b>WE TREAT EVERYONE WITH RESPECT</b></p>	<p><b>RYDYN NI I GYD YN CYDWEITHIO FEL UN TIM</b></p>  <p><b>WE ALL WORK TOGETHER AS ONE TEAM</b></p>
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