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## Putting Things Right Incident Reporting and Management Procedure

The aim of this procedure is to provide a structured overview of the incident management process within Public Health Wales. It covers the reporting and investigation processes for all clinical and non-clinical incidents including National Reportable Incidents (NRI's) requiring investigation, near misses and hazards and applies to incidents involving people who access our services, visitors, the public, employees of Public Health Wales.

### Linked Policies and Procedures

[All corporate policies and procedures are available on the Public Health Wales website](#)

Claims Management Policy & Procedure

Complaints Procedure

Duty of Candour Policy

Duty of Candour Procedure

Health & Safety Policy & procedure

Infection Prevention & Control Policy & Procedure

NHS Wales Information Governance Policy

National Policy on Patient Safety Incident Reporting & Management

Putting Things Right Policy

Redress Procedure

Risk Management Policy & Procedure

Safeguarding Policy & Procedure

All Wales Procedure for NHS Staff to raise concerns

Medical Devices and Equipment Management Policy & Procedure

### Related Documents

[The Duty of Candour Statutory Guidance 2023](#)

[The Duty of Candour Procedure \(Wales\) Regulations 2023](#)

[Health and Social Care \(Quality and Engagement\) \(Wales\) Act 2020](#)

[NHS Wales \(Concerns, Complaints and Redress Arrangements \(Wales\)](#)

[Regulations 2011\) as amended by National Health Service \(Concerns, Complaints and Redress Arrangements\) \(Wales\) \(Amendment\) Regulations 2023](#)

[Guidance on dealing with concerns about the NHS from 1 April 2011\(v3, 2013\)](#)

## Scope

This procedure applies to all Public Health Wales staff, visitors, contractors, agency staff and volunteers and any reference to staff should be interpreted as including these groups.

The procedure applies to all events which fall under the following criteria:

- Clinical and Non-Clinical Incidents
- Safeguarding incidents
- Near misses
- Nationally Reportable Incidents
- Never events
- Early Warnings
- Medical Devices Incidents

The procedure does not apply to the following:

- Error Non Incidents

The Incident, Complaints, Redress and Duty of Candour Procedures are closely aligned with this procedure and as such there are many parallel activities.

<b>Equality and Health Impact Assessment</b>	An Equality, Welsh Language and Health Impact Assessment has been completed and can be viewed on the policy webpages.
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### Disclaimer

**If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the [Board Business Unit](#)**

<b>Summary of reviews/amendments</b>				
<b>Version number</b>	<b>Date of Review</b>	<b>Date of Approval</b>	<b>Date published</b>	<b>Summary of Amendments</b>
2.0	03/12/2018			Extensive re-write
2.1	11/11/2020			Re-write under the new Putting Things Right Policy
2.2	29/03/2023			Streamline following implementation of Duty of Candour Regulations and Duty of Quality.

## **IMPORTANT NOTE**

**In the event of any incident occurring which requires immediate action, nothing in this procedure should prevent or delay any person taking any action required to save life, prevent harm or limit the damage caused by the incident.**

These actions are referred to as Remedial Actions, such as:

- Alert a First Aider should an individual(s) be injured
- Ensuring the area is safe to limit further harm or potential harm to others
- Stopping a process such as the reporting of results in an electronic system or samples being processed
- Removal or recall of personal information that has been misdirected/published inappropriately

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# **1. Introduction**

The aim of this procedure is to provide a structured overview of the incident management process in Public Health Wales from start to finish. It covers the reporting and investigation processes for all clinical and non-clinical incidents including Serious Incidents requiring investigation, near misses and hazards and applies to incidents involving people who access our services, visitors or carers, the public, employees or business of Public Health Wales (PHW).

The reporting and management of incidents is a critical tool in assisting the organisation to effectively manage risk. The reporting of incidents and near misses provides valuable information which can help improve safety, prevent the recurrence of incidents and facilitate organisational learning. The goal is to promote the prevention of loss or harm through the development of safer working practices that will benefit staff, people who access our services, and the general public, and improve the trust's services.

This procedure is for all staff includes the principles of "Being Open" and embraces the "Duty of Candour". Where incidents occur we need to evidence openness, honesty and transparency so that early warning systems can work. Expectations of the Duty of Candour include ensuring that any service user harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it. The Duty of Candour and Duty of Quality became a legal obligation from April 2023.

This procedure must be read in conjunction with the Putting Things Right Policy and Complaints, Redress and Duty of Candour Procedures.

## **2. Roles and Responsibilities**

### **Chief Executive**

The Chief Executive is the responsible officer for Public Health Wales and is accountable for ensuring that the organisation can discharge its legal duties in relation to the health and safety of, service users and visitors and staff.

### **Executive Director of Quality, Nursing and Allied Health Professionals**

Public Health Wales has designated the Executive Director of Quality, Nursing & Allied Health Professionals to act as the responsible officer to oversee the day to day management of the Incident Reporting and Management Procedure. They will:

- Brief the Chief Executive and/or Board as necessary on any incidents that need to be raised at Executive or Board level
- Maintain a Quality Management System that enables the organisation to report, monitor and learn from incident investigations, and where necessary implement appropriate changes to systems and processes.

## **Strategic Oversight**

Public Health Wales has designated the Vice Chair to have Strategic oversight of the PTR arrangements in Public Health Wales.

They are responsible for:

- Keeping an overview on how the organisation's arrangements are operating at a local level.
- Ensuring that Public Health Wales comply with the management of concerns as outlined within the Regulations.

## **Executive Directors**

Are responsible for:

- Ensuring that incidents within their areas of responsibility are reported on Datix Cloud, investigated and managed appropriately to fulfil responsibilities in accordance with this procedure.
- Highlighting any Nationally reportable incidents/Early Warning incidents to the Chief Executive
- Ensuring that effective analysis and learning systems are in place within their areas and that assurance and monitoring takes place from incidents
- Ensuring that following identified learning from incidents that plans are developed to implement improvements or changes.
- Commit to the requirement to follow the Duty of Candour, Duty of Quality and Being open requirements determined by the Health and Social Care Act
- Receiving and scrutinising incidents within their services and highlighting any areas of concern to QSIC

## **Divisional Directors**

Are responsible for:

- Operational oversight of Incident reporting and management responsibilities
- Ensure that service areas are appropriately resourced to support with incident management to include staff with dedicated roles to support with investigating incidents
- Ensure that service areas are trained to use the Datix Cloud system and in line with their incident reporting and management responsibilities
- Ensuring that effective analysis and learning systems are in place within their areas and that assurance and monitoring takes place.
- Ensuring that following identified learning from incidents that plans are developed to implement improvements or changes
- Receiving and scrutinising PTR elements of their services and highlighting any areas of concern to QSIC
- Ensuring incidents are progressed within 30 working days from reporting, and only in exceptional circumstances are incidents ongoing beyond this with explanation of outstanding actions and timescales for completion reflected within the incident record on datix.

## **Heads of Programme/Service/Managers**

Are responsible for:

- Responsible for management oversight of Incident reporting & management
- Ensuring that they, and all of their staff are familiar with and following this procedure
- Ensuring that all staff can access training covering incidents and support further training identified in relation to incident management, investigation and learning according to their roles.
- Ensuring incidents are reported and appropriately investigated within the required timescales as set out in this procedure.
- Take action to mitigate against recurrence and to provide feedback and learning through their local meetings or forums
- Support staff involved in and/or affected by a concern or incident
- Ensuring incidents are progressed within 30 working days from reporting, and only in exceptional circumstances are incidents ongoing beyond this with explanation of outstanding actions

and timescales for completion reflected within the incident record on datix.

## **Head of Putting Things Right**

Is responsible for:

- Maintaining a management system for the management of all matters concerned with Incidents
- Support PHW to meet its external reporting requirements to Welsh Government targets for the submission of Nationally Reportable Incidents, Early Warning notifications and never events.
- Scrutinising Incident data and escalating any areas of concern to the relevant Director, Divisional Lead, Quality Lead and Quality Safety and Improvement Committee
- Ensuring incidents are progressed within 30 working days from reporting, and only in exceptional circumstances are incidents ongoing beyond this with explanation of outstanding actions and timescales for completion reflected within the incident record on datix.

## **All Staff**

Every member of staff has the responsibility to report any event that falls into the criteria defined as an incident on Datix Cloud as soon as a reasonably practicable, but within 48 hours of identifying or first becoming aware of the incident.

## **3. Definitions**

### **3.1 What is an Incident?**

An incident is any unplanned event which leads to an undesirable impact on Public Health Wales, which also includes near misses. This can include impacts on:

- Safety of service users, staff, visitors or members of the public
- Quality of the service provided
- Staffing (availability of competent, trained staff)
- Legislative/Regulatory Compliance
- Adverse Publicity/Reputation

- Business Objectives/Projects
- Finance including claims
- Service Continuity
- Information Security
- Health & Safety – including medical devices

**All incidents must be reported on the Datix Cloud system.**

### **3.2 Why do we report incidents?**

We know we have an obligation to report incidents, but why do we do it?

- Datix Cloud is your “accident book” and should be used as a system to record and audit all of the incidents that occur within Public Health Wales.
- We have a duty to be open and honest when we have fallen below standards in line with Putting Things Right Regulations, Duty of Candour and Duty of Quality Legislation.
- To allow us to conduct thorough investigations and ensure lessons are learnt and actions are taken to prevent re-occurrence of incidents.
- We report our incident data publicly and strive to report accurate numbers of incidents, avoiding under-reporting.
- To ensure we are adhering to Health & Safety legislation and our legal obligations.
- The organisation is regularly audited on incident reporting and management.
- It’s just the right thing to do!

### **3.3 Definition List**

A full list of all incident definitions can be found [here](#) includes the following:

What is a early warning incident notification? (EWN)

What is a error-non incident?

What is a medical devices incident?

What is a Nationally Reportable incident (NRI)?

What is a near miss?

What is a Never event?

What is a patient safety incident?

What is a safeguarding incident?

What is Duty of Candour?

## **4. Process**

### **4.1 How to report an incident?**

For details on how to report an incident, please see Appendix 1 [here](#)

### **4.2 Incident Process Overview**

A flow chart is available at [here](#) of the incident process overview

### **4.3 Datix Incident processes**

The following flowchart must be adhered to for managing incidents within Datix Cloud which can be found [here](#)

### **4.4 Datix Incident Timescales**

<b>Incident Status</b>	<b>Timescale (from date reported on Datix)</b>	<b>Completed by</b>
Initial Review	24 hours	PTR Team
Management Review/Make it Safe	72 hours	Responsible Lead/Incident Manager
Under Investigation	1-30 days	Incident Manager
Awaiting Closure	1-30 days	Responsible Lead/Approver

*\*\* It is noted that, where appropriate, low-level incidents are able to be completed and closed under Management review on Datix \*\**

### **4.5 Actions and ongoing Actions**

Incidents should be managed with the use of the actions functionality on the incident module in Datix cloud. The PTR team can be contacted for support on how to use the actions function which offers support to remind staff to complete outstanding actions with regular automated reminders. Progress notes must be utilised when actions are being utilised, with monthly updates as a minimum visible on the Datix record.

Progress against the status of actions is monitored by the PTR team.

Incidents which have concluded the investigation process but may have ongoing actions are able to be closed with actions set within Datix to complete the outstanding actions. These incidents must be raised to the PTR team for approval and monitoring.

## **4.6 Quality Reviews**

Upon Closure of an incident, a monthly retrospective sample of incidents are subject to a quality review process involving the PTR Managers and the Quality & Clinical governance manager. Quality reviews look at the quality of the investigation, provide feedback where necessary and good practice is recognised. Themes and trends are monitored and shared as required.

## **4.7 Quality Assurance**

In order to support the organisations Duty of Quality obligations, once the incident investigation is complete (including an Investigation Report being populated using the appropriate methodologies and a safety improvement plan has been formulated and agreed as required), all associated documents must be uploaded to the Datix incident record. The incident investigation section must also be completed.

Where an investigation has been undertaken involving a Nationally Reportable Incident, Early Warning notification or Duty of Candour, the Putting Things Right Team must be notified that the investigation has been completed by emailing [incident.safety.phw@wales.nhs.uk](mailto:incident.safety.phw@wales.nhs.uk). For these more complex incidents, the Putting Things Right team will conduct a review of the record and either provide an indication for further information or agreement to progress for closure.

It will not normally be necessary for the incident to remain open until the safety improvement plan has been delivered as this may take many months. Actions should be created in the Datix Cloud record which staff can manage via the action dashboard within Datix Cloud. This will also be monitored by the PTR team.

## **4.8 Learning from Incidents**

It is important to remember that a key element of the incident management process is to identify learning in order to improve safety and reduce the risk of recurrences promoting continuous improvement.

Any incident investigation can identify learning for the organisation and must be shared as widely as possible across the organisation.

Safety Improvement plans and risk reduction measures are managed locally within Divisions by the Divisional Director and Divisional General Managers/Business Managers.

The Divisions are responsible for ensuring that any identified learning is shared and informs practice.

Within Public Health Wales, learning from incidents will be shared via the following routes:

- Team and Programme Meetings
- Directorate Senior Management Meeting
- Divisional Meetings
- Laboratory Safety Huddles/briefings
- Safety bulletins circulated to staff,
- Governance meetings and Committees

PHW shares safety lessons externally via the following:

- Liaising with staff from outside the organisation of incidents involving other Health boards and Trusts/ organisations.
- Reporting incidents externally via the National Reporting Incident mechanism which allows other Health Boards and Trusts to learn lessons from safety alerts published through the Alerting System

## **5. Protocol**

### **5.1 Incidents involving another Responsible Body**

If a member of PHW staff is made aware of an incident of which the cause of the incident was a result of another responsible body conducting its business, these should be raised with the appropriate responsible body.

These can be captured on PHW's incident module when there is a particular cause for concern, ensuring appropriate evidence is

uploaded to the incident record to demonstrate how the incident has been escalated to the responsible body.

If staff are unaware of whom to contact in another organisation, they should contact [phw.datix@wales.nhs.uk](mailto:phw.datix@wales.nhs.uk).

## **5.2 Incidents requiring joint investigations internally or with another Responsible Body**

If an incident has occurred as a result of two PHW departments or PHW and another responsible body conducting its business, a joint investigation will be required.

Some incidents that will require joint investigations, include:

### **1. Internal joint investigations**

- Different departments in PHW are involved in the incident

E.g., an incident has impacted health protection due to an action in microbiology

### **2. Commissioned services**

The joint investigation will normally be led by the primary department/organisation involved in the services user's care or the department/organisation in which the incident occurred.

For Commissioned services, the lead will likely be the organisation commissioning the service.

For all joint investigations, the final investigation report and action plan must be shared and approved by both organisations. It is the responsibility of the investigators from each responsible body to share these documents with each other.

## **5.3 Incidents and External agencies**

Some incidents require reporting to external agencies. **It is important to note that individuals are not responsible for externally reporting an incident, this will be done corporately.**

The types of incidents that require reporting and the designations of the individuals who are responsible for reporting these incidents are outlined below.

<b>Incident Type</b> (as defined by the relevant agency)	<b>External Agency</b>	<b>Responsible area</b>
Service user safety incident (Nationally Reportable incident)	NHS Wales Delivery Unit	Putting Things Right Team
RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrence Regulations)	Health & Safety Executive	Health and Safety Manager
Medical Devices /equipment incident	The Medicines Healthcare and Regulatory Agency (MHRA)	Medical Devices Management Group
Early warning notification (providing rapid information to Welsh Government on a range of issues, which may or may not relate to healthcare but may have reputational impact)	Welsh Government	Putting Things Right Team
Information Governance	Information Commissioner	Data Protection Officer
Failures of buildings, plant, nonmedical equipment or fire protection installations	Shared Services	Estates and Facilities Team
Estates /environmental issues	Estates and Facilities	Estates and Facilities Team
Infection Prevention Control	Health Protection Team, PHW	Lead Nurse for IPC
Significant disruption to service continuity / major incident	All Wales agencies/bodies as appropriate	Head of Emergency Preparedness and Response (EPRR)
Safeguarding	Local Authorities/agencies as appropriate	Named Lead for Safeguarding or if unavailable the person who has identified the safeguarding concern as there should not be a delay.

For guidance on each specific incident type and its management please refer to the guidance [here](#).

## 5.4 Incident Assurance

### Monthly

On a monthly basis, an integrated performance report is produced and shared with the Business Executive Team (BET), sharing a monthly analysis and data for incidents for the previous month.

### Quarterly

The PTR team submits a quarterly Putting Things Right report to the Quality, Safety and Improvement Committee (QSIC), which contains incident data for the previous quarter. This report contains:

- Numbers, types and levels of harm of incidents reported by Directorate and location
- Nationally Reportable Incidents
- Early Warning Notifications
- Never events (as applicable)
- Duty of Candours
- Numbers and themes of complaints (both formal and early resolution per Directorate
- Numbers of compliments

Staff are encouraged to positively report incidents onto Datix Cloud to ensure an accurate reflection of incident reporting is captured which can feed into Incident analysis. Incident reporting is a positive tool, and promotes a culture of openness, transparency and supports the organisations ethos of embedding continuous improvement.

## **5.5 Incident Information and Risk**

It should be noted that any potential risk identified from an incident, complaint or claim investigation should be included on the appropriate service line and corporate or strategic risk register, with outlined

risk reduction measures at any time following such an occurrence. Any high-level risks identified, i.e. risks scoring 15 or above are considered for inclusion on the strategic risk register. For further information please refer to the Risk Management Policy or contact the Risk Manager for risk support.

## **5.6 Being Open, Apologising and Duty of Candour**

All staff are encouraged to report service user safety incidents. Dependent upon the severity of the incident it may be necessary to inform a senior manager who can then ensure that the appropriate level of support is offered to the staff member(s) involved.

Where an incident occurs that has caused or may have caused moderate and above harm, then Duty of Candour regulations apply and this process must be followed. This includes informing the service user, their family and/ or carers that an incident has occurred, explain if something had gone wrong and apologise, if appropriate,

and explain what was learnt to reduce the likelihood of this happening again in line with 'duty of candour'.

Please refer to Duty Candour Procedure for further information regarding Duty of Candour, and contact [legalsupport.phw@wales.nhs.uk](mailto:legalsupport.phw@wales.nhs.uk).

## 6. Procedure

### Levels of Investigation and Investigation Tools

Information regarding the appropriate levels of investigation for incidents can be found at Appendix 3 [here](#).

#### 6.1 Incident Investigation Timescales

**All incidents must be investigated within 30 working days from the date reported on Datix.** Less complex incidents require a lesser timescale, and more complex incidents may require an extended investigation time requiring the systems-based approach investigation methodology.

Any incident investigations exceeding the 30-day timescale must be updated regularly within the Datix record, outlining outstanding actions and timescales for completion.

#### 6.2 Incident Investigation Tools

When investigating an incident which requires a comprehensive investigation, please refer to the Incident Investigation tools outlined in appendix 4 found [here](#).

#### 6.3 Completing a SMART Safety Improvement Plan

Information for completing a Safety Improvement plan (action plan) can be found at appendix 5 [here](#).

#### 6.4 Levels of Harm

All incidents must be graded at the point of reporting according to the **actual** impact and not the potential impact to the people involved and/or the organisation whilst receiving services and functions provided by Public Health Wales.

The guidance document found [here](#) provides support to staff on levels of harm.



### Top Tip!

Example of recording level of harm: If a microbiology test result is delayed and a service user passes away, but not as a result of the delayed microbiology test result the incident would not be categorised as Catastrophic/Death.

In this case, it's likely a categorisation of low harm would be appropriate.

If you are unsure on the categorisation of harm when reporting an incident contact the team via [incident.safety.phw@wales.nhs.uk](mailto:incident.safety.phw@wales.nhs.uk) who can help.

Further information on levels of harm can be found at Appendix 2 [here](#).

## 6.5 Nationally Reportable Incidents (NRI)

Any incidents that meet the criteria of a nationally reportable incident, which is set out [here](#) must be reported to the Delivery Unit at the earliest opportunity, but **no later than 7 working days following occurrence or point of knowledge of the incident.**

All NRI's must be recorded on Datix Cloud within 48 hours of identification and a email notification must be submitted to the Putting Things Right (PTR) team via [incident.safety.phw@wales.nhs.uk](mailto:incident.safety.phw@wales.nhs.uk) .

The reporting process found [here](#) should be followed.

The detail of the NRI will be checked by the PTR Team to confirm it meets the NRI threshold. The Divisional Lead will then be required to populate the Nationally Reportable Incident section within the Datix Cloud Incident record outlining details of the NRI. The guidance document found [here](#) should be followed to complete this process.

All Nationally Reportable Incidents must be reported on Datix Cloud and require a comprehensive investigation report and action plan,

utilising comprehensive investigation methodologies to identify actions and quality improvements which are then uploaded to the Datix record on conclusion. An outcome form is also required to be populated and submitted to the Delivery Unit within the agreed timescales on submission of the NRI notification form.

All documents must be reflected in the Datix Cloud Record along with comprehensive progress notes outlining the status of the incident investigation on a monthly basis as a minimum.

The Investigation must involve and have input from specialist areas as required E.g. Infection, Prevention & Control / Information Governance. Joint investigations are likely to be required in these instances.

## **Timescales for Nationally Reportable Incidents**

A summary of the timescale requirements for dealing with Nationally Reportable Incidents is listed below:

<b><u>Requirement</u></b>	<b><u>Timescale</u></b>
Datix Cloud Report	Within 48 hours of incident occurring/knowledge
NRI notification to Delivery Unit	No later than 7 working days from date of knowledge
Closure Report	30 working days (30+ to be agreed with PTR team)
Investigation Report & Action plan	30 working days (30+ to be agreed with PTR team)

## **NRI Incident Investigation Process**

The NRI Incident Investigation process followed [here](#) must be followed

### **6.6 Early Warning Incident Notifications (EWN)**

Early Warning Notifications (previously referenced as No Surprises) is a communication function within Welsh Government, which is defined [here](#).

Its purpose is to provide rapid information to Welsh Government on a range of issues, which may or may not relate to healthcare.

The Externally Reportable Incident Process found [here](#) must be followed for managing Early Warning Notifications.

All Early Warning Notifications must be reported on Datix Cloud. A comprehensive investigation is required for all Early Warnings which includes a investigation report and action plan, utilising comprehensive investigation methodologies to identify actions and quality improvements which are then uploaded to the Datix record on conclusion.

The Investigation must involve and have input from specialist areas as required E.g. Infection, Prevention & Control / Information Governance.

## **Early Warning Notification Timescales**

A summary of the timescale requirements for dealing with early warning notifications is listed below:

<b><u>Requirement</u></b>	<b><u>Timescale</u></b>
Datix Cloud Report	Within 48 hours of incident occurring/knowledge
Notification to Welsh Government	ASAP
Investigation Report & Action plan	30 working days (30+ to be agreed with PTR team)

## **Early Warning Notification Template**

The form below must be populated for an EWN.

[Early Warning notification form \(No Surprises\)](#)

## **EWN Incident Investigation Process**

The EWN Incident Investigation process followed [here](#) must be followed

## **EWN public relations Considerations**

Consideration must be given for any EWN that may have public relations implications e.g. adverse press

It is the responsibility of the area submitting the EWN to raise any potential public relations implications to the Corporate Communications Team.

## 6.7 Closure of Incidents

Information regarding closure times for incidents can be found at Appendix 6 [here](#).

## 7. Training

### 7.1 Internal Training

Public Health Wales offers training to all staff on the use of the Datix Cloud system for incident management.

All staff are required to complete Level 1 Incident Reporter training and Incident Investigators are required to complete Level 2 Incident Investigation Training.

Further information regarding Datix Cloud Incident training which is available on a monthly basis can be found on the PTR Team Incident SharePoint [here](#).

Please contact the team via [phw.datix@wales.nhs.uk](mailto:phw.datix@wales.nhs.uk) to book onto a Datix Cloud training session.

### 7.2 External Training

We are able to arrange for external training to support staff with the methodologies of investigating incidents such as the SBAR and Human Factors approach. To request training this training, please contact

## 8. Appendices – Links

Please find below, helpful links to various resources to support this procedure.

Resource Title	Externally available	Internally available
<a href="#">Link to report a Incident on Datix Cloud</a>		✓
<a href="#">How to report a Incident?</a>		✓
<a href="#">Incident Management Sharepoint</a>		✓
<a href="#">Level 1 Guide – Reporting an Incident on Datix Cloud</a>		✓
<a href="#">Incident Management Definition List</a>		✓
<a href="#">Levels of Harm PTR Guidance (Reporting Incidents)</a>	✓	✓
<a href="#">Levels of Harm Framework (Duty of Candour)</a>	✓	✓

<a href="#">Incident Process Overview</a>		✓
<a href="#">Incidents and External bodies/agencies</a>		✓
<a href="#">Just Culture Guide</a>	✓	✓
<a href="#">Datix Cloud Incident Management flowchart</a>		✓
<a href="#">List of Never Events</a>	✓	✓
<a href="#">Externally reportable Incident process</a>		✓
<a href="#">Nationally Reportable Incident Investigation Process</a>		✓
<a href="#">How to report a Nationally reportable Incident</a>		✓
<a href="#">Incident Investigation method- Systems Based Approach</a>		✓
<a href="#">Incident Investigation method- SEIPS approach</a>	✓	
<a href="#">Incident Investigation method- Yorkshire Contributory Factors Framework (YCF)</a>	✓	
<a href="#">Safety Improvement Plan Template (PHW)</a>		✓
<a href="#">RIDDOR reporting requirements</a>		✓
<a href="#">Nationally Reportable Incident (NRI) Criteria</a>		✓
<a href="#">Early Warning (No Surprises) notification form</a>	✓	✓
<a href="#">Early Warning Incident Investigation Process</a>		✓
<a href="#">Incident Severity Guidance Document</a>		✓
<a href="#">IRMER Reporting Information</a>	✓	
<a href="#">Data Breach Reporting Information</a>	✓	
<a href="#">RIDDOR Reporting Information</a>	✓	
<a href="#">Patient Safety Incident Response Framework</a>	✓	
<a href="#">PHW Incident Investigation Report template</a>		✓
<a href="#">Incident Investigation Timeline template</a>		✓
<a href="#">Reporting Medical Devices on Datix Cloud Flowchart</a>		✓
<a href="#">Level of Harm Guidance</a>		✓

## Appendix 1 - How to report an incident?

### Datix Cloud

All incidents, including Nationally Reportable Incidents (NRI), Early Warning notifications (EWN) and near misses, must be reported on Datix Cloud within 48 hours of identifying or first becoming aware of the incident. This is not only good practice but it also ensures that PHW complies with its regulatory and contractual obligations.

The NHS in Wales uses an electronic risk management system called the "Once for Wales Concerns Management System" known as Datix Cloud and all incidents should be reported using the incident reporting form on Datix Cloud. This can be accessed through PHW intranet home page [here](#).

Once logged in, staff are able to follow the instructions and fields using the boxes and drop-down menus indicated. A reference guide on how to report incidents on Datix Cloud is available [here](#).

**TOP TIP!** All staff will have Reporter permissions applied to their account upon commencement of employment. Reporter permissions enables you to report a incident, complaint or risk.

If you find yourself with a blank form when accessing Datix Cloud, please email [Phw.datix@wales.nhs.uk](mailto:Phw.datix@wales.nhs.uk) so that standard permissions can be added to your account.

## **Unavailability of Datix Cloud**

Should Datix Cloud be unavailable across the organisation (e.g information technology failure), staff must email their line manager and [phw.Datix@wales.nhs.uk](mailto:phw.Datix@wales.nhs.uk) to ensure that the Putting Things Right team are aware of an incident and remedial actions taken. Once Datix Cloud is available an incident should be recorded detailing all the information and actions taken to date, along with uploading associated documents to the record.

This ensures any immediate actions can be completed such as informing necessary colleagues (E.g Information Governance or Health and Safety colleagues) and/or any necessary external bodies are notified (such as the Delivery Unit or the Health and Safety Executive)

## **Staff access to Datix Cloud**

In the event an incident occurs where a staff member does not have access to the Datix Cloud system, it is recommended that written details of the incident are recorded which are then inputted into the Datix Cloud system as soon as reasonably possible (within 48 hours of the incident being identified).

In the event this is not possible, the staff member must make their Manager aware and email [phw.Datix@wales.nhs.uk](mailto:phw.Datix@wales.nhs.uk) to ensure that the Putting Things Right team are aware of an incident and share written details of the incident. Arrangements must be made for the incident to be reported onto Datix Cloud by the most appropriate person from the service area no later than 48 hours after the incident was identified.

## **How to access support**

If you require support on incident reporting (accessing the incident module or how to complete the incident form) please contact the Putting Things Right team via **[Phw.datix@wales.nhs.uk](mailto:Phw.datix@wales.nhs.uk)**.

If you require support in relation to incident management (level of harm, appropriate level of investigation, incident timescales) you can contact the Putting Things Right Managers for advice and support via **[incident.safety.phw@wales.nhs.uk](mailto:incident.safety.phw@wales.nhs.uk)**.

## **Appendix 2 – Levels of Harm**

### **Initial Assessment of harm at Incident Reporter Stage**

An initial assessment of the level of harm will be done by the reporter when submitting the incident on Datix Cloud.

The reporters assessment of the level of harm should align to the Levels of Harm Framework found [here](#) which aligns to Putting Things Right.

### **Assessment of harm at Management Review Stage**

Once an incident is reported onto Datix Cloud, a notification is sent to the appropriate Manager to review and complete the Management review. At this stage, the level of harm must be considered in line with the Duty of Candour level of harm framework which can be found [here](#).

The Level of harm must be kept under review during the investigation process and a final determination of harm must be made on completion of the incident investigation.

If the level of harm is categorised as moderate or above, it is important to ask if the incident meets the criteria for a Nationally Reportable Incident, Early Warning Notification, 'Never Event' or if Duty of Candour is applicable?

Any incidents with the level of harm moderate or above at the time of reporting will be notified to the Legal Manager for consideration of Duty of Candour.

If during the course of the investigation process it becomes apparent that the level of harm is moderate or above and had not initially been reported as such then the Legal Support Manager should be informed via

[legalsupport.phw@wales.nhs.uk](mailto:legalsupport.phw@wales.nhs.uk) who can advise and support the incident investigator further.

## **Appendix 3 – Levels of Investigation**

The level of the investigation should always be proportionate to the issue identified and should be considered on a case-by-case basis. The nature, severity and complexity of each incident will determine the appropriate level of investigation. This could range from an investigation completed locally by one nominated individual, through to a complex, serious incident investigation supported by the Putting Things Right team.

### **Incidents initially reported as Moderate to Severe Harm**

Incidents that are reported and categorised as moderate to severe harm are reviewed by either Head of Programme /service and/or Assistant Director of Nursing and Allied Health Professionals within 48 working hours, to confirm the category of incident. This is to ensure that incidents that meet the criteria for external reporting requirements are managed appropriately.

### **Incidents reported as No to Low Harm**

Incidents that are reported and categorised as No to Low harm are reviewed and managed and reviewed through service line arrangements

For some incidents, the level of investigation required may be obvious; however, where it is not clear this can be determined through a review meeting with the PTR Team. The following levels of investigation give an indication of the proportionate response, however once the investigation has begun, this may be subject to change dependent upon the findings of initial enquiries.

#### **Level 1 DATIX CLOUD investigation**

A concise investigation is suitable for less complex, incidents, which can be investigated and managed by individuals or small teams and documented within the DATIX CLOUD incident record. An investigation manager must be assigned and most incidents in this category can be investigated by completing the Management Review on Datix Cloud.

*A level 1 investigation is usually for incidents resulting in no or low harm, or some moderate harm incidents, but this is on a case-by-case basis.*

### **Level 2 Concise, internal investigation**

This is a concise investigation suited to less complex incidents, which can be managed, by appropriately investigation trained individuals at a local level. The recommended investigation methodology for a level 2 investigation is a chronology of events using the Systems based Investigation approach. There is a requirement to produce an investigation report outlining these investigation methodologies and completion of the Under Investigation section of Datix Cloud. The investigation report must outline lessons learnt and a safety improvement plan. All documents must be uploaded to the Datix Cloud incident record.

*A Level 2 investigation is usually incidents resulting in moderate harm.*

### **Level 3 Comprehensive, internal investigation**

This is a comprehensive investigation suited to complex issues, which should be managed by a multidisciplinary team involving experts and/or specialist investigators and will involve senior members of the PTR Team.

The recommended investigation methodology for a level 3 investigation is a comprehensive systems-based investigation with the use of a chronology timeline and a range of investigation tools used as part of the investigation process.

There is a requirement to produce a comprehensive investigation report outlining these investigation methodologies supported with a separate action plan. The Under Investigation section of Datix Cloud must also be completed to reflect the outcome of the investigation. All documents must be uploaded to the Datix Cloud incident record.

When an investigation report has been completed (level 1, 2 or 3) and approved, the actions from the safety improvement plan will be logged onto the incident reporting and management system, Datix Cloud, by the lead incident manager.

The Clinical Director or Head of Programme are responsible for ensuring that governance processes are in place to implement and monitor actions for all recommendations, and also have

accountability for ensuring changes in practice in order to embed learning and mitigate the potential for recurrence of similar incidents.

The Incident manager is responsible for updating Datix Cloud to report progress against actions on receipt of evidence. Progress notes within the incident module must be utilised regularly to provide comprehensive updates on the incident investigation.

*Level 3 incidents usually result in moderate/severe harm or death and could be Nationally Reportable Incidents (NRI's) , Early Warning Notifications and Duty of Candour incidents.*

## **Appendix 4 - Incident Investigation Tools**

There are several investigation tools available to support the investigator/investigation team in drilling down to identify the contributory factors and underlying cause of an incident, however the following tools are recommended for their thoroughness and reliability. The investigator/team can choose which tool works best for them and the completed tool should be included in the report to demonstrate thorough processes and decision-making.

### **A Systems-Based Approach (SBA)**

A Systems-Based approach (SBA) is one method for objectively determining the underlying, as well as the immediate, causes of incidents and events, enabling staff and management to learn from and avoid similar incidents and events in the future. It is also a transferable methodology that can be used not only for investigating serious untoward incidents but also for managing complaints and undertaking disciplinarians.

The key methods from SBA support the Patient Safety Incident Response framework found [here](#).

The key aim of a PSII (Patient Safety Incident Investigation) is to provide a clear explanation of how an organisation's systems and processes contributed to a patient safety incident. Recognising that mistakes are human, PSIIs examine 'system factors' such as the tools, technologies, environments, tasks and work processes involved. Findings from a PSII are then used to identify actions that will lead to improvements in the safety of the care patients receive.

PSIIs begin as soon as possible after the incident and are normally completed within three months. This timeframe may be extended with the agreement of those affected, including patients, families, carers and staff.

Using the SBA, an Investigator will:

1. Establish a timeline of the events.
2. Use a Systems Based Approach investigation methodology.
3. If any potential professional conduct issues are identified, these should be referred for consideration through the organisation's processes.
4. Make recommendations needed to prevent a similar incident/s happening; and / or to improve the organisation's systems, standards and practice, where appropriate
5. Engage with the individual involved, their representative or family in an open and transparent manner with the utmost care and sensitivity.
6. Offer support to any staff affected.
7. To report all findings and recommendations

Further information on the SBA methodology can be found [here](#).

## **System Engineering Initiative for Patient Safety (SEIPS)**

SEIPS is a framework for understanding outcomes within complex socio-technical systems

Further information on the SEIPS methodology can be found [here](#).

## **Yorkshire Contributory Factors Framework (YCCF)**

The Yorkshire Contributory Factors Framework is a tool which has an evidence base for optimising learning and addressing causes of patient safety incidents (PSI) by helping clinicians, risk managers and patient safety officers identify contributory factors of PSIs. You may wish to use the associated forms below to help guide and documents all the relevant factors.

The form for considering the YCCF that to assist your incident investigation can be found [here](#). The YCF are also embedded into the Datix Cloud Incident investigation form, and should be completed within the Datix record when prompted.

## **Appendix 5 – Safety Improvement plan**

### **Completing a SMART Safety Improvement Plan**

A SMART (**S**pecific, **M**easurable, **A**chievable, **R**elevant, **T**imely) safety improvement plan should be aligned to the investigation of an incident that clearly sets out the actions that will need to be taken to address any problems identified in order to reduce the risk of reoccurrence. These actions should be identified in the investigation process and highlighted with the learning and recommendation sections of the report.

#### **What makes an Safety Improvement Plan SMART?**

#### **Components of a Safety Improvement Plan include:**

- A well-defined description of the goal to be achieved
- Tasks/ steps that need to be carried out to reach the goal
- People who will be in charge of carrying out each task
- When will these tasks be completed (deadlines and milestones)
- Resources needed to complete the tasks
- Measures to evaluate progress

The safety improvement plan will need to be completed using the Public Health Wales template [here](#).

## **Appendix 6 – Closure of Incidents**

### **Low level incidents – no or low harm**

Once the investigation has been finalised to the satisfaction of the Service team, the incident should be closed which must be within 30 days of the incident being reported on Datix. The majority of low level incidents can be closed under Management review providing adequate information is provided outlining the actions taken from the incident.

### **Medium level incidents- moderate harm**

The final investigation must include the production of an investigation report outlining the relevant investigation methodologies and completion of the Under Investigation section of Datix Cloud. All documents must be uploaded to the Datix Cloud incident record. Any Nationally reportable incidents, Early Warning notifications or Duty of Candour must be notified to the PTR Team on conclusion of the investigation for consideration. All incidents categorised as moderate

harm or above will require an incident investigation review and closure panel that involves the quality leads /key service leads which will be overseen by the Putting Things Right Team.

### **High level incidents- severe harm or death**

High level incidents must have a comprehensive systems-based investigation with the use of a chronology timeline and tools such as the "5-whys" or "SEIPS".

There is a requirement to produce a comprehensive investigation report outlining these investigation methodologies supported with a separate safety improvement plan. The Under Investigation section of Datix Cloud must also be completed to reflect the outcome of the investigation. All documents must be uploaded to the Datix Cloud incident record.

The Investigation report and safety improvement plan must be submitted to the PTR mailbox and an agreement for closure will be returned to the Service Team. The PTR Team should action closure when they are finally assured that the incident investigation is completed. DATIX CLOUD should also be updated by the Putting Things Right Team for final closure.